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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 271, 272, 275 and 277

[Amdt. No. 328]

RIN 0584-AA76

Food Stamp Program: Miscellaneous Quality Control Provisions of the Hunger Prevention Act of 1988

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: On January 31, 1991 (56 FR 3788) the Department of Agriculture published proposed changes to Food Stamp Program regulations based on section 320, section 602, and parts of section 604 of the Hunger Prevention Act of 1988 (Pub. L. 100–435, enacted September 19, 1988). Section 320 requires changes in the corrective action planning State agencies must complete because of quality control (QC) errors. Section 602 requires State agencies to pay interest on unpaid QC related claims assessed against State agencies with payment error rates which exceed an established tolerance level. The portions of section 604 which were addressed involve the Food Stamp Act provisions relating to enhanced funding (an increased Federal share of program administrative costs), and QC liabilities (the sharing of costs of payment error by State agencies with error rates which exceed a national error tolerance level). In addition, the proposed rule addressed the issue of Federal sample sizes in QC, and certain technical changes in regulations related to State agency QC sampling. This final rule addresses significant comments received in response to the regulatory changes proposed in the rule published January 31, 1991.

EFFECTIVE DATE: Section 701 of Public Law 100–435 sets effective dates for the various provisions of Public Law 100–435 addressed in this rule. The provisions contained in 7 CFR 271.2, 275.10(a), 275.16(b)(2), 275.23(c), 275.23(e)(2), (3), (4), and (9) were effective October 1, 1985. The provisions contained in 7 CFR 275.1(b), 275.23(d), and 277.4(b) of this rule were effective October 1, 1988. The provision contained in 7 CFR 275.16(b)(6) was effective July 1, 1989.

The provisions contained in 7 CFR 275.11 (a), and (b) are effective December 27, 1991. The provisions contained in 7 CFR 275.3(c) are effective December 27, 1991, and applies to review periods starting with the Fiscal Year 1991 review period. The provisions contained in 7 CFR 275.23(e)(7) are effective December 27, 1991. The provisions contained in the implementing paragraph at 7 CFR 272.1(g) including those provisions relating to the arbitration of underissuance cases are effective December 27, 1991.

FOR FURTHER INFORMATION CONTACT: John Knaus, Chief, Quality Control Branch, Program Accountability Division, Food and Nutrition Service, USDA, Alexandria, Virginia 22302, (703) 305–2472.

SUPPLEMENTARY INFORMATION:

Classification

Executive Order 12291/Secretary's Memorandum 1512–1

This action has been reviewed under Executive Order 12291 and Secretary's Memorandum No.1512–1. Betty Jo Nelsen, Administrator of the Food and Nutrition Service (FNS), has classified this rule as non-major. The rule's effect on the economy will be less than $100 million. The rule will have no effect on costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions. It will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Regulatory Flexibility Act

This action has been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 (Pub. L. 96–354, 94 Stat. 1164, September 19, 1980). Betty Jo Nelsen, Administrator, FNS, has certified that this rule does not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

One of the provisions of this rule modifies the required contents for QC sampling plans. 7 CFR 272.2 requires each State agency to submit a QC sampling plan as part of the annual update of its State Plan of Operations (OMB authorization number 0584–0083). The reporting burden for this collection of information is estimated to average 10 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The modifications made by this rule eliminate some superfluous sampling plan requirements for State agencies that do not employ alternative sample designs. For State agencies that do employ alternative sample designs, the modifications simply clarify current requirements. The modifications will not change the average reporting burden of 10 hours per response for a State agency to prepare annual updates to its State Plan of Operations as approved under 0584–0083.

No other provisions of this rulemaking contain reporting or recordkeeping requirements subject to approval by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Executive Order 12372

The Food Stamp Program (Program) is listed in the Catalog of Federal Domestic Assistance under No. 10.551. For the reasons set forth in the final rule at 7 CFR 3015, subpart V and related notice (48 FR 29115, June 24, 1983), this Program is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Background

On January 31, 1991 (56 FR 3788) the Department of Agriculture (Department) proposed regulations to amend the food stamp QC system, primarily based on mandatory changes contained in the Hunger Prevention Act of 1988, Public Law 100–435, enacted September 19, 1988. In addition to the changes that

were mandated by Public Law 100–435 the Department proposed several minor changes related to the QC system. These changes included technical changes to the requirements for State agency sampling plans, and the required federal sample sizes in situations where State agencies had not completed their originally estimated required number of active QC reviews, or had implemented changes in their sampling plans without informing FNS. A full explanation of the rationale and purpose of these regulatory changes was provided in the preamble of the proposed rulemaking. This preamble deals with significant issues raised by commenters and the changes made as a result of their comments. It is recommended that the reader reference the proposed rulemaking, as well as this final rulemaking for a more complete understanding of the regulatory changes that the Department is implementing. The Department received 22 comment letters concerning the proposed rule.

Definitions—Section 271.2

Three organizations provided comments on the proposed regulatory changes to § 271.2 regarding definitions. Two commenters were concerned that the proposed definition for "overpayment error rate" was expressed as a percentage, and the definition for "underpayment error rate" was expressed as a ratio. These commenters recommended that the methodology for computing the overpayment and underpayment error rates be aligned. In addition, these commenters felt that it was inappropriate for the overpayment and underpayment error rates to be computed separately and then combined to create the payment error rate. One of the commenters has suggested that the denominator of the overpayment and underpayment error rates should be redefined as the sum of the value of all allotments issued plus the value of all allotments underissued in order to more precisely assess overall payment accuracy. The Department is unable to consider the suggested changes to the proposed regulations since the proposed regulatory provisions are specifically mandated by the law. Public Law 100–435, section 604 provides specific language for the definitions of "overpayment error rate", "underpayment error rate", and "payment error rate".

One commenter recommended changes to the definition of "underissuance" which would have eliminated from the definition any cases in which the underissuance was caused by a food stamp recipient's failure to report changes in household circumstances. It should be noted that although the Department has proposed adding a new definition to describe "underpayment error rate", no proposal to change the definition of "underissuance" has been made. Inasmuch as no change to the definition of "underissuance" was proposed in the regulations published January 31, 1991 (56 FR 3788) the Department deems it inappropriate to consider any change in this area as a part of this final rulemaking. In addition, the House of Representatives Committee on Agriculture Report (Report 100–828) states, in part, "* * * the Committee took into consideration a number of additional concerns that had been raised about the system currently in place. Among the concerns that were not directly addressed in this legislation were * * * (3) the appropriate response to the distinction between errors that the State agencies can correct and those that are most difficult to influence (the so-called client/agency definition) * * * The legislation as a whole, particularly the higher tolerance levels, incorporates implicit relief if problems such as those listed above that have in the past made it difficult for States to achieve the national error rate goal."(H.R. Report No. 100–828, part 1, 100th Cong., 2nd Sess., 37). Based on this expression of Congressional intent, the Department is retaining the current definition of "underissuance".

Federal Sample Size—Section 275.3

A total of ten organizations provided comments on the proposed regulatory changes to § 275.3 regarding Federal sample size. Six commenters disapproved of the proposed change arguing that anything less than the currently required Federal sample sizes would result in a less accurate, and possibly statistically invalid Federal validation review of a State agency's QC system. The matter of accuracy and consistency was of particular concern to these commenters because the tolerance level for QC fiscal liabilities is based on the national performance measure, which is in turn, based on the Federally regressed Payment Error Rates of all State agencies for a given fiscal year. In general, the commenters concerned with accuracy made the argument that any decrease in the number of cases in the Federal sample would reduce the statistical precision of the Federal regressed error rate. The commenters concerned with consistency made the argument that without a specific formula to be followed in situations where a State agency had failed to complete its originally estimated required number of reviews or had made changes in its sampling plan without informing the FNS Regional Office, that Regional Office QC staffs could apply the provisions for a smaller sample size in a manner that was inconsistent from Region to Region, or even from State to State within a single Region. The Department has considered the comments concerning accuracy but has not adopted them. While the commenters argue that a less accurate statistical precision may result from the use of a smaller Federal sample, it should be recognized that it is within the power of the State agencies to avoid this possibility by completing their originally estimated required number of reviews, and informing the appropriate FNS Regional Offices of any changes in their sampling plans. The Department is not attempting to penalize State agencies through this regulatory change. This change is only meant to enable the Department to resolve situations which are beyond the control of the Department. The concerns relating to consistency are addressed with the comments relating specifically to the need for a formula to be applied in these situations.

Two commenters endorsed the proposed regulatory change, but indicated a need for some formula to establish the minimum required Federal sample size. Three other commenters disapproved of the change specifically because no formula was included in the proposed regulatory language. The Department has considered these comments, along with the concerns regarding consistency, and decided to adopt them. In proposing this regulatory change it was not the intent of the Department to remove all Federal sample size requirements in situations where a State agency had failed to complete its required number of reviews or had made changes in its sampling plan without informing the FNS Regional Office. The Department has added language to the regulations to indicate that any shortage in the Federal sample will be based on the magnitude of the State agency's failure to complete its originally estimated required number of cases. Essentially this will mean a proportional reduction in sample sizes as suggested by one of the commenters. For example, if a State agency's sample size is 1200, the Federal sub-sample is 400, and the Federal selection interval is 3 (1200/400). If the State agency completes only 1000 cases, the Federal sample selected would be only 333 cases (1000/3). The shortfall that would be allowed for the Federal sample would be 67 cases (the 200 cases the State agency failed to complete divided by the

Federal sampling interval of 3 (200/3)). This will make the Federal shortfall proportionate to the State agency's shortfall (200/1200 or 16.66% vs. 67/400 or 16.75%).

State Agency Sampling—Section 275.11

Three organizations provided comments on the proposed regulatory changes to § 275.11 regarding State agency sampling plans. One commenter has pointed out that the proposed regulatory language would still require State agencies with integrated sampling designs to document all the criteria to be met for alternate sampling designs. This commenter argues that most State agencies have been integrating samples for years, and it would be a waste of effort for these State agencies to annually address the four criteria that apply only to alternative sample designs. The Department has considered this comment and decided to adopt it. The final regulatory language specifies that only State agencies proposing sampling plans with non-proportional integrated sampling, or alternative sampling designs must document compliance with the approval criteria in paragraph (b)(4) of this section.

One commenter disapproved of the proposed change. This commenter felt that it was good statistical practice to detail and document the four criteria in question for all sampling plans, not just those plans employing an alternative design. The Department has considered this comment but decided not to adopt it. For State agencies employing systematic or simple random sampling plans the four criteria do not apply. For example, it is impossible for a State agency to demonstrate a precision which is equal to or better than the precision of systematic sampling if it is using a systematic sampling plan. Similarly, it is impossible to describe weighting procedures for a systematic or simple random sampling plan which does not employ weighting. One commenter felt that requiring State agencies to explain their procedures, even if a systematic or simple random design is used, would help ensure that QC staff are in fact knowledgeable about statistical theory and data systems management procedures. For this reason, this commenter recommended that the four criteria not be eliminated from any sampling plans. The Department has considered this comment but decided not to adopt it. As already indicated, the four criteria do not apply to systematic and simple random sampling plans. If State agencies employing these plans wish to have their statistical staffs address these four criteria as a training exercise, the regulations will not prohibit this practice.

Corrective Action Plans (CAPs)—Section 275.16

A total of seven organizations provided comments on the proposed regulatory changes to § 275.16 regarding Corrective Action Plans (CAPs).

State Agencies Not Entitled to Enhanced Funding

Four commenters opposed the proposed change in regulations at 7 CFR 275.16(b)(2) to require the development of a CAP by any State agencies that did not qualify for enhanced funding. In general, these commenters felt that CAPs should not be mandated in situations where State agencies did not exceed the tolerance level for fiscal sanctions (lowest ever national average payment error rate plus 1 percent). The Department is unable to consider any suggested changes to the proposed regulations which are specifically mandated by the law. Public Law 100–435, section 604 specifically mandates that "the Secretary shall foster management improvements by the States pursuant to subsection (b) by requiring State agencies other than those receiving adjustments under subparagraph (A) (related to enhanced funding) to develop and implement corrective action plans to reduce payment errors".

Systemic Problems Resulting in Underissuances, or Improper Denials and Terminations

The comments from the other three organizations relating to the proposed regulatory changes regarding CAPs dealt specifically with the Department's proposal to require the development of a CAP in situations where underissuances, or improper denials/terminations are the result of State agency practices, rules, or procedures which are inconsistent with the Food Stamp Act, or regulations and policies of the Secretary. One commenter pointed out that Public Law 100–435, section 320 does not specifically mandate the development of a corrective action plan in these situations, only that steps be taken to prevent a recurrence of such errors. This commenter, along with one other, suggested that if CAPs were going to be required for systemic problems, that the regulations more clearly define what constitutes a systemic problem, and that standards be developed to determine when a CAP would be needed. It was suggested, as an example, that CAPs only be required if systemic problems resulted in a negative error rate of one percent or more, and/or an underissuance error rate of two percent or more. The Department has considered these comments but decided not to adopt them. Public Law 100–435, section 320 states, in part, that State agencies "shall take other steps to prevent a recurrence of such errors where such error was caused by the application of State agency practices, rules or procedures inconsistent with the requirements of this (Food Stamp) Act or with regulations or policies of the Secretary issued under the authority of this Act." While Public Law 100–435 does not specifically require the development of a CAP in order to prevent a recurrence of such errors the Department deems corrective action planning to be the most suitable method of insuring that appropriate efforts are taken to correct systemic problems. In regards to the suggestion that systemic errors be defined to include standards such as a negative error rate of one percent, and/or an underissuance rate of two percent, the Department deems it inappropriate to apply such standards in situations where Food Stamp Program recipients are being harmed, through the loss of benefits, due to the rules, practices, or procedures of the State agency. In such situations the Department considers it important that corrective action be taken, regardless of the number of recipients or magnitude of the errors involved.

One commenter has recommended that the CAPs for systemic problems be kept simple, rather than requiring the usual detailed narrative and statistical analysis that typically is part of a CAP. The Department notes that the content requirement for CAPs is specified in 7 CFR 275.17(b). In the case of systemic problems, the CAPs need only be as detailed as is necessary to meet the basic requirements contained in that section of the regulations.

Determination of State Agency Program Performance—Section 275.23

National Payment-Error Tolerance Level/State Agencies Subject to Liabilities

A total of twelve organizations provided comments on the proposed regulatory changes to § 275.23(e) regarding the establishment of a national payment-error tolerance measure, the determination of payment error rates, and the calculation of QC liability claims. One commenter endorsed the establishment of a category not subject to either liabilities or enhanced funding. Four commenters objected to the proposed tolerance level as a basis for establishing QC liabilities.

Two of these commenters acknowledged that the proposed provisions are required in Public Law 100–435, but objected anyway. The other two commenters proposed that the tolerance level be the national average for each year plus 1 percent (rather than the lowest national average ever achieved), or that separate tolerance levels be established for each State agency. The Department is unable to consider the changes suggested by these comments. Public Law 100–435, section 604 mandates, in part, that "(t)he announced national performance measure shall be used to establish a payment-error tolerance level. Such tolerance level for any fiscal year will be one percentage point added to the lowest national performance measure ever announced up to and including such fiscal year under this section. The payment-error tolerance level shall be used in determining the State share of the cost of payment error * * *".

One commenter objected to QC liabilities being based on total food stamp issuance in a State rather than on administrative funding. The Department is also unable to consider this suggestion. Public Law 100–435, section 604 mandates, in part, that "the State agency shall pay to the Secretary an amount equal to its payment error rate less such tolerance level times the total value of allotments issued in such a fiscal year by such State agency."

Two commenters were concerned that once established, the National Performance Measure for a given fiscal year is not subject to change, although individual State agency payment error rates are subject to change as a result of arbitration or correction of computational problems. These commenters felt that either the deadline for announcing the national performance measure should be extended, or that FNS should be required to complete all arbitrations prior to the announcement of the national measure, even if it meant agreeing with the State agency's position by default. The Department has considered these comments but has not adopted them. Sections 16(c)(5) and (6) of the Food Stamp Act mandate that the Department determine State agencies' payment error rates, announce a national performance measure based on these error rates, and notify the State agencies of these rates within nine months following the end of each fiscal year (June 30). Because it is legislatively mandated that FNS make its announcement no later than June 30 each year the Department cannot consider the suggestion that the deadline for announcing the national performance measure be extended. In the matter of arbitration decisions, the Department recognizes that State agency error rates, and subsequently, the national average, may change as a result of arbitration decisions arrived at after the deadline for announcement of the national performance measure. However, it is anticipated that the number of such cases will be small. In addition, it should be recognized that any arbitration decisions made after the announcement of the national performance measure which uphold a State agency's position would tend to lower the State agency's payment error rate, and subsequently, the national average. Thus, a national performance measure subject to change after its announcement, would create a lower, and possibly more difficult to achieve payment-error tolerance level. Despite the fixed nature of the national performance measure, arbitration decisions subsequent to the announcement will continue to be incorporated into the State agencies' final payment error rates and the determination of any QC claim assessed against a State agency.

Three commenters have argued that the error-rate estimation procedures that FNS currently uses in determining the payment error rate, and has proposed to use in determining the redefined payment error rate, are inaccurate, and have made recommendations for alternative procedures. The Department has considered these comments but has not adopted them. The Department believes that the current procedures are statistically sound. As indicated in the preamble of the proposed rulemaking, extensive research has demonstrated that the Department's error-rate estimation procedures produce statistically valid results (Morris Hansen and Benjamin Tepping, A Statistical Evaluation of Food Stamp Quality Control (1987)).

One commenter disagrees with the use of point estimates of sampling to define and determine the payment error rate. Another commenter objects to the overissuance and underissuance error rates being regressed separately, and then combined to determine a State agency's payment error rate. The Department is unable to consider these suggested changes. Public Law 100–435, section 604 provides specific language for the definitions of "overpayment error rate", "underpayment error rate", and "payment error rate" including the use of the point estimates, and the fact that the payment error rate is the sum of the separately determined overpayment and underpayment error rates. The Department is unable to consider any suggested changes to the proposed regulations which are specifically mandated by the law.

One commenter disagreed with the method FNS uses to adjust an error rate to compensate for nonsampling errors. It should be noted that although the Department proposed a technical change in the regulatory language so that the narrative description of the non-completion adjustment would be replaced with the equivalent calculation formulas, no proposal was made to change the actual procedures. Inasmuch as no change to the procedures for adjusting for non-completion has been made or proposed, the Department deems it inappropriate to consider any change in this area as a part of this final rulemaking.

State Agencies Entitled to Enhanced Funding

A total of six organizations provided comments on the proposed regulatory changes to § 275.23(d)(2) regarding entitlement to enhanced administrative funding. One commenter argued that a payment error rate of 6 percent was too low a benchmark to set in order to qualify for enhanced funding. Two commenters disapproved of the proposed provision that a State agency's payment error rate must be at least one full tenth of a percentage point under six percent (at least 5.90 percent), with enhanced funding increasing in distinct one percent increments for each full tenth of a percentage point below the 5.90 percent level, before qualifying for enhanced funding. The Department is unable to consider these suggestions to amend the proposed rule. Public Law 100–435, section 604 mandates, in part, that "the Secretary shall adjust a State agency's federally funded share of administrative costs * * * by increasing such share of all such administrative costs by one percentage point to a maximum of 60 percent of all such administrative costs for each full one-tenth of a percentage point by which the payment error rate is less than 6 percent, * * *".

Four comments concerned the stipulation in the proposed regulations that a State agency must have a negative case error rate that is less than the national weighted mean negative case rate for the prior fiscal year in order to qualify for enhanced funding. One commenter felt that there should be no requirement to meet goals for the negative error rate in order to qualify for enhanced funding. The Department is unable to accommodate these commenters because Public Law 100–

435, section 604 mandates, in part, that "only States whose rate of invalid decisions in denying eligibility is less than a nationwide percentage that the Secretary determines to be reasonable shall be entitled to the adjustment prescribed in this subsection (enhanced funding)".

One commenter stated that the national weighted mean negative case rate has never been established or described, and requested a description of how the rate is determined. One commenter wanted justification for why the proposed procedures use the national weighted mean average as the benchmark for enhanced funding. The national weighted mean negative case rate is a weighted average of the actual individual State agency reported negative case error rates. The weights are based on estimates of the States' average monthly negative case caseloads that are subject to review. The national weighted mean negative case rate is calculated and reported each year by the statistical staff of the FNS National Office. With respect to the use of the national weighted mean negative case rate as a benchmark for enhanced funding the Department notes that this rate was first placed into regulations as a target goal for enhanced funding in an interim rulemaking published May 27, 1983 (48 FR 23797). Since this rate has been used as a target for the qualification for enhanced funding since Fiscal Year 1983, it should be familiar to all State agencies by this time. Following concerns expressed by State agencies that using the rate for the same fiscal year in which the State agencies were trying to qualify for enhanced funding did not provide a quantified target known in advance of the review period, the Department changed the goal to the national weighted mean negative error rate for the prior fiscal year in the final rulemaking published on February 17, 1984 (49 FR 6292). The Department deems the national weighted mean negative error rate for the prior fiscal year to be a reasonable, equitable benchmark for entitlement to enhanced administrative funding for which the goal will be known in advance and yet is related to standards met by many State agencies. In addition, the House of Representatives Committee on Agriculture Report (Report 100–828) states, in part, "* * * the Committee expects the Secretary to continue the current method of setting the standard for invalid denials and terminations that is used in determining eligibility for enhanced funding until any legislated changes occur following the completion of the study mandated elsewhere in this section." (H.R. Report No. 100–828, part 1, 100th Cong., 2nd Sess., 33). Based on this expression of Congressional intent, the Department is retaining the national weighted mean negative error rate for the prior fiscal year as the benchmark for entitlement to enhanced administrative funding.

One commenter addressed the review procedures for a specific group of negative cases. While the Department deems it inappropriate to address this comment as part of this rule (since no proposal to change the review procedures on negative cases has been made) it will consider the comment when examining proposals to revise negative case review procedures. This review is currently underway.

Interest Charges

A total of eight organizations provided comments on the proposed regulatory changes to § 275.23(e)(9) regarding interest charges.

One commenter opposed all aspects of the statutory provisions and regulatory proposals concerning interest charges. Four commenters opposed the proposal to begin charging interest (if a State agency is appealing the claim) from the date of the decision on the administrative appeal, or 2 years after the date the bill for the claim is received, whichever is earlier. These commenters felt that the collection of interest for a period prior to the completion of the administrative appeal process was inequitable. The Department is unable to consider these suggested changes in the proposed rule. Public Law 100–435, section 602 mandates the imposing of interest on QC claims, and in part, specifically requires that "If the State agency appeals such claim (in whole or in part), the interest on any unpaid portion of the claim shall accrue from the date of the decision on the administrative appeal, or from a date that is 2 years after the date the bill is received, whichever is earlier, until the date the unpaid portion of the payment is received."

Two commenters expressed concern that the interest provisions would provide incentive for State agencies to resolve QC claims rapidly, but would provide no such incentive to the Federal government to resolve these claims. It should be stressed that Public Law 100–435, section 602 specifies that if a State agency pays a claim at any time during the appeal process, and the claim is subsequently overturned through administrative or judicial appeal, that the amount paid would be returned, together with interest accruing from the date of payment to the date it is returned. The Department anticipates that some State agencies may pay QC claims, while continuing to pursue an appeal, in order to avoid the possibility of interest payments. In such cases the Federal government would be required to pay interest to State agencies which eventually won their appeals. The Department would therefore have an incentive to see a speedy resolution to claims.

One commenter was concerned that the proposed regulations did not address any requirements on the part of State agencies to report interest accrued on QC claims, nor go into specifics on how it should be reported, verified, and monitored. The Department does not anticipate any requirements on the part of State agencies to report, verify, or monitor interest accrued on QC claims. The Financial Management staffs of the servicing finance offices currently responsible for the billings of QC claims (the FNS Regional Offices) shall be responsible for the collection of interest.

One commenter felt that State agencies and the general public have a right to know how indebtedness to the Federal government will be calculated, and that the methodology used to calculate the interest should be specified in the regulatory language rather than explained in the "Background" section. The Department has adopted this suggested change in the proposed rule. The methodology to be used in calculating interest has been included in the regulatory language at 7 CFR 275.23(e)(9)(iii) in this final rule.

Claims Collection

A total of three organizations provided comments on the proposed change in regulatory language at 7 CFR 275.23(e) regarding the payment of QC liability claims. The current wording of the regulations specifies that "FNS shall reduce the money it pays for the State agency's Food Stamp Program administrative costs * * *" in order to collect a QC claim. The Department has proposed to change this language to "the State agency shall pay or have its share of administrative costs reduced * * *" in order to collect a QC claim. One commenter endorsed the proposal to allow alternative methods of payment for QC liability claims. One commenter has expressed concern over the statement in the preamble to the proposed rule indicating that the Department retains the authority under section 13(a)(1) of the Food Stamp Act to reduce administrative funding in order to collect unpaid claims assessed against State agencies (56 FR 3792). This commenter interpreted this statement as

an attempt on the part of FNS to assert authority to collect a QC claim prior to the completion of any administrative or judicial appeal of the claim. This commenter is mistaken as to the Department's intentions regarding QC claims collections, as addressed in the proposed rulemaking. Contrary to the commenter's concern, it is the Department's intention to only address the method of collection, not when the collection would be made as part of these rules.

One commenter was concerned that FNS retains ultimate authority to reduce administrative funding. The commenter saw this as meaning that any time FNS did not like an alternative method of payment proposed by a State agency FNS could unilaterally reject the alternative method and withhold administrative funding to collect a QC claim. This commenter proposed the use of an arbitrator to intervene when FNS and a State agency could not arrive at a mutually agreed upon alternative method of payment. The Department has considered this comment but has not adopted it as it would be in conflict with the provisions of the Food Stamp Act which specifies in section 13(a)(1) that "(t)he Secretary shall have the power to reduce amounts otherwise due to a State agency under section 16 of this Act to collect unpaid claims assessed against the State agency if the State agency has declined or exhausted its appeal rights under section 14 of this Act".

Arbitration for Underissuance Cases

A total of three organizations provided comments on the proposal to allow a 60 day period of time for State agencies to request arbitration of any federally subsampled underissuance cases for which the State agency received FNS regional office QC findings or regional Arbitrator findings on or after February 22, 1988 (the effective date of a final rule published on January 21, 1988 (53 FR 1603) which limited to 28 days the timeframe for State agencies requesting arbitration). This would apply to any subsampled case in which the State agency, FNS regional office QC unit, or regional Arbitrator had concluded that an underissuance had existed.

Two commenters endorsed the proposed 60 day arbitration period. The third commenter endorsed the 60 day arbitration period, but suggested that it apply to any underissuance cases retroactive to October 1, 1985 (the effective date for the change to the definition for "payment error rate" so that underissuances would be included in the definition). This suggestion was based primarily on another suggestion from this commenter that the definition of what constitutes an underissuance case be changed effective October 1, 1985. As noted in the section entitled Definitions—Section 271.2 the Department is not changing the definition of "underissuance". Therefore, the Department has decided not to adopt the suggestion that the arbitration period apply to all underissuances dating back to October 1, 1985. A paragraph has been included in this final rule at 7 CFR 272.1(g)(119) providing for a 60 day arbitration period for any underissuance cases for which Federal findings were received on, or after February 22, 1988.

Implementation

The provision of section 604 that amended section 16(c) of the Food Stamp Act, relating to the requirement to develop a CAP if a State agency does not qualify for enhanced funding, was effective and implemented on October 1, 1985. The corrective action provision of section 320 was effective and implemented on July 1, 1989. The provisions regarding State agency sampling plans are effective and must be implemented December 27, 1991. The provisions regarding the arbitration of underissuance cases are effective December 27, 1991, and must be implemented by January 27, 1992.

List of Subjects

7 CFR Part 271

Administrative practice and procedure, Food stamps, Grant programs-Social programs.

7 CFR Part 272

Alaska, Civil rights, Food stamps, Grant programs-social programs, Reporting and recordkeeping requirements.

7 CFR Part 275

Administrative practice and procedure, Food stamps, Reporting, and recordkeeping requirements.

7 CFR Part 277

Food stamps, Government procedure, Grant programs-Social programs, Investigations, Records, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, parts 271, 272, 275 and 277 of subchapter C of chapter II of title 7 Code of Federal Regulations are amended as follows:

PART 271—GENERAL INFORMATION AND DEFINITIONS

1. The authority citation for part 271 continues to read as follows:

Authority: 7 U.S.C. 2011–2031.

2. In § 271.2, the definition of "payment error rate" and "underissuance error rate" are revised and two new definitions "overpayment error rate" and "underpayment error rate" are added in alphabetical order.

The revision and additions read as follows:

§ 271.2 Definitions.

* * * * *

Overpayment error rate means the percentage of the value of all allotments issued in a fiscal year that are either:

(1) Issued to households that fail to meet basic program eligibility requirements, or

(2) Overissued to eligible households.

Payment error rate means the sum of the point estimates of two component error rates: an overpayment error rate and an underpayment error rate. Each component error rate is the value of allotments either overissued or underissued expressed as a percentage of all allotments issued to completed active sample cases, excluding those cases processed by SSA personnel or participating in certain demonstration projects designated by FNS.

* * * * *

Underissuance error rate. (See *Underpayment error rate.*)

Underpayment error rate means the ratio of the value of allotments underissued to recipient households to the total value of allotments issued in a fiscal year by a State agency.

* * * * *

PART 272—REQUIREMENTS FOR PARTICIPATING STATE AGENCIES

3. The authority citation for part 272 continues to read as follows:

Authority: 7 U.S.C. 2011–2031.

4. In § 272.1, a new paragraph (g)(119) is added in numerical order to read as follows:

§ 272.1 General terms and conditions.

* * * * *

(g) *Implementation.* * * *

(119) *Amendment No. 328.* (i) The requirements for State agencies to begin implementation or corrective action for deficiencies which are the cause for non-entitlement to enhanced funding for the Fiscal Year 1986 review period, and review periods thereafter were effective as of October 1, 1985, pursuant to section 604 of Public Law 100–435.

(ii) The requirements for State agencies to begin the implementation of corrective action for deficiencies which result in underissuances, improper

denials or improper terminations of benefits to eligible households where such errors are caused by State agency rules, practices or procedures were effective July 1, 1989, pursuant to section 320 of Public Law 100–435. The corrective action must address all such deficiencies which occurred on or after July 1, 1989.

(iii) The State agency shall have until December 27, 1991, to implement changes in the development of quality control sampling plans, such that only those State agencies proposing non-proportional integrated, or other alternative sampling plan designs must:

(A) Demonstrate that the alternative design provides payment error rate estimates with equal-or-better predicted precision than would be obtained had the State agency reviewed simple random samples of the sizes specified in § 275.11(b)(1) of the regulations,

(B) Describe all weighting, and estimation procedures if the sample design is non-self-weighted, or uses a sampling technique other than systematic sampling,

(C) Demonstrate that self-weighting is actually achieved in sample designs claimed to be self-weighting.

(iv) The State agency shall have until January 27, 1992, to request regional arbitration of any federally subsampled underissuance cases for which the State agency received FNS regional office QC findings on or after February 22, 1988.

(v) The State agency shall have until January 27, 1992, to request national arbitration of any regional arbitration decisions involving underissuance cases for which the State agency received FNS regional arbitration findings on or after February 22, 1988.

PART 275—PERFORMANCE REPORTING SYSTEM

5. The authority citation for part 275 continues to read as follows:

Authority: 7 U.S.C. 2011–2031.

6. In § 275.1, paragraph (b) is revised to read as follows:

§ 275.1 General scope and purpose.

* * * * *

(b)(1) The Food Stamp Act authorizes the Secretary to pay each State agency an amount equal to 50 percent of all administrative costs involved in each State agency's operation of the program. The Act further authorizes the Secretary to increase the percentage share if:

(i) The State agency's payment error rate is less than or equal to 5.90 percent, and

(ii) The State agency's negative case error rate is less than the national weighted mean negative case error rate for the prior fiscal year.

(2) If a State agency qualifies for an increased percentage share, the amount of increase will be an additional percentage point for each full tenth of a percentage point by which the payment error rate is less than six percent, up to a maximum of 60 percent of administrative costs. Those State agencies not receiving the increased share of funding shall develop and implement corrective action plans to reduce payment errors. Corrective action shall be completed as required in subpart E of this section.

7. In § 275.3:

a. Paragraphs (c)(1)(i)(A) and (c)(3)(i)(A) are revised;

b. Paragraphs (c)(1)(i)(B) and (c)(3)(i)(B) are redesignated as paragraphs (c)(1)(i)(C) and (c)(3)(i)(C) respectively;

c. New paragraphs (c)(1)(i)(B) and (c)(3)(i)(B) are added.

The revisions and additions read as follows:

§ 275.3 Federal monitoring.

* * * * *

(c) *Validation of State Agency Error Rates.* * * *

(1) *Payment error rate.* * * *

(i) * * *

(A) In the above formula, n is the minimum number of Federal review sample cases which must be selected when conducting a validation review, except that FNS may select a lower number of sample cases if:

(*1*) The State agency does not report a change in sampling procedures associated with a revision in its required sample size within 10 days of effecting the change; and/or

(*2*) The State agency does not complete the number of case reviews specified in its approved sampling plan.

(B) The reduction in the number of Federal cases selected will be equal to the number of cases that would have been selected had the Federal sampling interval been applied to the State agency's shortfall in its required sample size. This number may not be exact due to random starts and rounding.

* * * * *

(3) *Negative case error rate.* * * *

(i) * * *

(A) In the above formula, n is the minimum number of Federal review sample cases which must be selected when conducting a validation review, except that FNS may select a lower number of sample cases if:

(*1*) The State agency does not report a change in sampling procedures associated with a revision in its required sample size within 10 days of effecting the change; and/or

(*2*) The State agency does not complete the number of case reviews specified in its approved sampling plan.

(B) The reduction in the number of Federal cases selected will be equal to the number of cases that would have been selected had the Federal sampling interval been applied to the State agency's shortfall in its required sample size. This number may not be exact due to random starts and rounding.

* * * * *

§ 275.10 [Amended]

8. In § 275.10, the last sentence of paragraph (a) is amended by removing the words "with combined payment error and underissuance error rates of 5 percent or more" and adding the words "that is not entitled to enhanced funding" in their place.

9. In § 275.11:

a. The introductory text of paragraph (a)(2) is amended by adding a new sentence between the heading and the first sentence;

b. Paragraphs (a)(2)(ii), (a)(2)(iii), (a)(2)(iv), and (a)(2)(v) are removed, and paragraphs (a)(2)(vi), (a)(2)(vii), and (a)(2)(viii) are redesignated as paragraphs (a)(2)(ii), (a)(2)(iii), and (a)(2)(iv) respectively;

c. The last sentence of paragraph (b)(4) is revised:

d. New paragraphs (b)(4)(i), (b)(4)(ii), and (b)(4)(iii) are added.

The revision and additions read as follows:

§ 275.11 Sampling.

(a) *Sampling plan.* * * *

(2) *Criteria.* Sampling plans proposing non-proportional integrated sampling, or other alternative designs shall document compliance with the approval criteria in paragraph (b)(4) of this section. * * *

* * * * *

(b) *Sample size.* * * *

(4) *Alternative designs.* * * * To receive FNS approval, proposals for any type of alternative design must:

(i) Demonstrate that the alternative design provides payment error rate estimates with equal-or-better predicted precision than would be obtained had the State agency reviewed simple random samples of the sizes specified in paragraphs (b)(1) and (b)(2) of this section.

(ii) Describe all weighting, and estimation procedures if the sample design is non-self-weighted, or uses a sampling technique other than systematic sampling.

(iii) Demonstrate that self-weighting is actually achieved in sample designs claimed to be self-weighting.

* * * * *

10. In § 275.16:

a. Paragraph (b)(2) is revised;

b. A new paragraph (b)(6) is added.

The revision and addition read as follows:

§ 275.16 Corrective action planning.

* * * * *

(b) * * *

(2) Are the cause for non-entitlement to enhanced funding for any reporting period (actions to correct errors in individual cases however, shall not be submitted as part of the State agency's corrective action plan);

* * * * *

(6) Result in underissuances, improper denials, or improper terminations of benefits to eligible households where such errors are caused by State agency rules, practices or procedures.

* * * * *

11. In § 275.23:

a. Paragraph (c)(2) is revised;

b. Paragraph (c)(3) is amended by adding the words "Prior to Fiscal Year 1986," at the beginning of the text of that paragraph;

c. Paragraph (d)(2) is revised;

d. The heading of paragraph (e)(2) is revised;

e. Paragraph (e)(2)(i) is revised;

f. The heading of paragraph (e)(3) is revised;

g. Paragraphs (e)(4), (e)(5), (e)(6) and (e)(7) are redesignated as (e)(5), (e)(6), (e)(7) and (e)(8), respectively and a new paragraph (e)(4) is added;

h. Newly redesignated paragraph (e)(7)(i) is revised;

i. Newly redesignated paragraph (e)(7)(iii) is revised;

j. A new paragraph (e)(9) is added.

The revisions and additions read as follows:

§ 275.23 Determination of State agency program performance.

* * * * *

(c) *State agency error rates.* * * *

(2) *Payment error rate.*

(i) For fiscal years prior to Fiscal Year 1986, the payment error rate shall include the value of the allotments overissued, including overissuances to ineligible cases, for those cases included in the active error rate.

(ii) For Fiscal Year 1986 and subsequent fiscal years, the payment error rate shall include the value of the allotments overissued, including those to ineligible cases, and the value of allotments underissued for those cases included in the active error rate.

* * * * *

(d) *Federal enhanced funding.* * * *

(2) After validation and any necessary adjustment of estimated error rates:

(i) A State agency with a combined payment error rate and underissuance error rate of less than five percent for an annual review period for Fiscal Year 1983 through Fiscal Year 1985, or a payment error rate of less than five percent for an annual review period for Fiscal Year 1986 through Fiscal Year 1988, shall be eligible for a 60 percent Federally funded share of administrative costs, provided that the State agency's negative case error rate for that period is less than the national weighted mean negative case error rate for the prior fiscal year;

(ii) Beginning with Fiscal Year 1989, a State agency with a payment error rate less than or equal to 5.90 percent and with a negative case error rate less than the national weighted mean negative case rate for the prior fiscal year will have its Federally funded share of administrative costs increased by one percentage point to a maximum of 60 percent for each full one-tenth of a percentage point by which the payment error rate is less than six percent.

* * * * *

(e) *State agencies' liabilities for payment error rates.*

* * * * *

(2) *Establishment of payment error rate goals—Fiscal Year 1983 through Fiscal Year 1985.*

(i) Each State agency's payment error rate goal for Fiscal Year 1983 shall be nine percent. Each State agency's payment error rate goal for Fiscal Year 1984 shall be seven percent. Each State agency's payment error rate goal for Fiscal Year 1985 shall be five percent. State agencies' payment error rates for any fiscal year shall be derived from the review period corresponding to the fiscal year.

* * * * *

(3) *State agencies failing to achieve payment error rate goals—Fiscal Year 1983 through Fiscal Year 1985.* * * *

(4) *State agencies' liabilities for payment error—Fiscal Year 1986 and Beyond.* Each State agency that fails to achieve its payment error rate goal during a fiscal year shall be liable as specified in the following paragraphs.

(i) For Fiscal Year 1986 and subsequent years, FNS shall announce a national performance measure within nine months following the end of each fiscal year that is the sum of the products of each State agency's payment error rate times that State agency's proportion of the total value of national allotments issued for the fiscal year using the most recent issuance data available at the time the State agency is initially notified of its payment error rate. Once announced, the national performance measure for a given fiscal year will not be subject to change. This national performance measure is used to establish a payment-error tolerance level. The payment-error tolerance level for any fiscal year shall be one percentage point added to the lowest national performance measure ever announced up to and including such fiscal year.

(ii) For any fiscal year in which a State agency's payment error rate exceeds the payment-error tolerance level, the State agency shall pay or have its share of administrative costs reduced by an amount equal to the difference between its payment error rate less such tolerance level as a quantity, multiplied by the total value of the allotments issued in the fiscal year by that State agency.

* * * * *

(7) *Determination of payment error rates.* * * *

(i) Once the Federal case reviews have been completed and all differences with the State agency have been identified, FNS shall calculate regressed error rates using the following linear regression equations.

(A) $y_1' = y_1 + b_1(X_1 - x_1)$, where y_1' is the average value of allotments overissued to eligible and ineligible households; y_1 is the average value of allotments overissued to eligible and ineligible households in the rereview sample according to the Federal finding. b_1 is the estimate of the regression coefficient regressing the Federal findings of allotments overissued to eligible and ineligible households on the corresponding State agency findings, x_1 is the average value of allotments overissued to eligible and ineligible households in the rereview sample according to State agency findings, and X_1 is the average value of allotments overissued to eligible and ineligible households in the full quality control sample according to State agency's findings. In stratified sample designs Y_1, X_1, and x_1 are weighted averages and b_1 is a combined regression coefficient in which stratum weights sum to 1.0 and are proportional to the estimated stratum caseloads subject to review.

(B) $y_2' = y_2 + b_2(X_2 - x_2)$, where y_2' is the average value of allotments underissued to households included in

the active error rate, y_2 is the average value of allotments underissued to participating households in the rereview sample according to the Federal finding, b_2 is the estimate of the regression coefficient regressing the Federal findings of allotments underissued to participating households on the corresponding State agency findings, x_2 is the average value of allotments underissued to participating households in the rereview sample according to State agency findings, and X_2 is the average value of allotments underissued to participating households in the full quality control sample according to the State agency's findings. In stratified sample designs y_2, X_2, and x_2 are weighted averages and b_1 is a combined regression coefficient in which stratum weights sum to 1.0 and are proportional to the estimated stratum caseloads subject to review.

(C) The regressed error rates are given by $r_1'=y_1'/u$, yielding the regressed overpayment error rate, and $r_2'=y_2'/u$, yielding the regressed underpayment error rate, where u is the average value of allotments issued to participating households in the State agency sample.

(D) After application of the adjustment provisions of paragraph (e)(7)(iii) of this section, the adjusted regressed payment error rate shall be calculated to yield the State agency's payment error rate for use in the reduced and enhanced funding determinations described in paragraphs (d) and (e) of this section. Prior to Fiscal Year 1986, the adjusted regressed payment error rate is given by r_1''. For Fiscal Year 1986 and after, the adjusted regressed payment error rate is given by $r_1''+r_2''$.

* * * * *

(iii) Should a State agency fail to complete all of its required sample size, FNS shall adjust the State agency's regressed error rates using the following equations:

(A) $r_1''=r_1'+2(1-C)S_1$, where r_1'' is the adjusted regressed overpayment error rate, r_1' is the regressed overpayment error rate computed from the formula in paragraph (e)(7)(i)(C) of this section, C is the State agency's rate of completion of its required sample size expressed as a decimal value, and S_1 is the standard error of the State agency sample overpayment error rate. If a State agency completes all of its required sample size, then $r_1''=r_1'$.

(B) $r_2''=r_2'+2(1-C)S_2$, where r_2'' is the adjusted regressed underpayment error rate, r_2' is the regressed underpayment error rate computed from the formula in paragraph (e)(7)(i)(C) of this section, C is the State agency's rate of completion of its required sample size expressed as a decimal value, and S_2 is the standard error of the State agency sample underpayment error rate. If a State agency completes all of its required sample size, then $r_2''=r_2'$.

* * * * *

(9) *Interest charges.* (i) To the extent that a State agency does not pay a claim established under § 275.23(e)(4) within 30 days from the date on which the bill for collection (after a determination on any request for a waiver for good cause) is received by the State agency, the State agency shall be liable for interest on any unpaid portion of such claim accruing from the date on which the bill for collection was received by the State agency. This situation applies unless the State agency appeals the claim under § 276.7 of the regulations. If the State agency agrees to pay the claim through reduction in Federal financial participation for administrative costs, this agreement shall be considered to be paying the claim. If the State agency appeals such claim (in whole or in part), the interest on any unpaid portion of the claim shall accrue from the date of the decision on the administrative appeal, or from a date that is 2 years after the date the bill is received, whichever is earlier, until the date the unpaid portion of the payment is received.

(ii) If the State agency pays such claim (in whole or in part) and the claim is subsequently overturned through administrative or judicial appeal, any amounts paid by the State agency above what is actually due shall be promptly returned with interest, accruing from the date the payment was received until the date the payment is returned.

(iii) Any interest assessed under this paragraph shall be computed at a rate determined by the Secretary based on the average of the bond equivalent of the weekly 90-day Treasury bill auction rates during the period such interest accrues. The bond equivalent is the discount rate (i.e., the price the bond is actually sold for as opposed to its face value) determined by the weekly auction (i.e., the difference between the discount rate and face value) converted to an annualized figure. The Secretary shall use the investment rate (i.e., the rate for 365 days) compounded in simple interest for the period for which the claim is not paid. Interest billings shall be made quarterly with the initial billing accruing from the date the interest is first due. Because the discount rate for Treasury bills is issued weekly, the interest rate for State agency claims shall be averaged for the appropriate weeks.

PART 277—PAYMENTS OF CERTAIN ADMINISTRATIVE COSTS OF STATE AGENCIES

12. The authority citation for part 277 continues to read as follows:

Authority: 7 U.S.C. 2011–2031.

13. In § 277.4:

a. Paragraph (b)(2) is revised;

§ 277.4 [Amended]

b. Paragraph (b)(8), is amended by changing the regulatory reference to "§ 275.25" to read "§ 275.23".

The revision reads as follows:

§ 277.4 Funding.

* * * * *

(b) *Federal Reimbursement Rate.*

* * *

(2) A State agency's federally funded share of Food Stamp Program administrative costs shall be increased when its error rate, as determined through the quality control process described in part 275, meets certain standards.

(i) For the period beginning October 1, 1982, through September 30, 1988, a State agency with a payment error rate of five percent or less in the corresponding fiscal year shall have its federally funded share of Program administrative costs increased to 60 percent, provided that the State agency's negative case error rate is less than the national weighted mean negative case rate for the fiscal year prior to the period of enhanced funding.

(ii) For the period beginning October 1, 1988, and review periods thereafter, a State agency with a payment error rate less than or equal to 5.90 percent and with a negative case error rate less than the National weighted mean negative case error rate for the prior fiscal year shall have its Federally funded share of Food Stamp Program administrative costs increased by one percentage point to a maximum of 60 percent for each full one-tenth of a percentage point by which the payment error rate is less than six percent.

* * * * *

Dated: November 19, 1991.

Betty Jo Nelsen,

Administrator.

[FR Doc. 91–28288 Filed 11–26–91; 8:45 am]

BILLING CODE 3410-30-M

FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Regulation D; Docket No. R-0741]

Reserve Requirements of Depository Institutions; Reserve Requirement Ratios

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending 12 CFR part 204 (Regulation D—Reserve Requirements of Depository Institutions) to increase the amount of transaction accounts subject to a reserve requirement ratio of three percent, as required by section 19(b)(2)(C) of the Federal Reserve Act (12 U.S.C. 461(b)(2)(C)), from $41.1 million to $42.2 million of net transaction accounts. This adjustment is known as the low reserve tranche adjustment. The Board has increased from $3.4 million to $3.6 million the amount of reservable liabilities of each depository institution that is subject to a reserve requirement of zero percent. This action is required by section 19(b)(11)(B) of the Federal Reserve Act (12 U.S.C. 461(b)(11)(B)), and the adjustment is known as the reservable liabilities exemption adjustment. The Board is also increasing from $44.0 million to $44.8 million the deposit cutoff level that is used in conjunction with the reservable liabilities exemption amount to determine the frequency of deposit reporting.

DATES: *Effective Date:* December 17, 1991.

Compliance Dates: For depository institutions that report weekly, the low reserve tranche adjustment and the reservable liabilities exemption adjustment will be effective on the reserve computation period that begins Tuesday, December 24, 1991, and on the corresponding reserve maintenance period that begins Thursday, December 26, 1991. For institutions that report quarterly, the low reserve tranche adjustment and the reservable liabilities exemption adjustment will be effective on the reserve computation period that begins Tuesday, December 17, 1991, and on the corresponding reserve maintenance period that begins Thursday, January 16, 1992. For all depository institutions, the increase in the deposit cutoff level will be used to screen institutions in the second quarter of 1992 to determine the reporting frequency for the twelve month period that begins in September 1992.

FOR FURTHER INFORMATION CONTACT: Patrick J. McDivitt, Attorney (202/452-3818), Legal Division, or June O'Brien, Economist (202/452-3790), Division of Monetary Affairs; for users of the Telecommunications Device for the Deaf (TDD), Dorothea Thompson (202/452-3544); Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION: Section 19(b)(2) of the Federal Reserve Act requires each depository institution to maintain reserves against its transaction accounts and nonpersonal time deposits, as prescribed by Board regulations. The initial reserve requirements imposed under section 19(b)(2) were set at three percent for total transaction accounts of $25 million or less and at 12 percent on total transaction accounts above $25 million for each depository institution. Section 19(b)(2) also provides that, before December 31 of each year, the Board shall issue a regulation adjusting for the next calendar year the total dollar amount of the transaction account tranche against which reserves must be maintained at a ratio of three percent. The adjustment in the tranche is to be 80 percent of the percentage change in total transaction accounts at all depository institutions over the one-year period that ends on the June 30 prior to the adjustment.

Currently, the low reserve tranche on transaction accounts is $41.1 million. The increase in the total of net transaction accounts of all depository institutions from June 30, 1990, to June 30, 1991 was 3.3 percent (from $592.7 billion to $612.1 billion). In accordance with section 19(b)(2), the Board is amending Regulation D to increase the low reserve tranche for transaction accounts for 1992 by $1.1 million to $42.2 million.

Section 19(b)(11)(A) of the Federal Reserve Act provides that $2 million of reservable liabilities [1] of each depository institution shall be subject to a zero percent reserve requirement. Section 19(b)(11)(A) permits each depository institution, in accordance with the rules and regulations of the Board, to designate the reservable liabilities to which this reserve requirement exemption is to apply. However, if transaction accounts are designated, only those that would otherwise be subject to a three percent reserve requirement (i.e., transaction accounts within the low reserve requirement tranche) may be so designated.

[1] Reservable liabilities include transaction accounts, nonpersonal time deposits, and Eurocurrency liabilities as defined in section 19(b)(5) of the Federal Reserve Act.

Section 19(b)(11)(B) of the Federal Reserve Act provides that, before December 31 of each year, the Board shall issue a regulation adjusting for the next calendar year the dollar amount of reservable liabilities exempt from reserve requirements. Unlike the adjustment for transaction accounts, which adjustment can result in a decrease as well as an increase, the change in the exemption amount is to be made only if the total reservable liabilities held at all depository institutions increases from one year to the next. The percentage increase in the exemption is to be 80 percent of the increase in total reservable liabilities of all depository institutions as of the year ending June 30. Total reservable liabilities of all depository institutions from June 30, 1990, to June 30, 1991, increased by 6.0 percent (from $1,223.0 billion to $1,296.3 billion). Under section 19(b)(11)(B), the reservable liabilities exemption amount will be increased by $0.2 million. Consequently, the reservable liabilities exemption amount for 1992 will increase to $3.6 million.

The effect of the application of section 19(b) of the Federal Reserve Act to the change in the total net transaction accounts and the change in the total reservable liabilities from June 30, 1990 to June 30, 1991 is to increase the low reserve tranche to $42.2 million, to apply a zero percent reserve requirement on the first $3.6 million of transaction accounts, and to apply a three percent reserve requirement on the remainder of the low reserve tranche.

The tranche adjustment and the reservable liabilities exemption adjustment for weekly reporting institutions will be effective on the reserve computation period beginning Tuesday, December 24, 1991, and on the corresponding reserve maintenance period beginning Thursday, December 26, 1991. For institutions that report quarterly, the tranche adjustment and the reservable liabilities exemption adjustment will be effective on the computation period beginning Tuesday, December 17, 1991, and on the reserve maintenance period beginning Thursday, January 16, 1992. In addition, all institutions currently submitting Form FR 2900 must continue to submit reports to the Federal Reserve under current reporting procedures.

In order to reduce the reporting burden for small institutions, the Board has established a deposit reporting cutoff level to determine deposit reporting frequency. Institutions are screened during the second quarter of each year to determine reporting frequency beginning the following

September. In March of 1985, the Board indexed this reporting cutoff level in an amount equal to 80 percent of the annual rate of increase of total deposits.[2] In July of 1988, in conjunction with approval of the extension of the deposit reporting system, the Board increased the cutoff level upon which the indexing is to be applied to $40 million. The current reporting cutoff level is $44.0 million.

From June 30, 1990, to June 30, 1991, total deposits grew 2.1 percent, from $3,712.3 billion to $3,791.9 billion. This results in an increase of $0.8 million in the deposit cutoff level that determines the frequency of reporting from the current $44.0 million to $44.8 million. Based on the indexation of the reserve requirement exemption, the cutoff level for total deposits above which reports of deposits must be filed will rise from $3.4 million to $3.6 million. Institutions with total deposits below $3.6 million are excused from reporting if their deposits can be estimated from other data sources. The $44.8 million cutoff level for weekly versus quarterly FR 2900 reporting and for quarterly FR 2910q versus annual FR 2910a reporting, and the $3.6 million level threshold for reporting will be used in the second quarter 1992 deposits report screening process, and the adjustments will be made when the new deposit reporting panels are implemented in September 1992.

All U.S. branches and agencies of foreign banks and all Edge and Agreement Corporations, regardless of size, are required to file weekly the Report of Transaction Accounts, Other Deposits and Vault Cash (FR 2900). All other institutions that have reservable liabilities in excess of the exemption level prescribed by section 19(b)(11) of the Federal Reserve Act (known as "nonexempt institutions") and total deposits at least equal to the deposit level ($44.8 million) are also required to file weekly the Report of Transaction Accounts, Other Deposits and Vault Cash (FR 2900). However, nonexempt institutions with total deposits less than the deposit cutoff level ($44.8 million), may file the FR 2900 quarterly for the twelve month period starting September 1992. Institutions that obtain funds from non-U.S. sources or that have foreign branches or international banking facilities are required to file the Report of Certain Eurocurrency Transactions (FR 2950/2951) on the same frequency as they file the FR 2900.

Institutions with reservable liabilities at or below the exemption level ($3.6 million) (known as "exempt institutions") must file the Quarterly Report of Selected Deposits, Vault Cash, and Reservable Liabilities (FR 2910q) if their total deposits are not below the deposit cutoff level ($44.8 million). Exempt institutions with total deposits less than the deposit cutoff level but more than the exemption amount must file the Annual Report of Total Deposits and Reservable Liabilities (FR 2910a). Institutions that have total deposits less than the exemption amount ($3.6 million) are not required to file deposit reports if their deposits can be estimated from other data sources.

Finally, the Board may require a depository institution to report on a weekly basis, regardless of the cutoff level, if the institution manipulates its total deposits and other reservable liabilities in order to qualify for quarterly reporting. Similarly, any depository institution that reports quarterly may be required to report weekly and to maintain appropriate reserve balances with its Reserve Bank if, during its computation period, it understates its usual reservable liabilities or it overstates the deductions allowed in computing required reserve balances.

Notice and Public Participation

The provisions of 5 U.S.C. 553(b) relating to notice and public participation have not been followed in connection with the adoption of these amendments because the amendments involve adjustments prescribed by statute and by an interpretative statement reaffirming the Board's policy concerning reporting practices. The amendments also reduce regulatory burdens on depository institutions. Accordingly, the Board finds good cause for determining, and so determines, that notice and public participation are unnecessary and contrary to the public interest.

The provisions of 5 U.S.C. 553(d) relating to notice of the effective date of a rule have not been followed in connection with the adoption of these amendments because the amendments relieve a restriction on depository institutions, and for this reason there is good cause to determine, and the Board so determines, that such notice is not necessary.

Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. No. 96–354, 5 U.S.C. 601 *et seq.*), the Board certifies that the proposed amendments will not have a significant economic impact on a substantial number of small entities. The proposed amendments reduce certain regulatory burdens for all depository institutions, reduce certain burdens for small depository institutions, and have no particular effect on other small entities.

List of Subjects in 12 CFR Part 204

Banks, banking, Currency, Federal Reserve System, Mortgages, Penalties, Reporting and record keeping requirements.

Pursuant to the Board's authority under section 19 of the Federal Reserve Act, 12 U.S.C. 461 *et seq.*, the Board is amending 12 CFR Part 204 as follows:

PART 204—RESERVE REQUIREMENTS OF DEPOSITORY INSTITUTIONS

1. The authority citation for part 204 continues to read as follows:

Authority: Sections 11(a), 11(c), 19, 25, 25(a) of the Federal Reserve Act (12 U.S.C. 248(a), 248(c), 371a, 371b, 461, 601, 611); section 7 of the International Banking Act of 1978 (12 U.S.C. 3105); and section 411 of the Garn St-Germain Depository Institutions Act of 1982 (12 U.S.C. 461).

2. In § 204.9 paragraphs (a)(1) and (a)(2) are revised to read as follows:

§ 204.9 Reserve requirement ratios.

(a)(1) Reserve percentages. The following reserve ratios are prescribed for all depository institutions, Edge and Agreement Corporations, and United States branches and agencies of foreign banks:

Category	Reserve requirement
Net transaction accounts:[1]	
$0 to $42.2 million	3 percent of amount.
Over $42.2 million	$1,266,000 plus 12 percent of amount over $42.2 million.
Nonpersonal time deposits.	0 percent.
Eurocurrency liabilities	0 percent.

[1] Dollar amounts do not reflect the adjustment to be made by the next paragraph.

(2) Exemption from reserve requirements. Each depository institution, Edge or agreement corporation, and U.S. branch or agency of a foreign bank is subject to a zero percent reserve requirement on an amount of its transaction accounts subject to the low reserve tranche in paragraph (a)(1) of this section not in excess of $3.6 million determined in accordance with § 204.3(a)(3) of this part.

* * * * *

[2] In November of 1985, the Board amended the definition of "total deposits" as used in determining the cutoff level to include not only gross transaction deposits, savings accounts, and time deposits, but also reservable obligations of affiliates, ineligible acceptance liabilities, and net Eurocurrency liabilities.

By order of the Board of Governors of the Federal Reserve System, November 21, 1991.

William W. Wiles,

Secretary of the Board.

[FR Doc. 91-28441 Filed 11-26-91; 8:45 am]

BILLING CODE 6210-01-M

12 CFR Part 263

[Docket No. R-0733]

RIN 7100-AB23

Uniform Rules of Practice and Procedure; Corrections

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule; correction.

SUMMARY: This notice corrects a previous **Federal Register** notice (FR Doc. 91-18913) that implemented a final rule revising rules of practice and procedure for administrative hearings.

FOR FURTHER INFORMATION CONTACT: Douglas B. Jordan, Senior Attorney, Legal Division, (202/452-3787).

EFFECTIVE DATE: August 9, 1991.

SUPPLEMENTARY INFORMATION: This notice corrects a previous **Federal Register** notice (FR Doc. 91-18913) published at page 38048, column 1, of the issue for Friday, August 9, 1991.

1. On page 38052, column 1, the amendment to § 262.3 contains a cross reference to the Board's Rules of Practice for Hearings "[part 262 of this chapter]" which should be corrected to read "[part 263 of this chapter]".

2. On page 38056, column 2, § 263.16, the word "Agency" should be removed and the words "Board or any Federal Reserve Bank" added in its place.

Board of Governors of the Federal Reserve System, November 21, 1991.

William W. Wiles,

Secretary of the Board.

[FR Doc. 91-28444 Filed 11-26-91; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 91-CE-83-AD; Amendment 39-8109; AD 91-25-08]

Airworthiness Directives; Cessna Models 421C and 425 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Cessna Models 421C and 425 airplanes. This AD action requires initial and repetitive inspections of both wing front spar upper caps for cracks, and repair of a spar if cracks are found that exceed certain criteria. Cracks have been found in the wing front spar upper cap at the main landing gear actuating cylinder attachment fitting on three of the affected airplanes. The actions specified by this AD are intended to prevent wing failure because of excessive wing spar cracking.

DATES: *Effective* December 23, 1991.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the **Federal Register** as of December 23, 1991.

Comments for inclusion in the Rules Docket must be received on or before January 31, 1992.

ADDRESSES: Cessna Service Bulletin (SB) MEB91-7 and SB CQB91-8, both dated October 18, 1991, may be obtained from the Cessna Aircraft Company, Customer Service Department 753, P.O. Box 7704, Wichita, Kansas 67277; Telephone (316) 941-7550; Facsimile (316) 942-9008. This information may also be examined at the Rules Docket at the address below.

Send comments on this AD in triplicate to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket 91-CE-83-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: Mr. Larry Abbott, Aerospace Engineer, Wichita Aircraft Certification Office, 1801 Airport Road, room 100, Mid-Continent Airport, Wichita, Kansas 67209; Telephone (316) 946-4123; Facsimile (316) 426-4407.

SUPPLEMENTARY INFORMATION: Cracks have been found in the wing front spar upper cap on three Cessna Models 421C and 425 airplanes. These cracks were located at the main landing gear actuating cylinder attachment fitting outboard of the front spar wing attach fittings.

The Cessna Aircraft Company has issued Cessna Service Bulletin (SB) MEB91-7 and Cessna SB CQB91-8, both dated October 18, 1991, which specify procedures for inspecting both wing front spar upper caps for cracks on Cessna Models 421C and 425 airplanes. The FAA examined the above situation, reviewed all available information, and has determined that, in order to prevent wing failure caused by cracked front spar upper caps, airworthiness directive (AD) action should be taken.

Since the condition described is likely to exist or develop in other Cessna Models 421C and 425 airplanes of the same type design, this AD requires initial and repetitive inspections of both wing front spar upper caps at the main landing gear actuating cylinder attachment fittings in accordance with the instructions in Cessna SB MEB91-7 or Cessna SB CQB91-8, whichever is applicable. It requires repair of a wing front spar upper cap if cracks are found that exceed certain criteria. This action also requires an inspection reporting program. Based on the information received from this program, additional rulemaking may be initiated.

Because an emergency condition exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable and that good cause exists for making this amendment effective in less than 30 days. Although this action is in the form of a final rule that involves requirements affecting immediate flight safety and, thus, was not preceded by notice and public procedure, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments will be considered and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing data for comments, in the Rules Docket at the address given above. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not

have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation in an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Executive Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket (otherwise, an evaluation is not required). A copy of it, if filed, may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new AD:

91-25-08 Cessna: Amendment 39-8109; Docket No. 91-CE-83-AD. Applicability: Model 421C airplanes (serial numbers (S/N) 421C0801 through 421C1807) and Model 425 airplanes (S/N 425-0002 through 425-0236), certificated in any category.

Compliance: Required as indicated, unless already accomplished.

Note: The compliance time in this AD takes precedence over that cited in the referenced service information.

To prevent wing failure caused by cracks in a wing front spar upper cap, which could result in loss of control of the airplane, accomplish the following:

(a) Upon the accumulation of 3,000 hours time-in-service (TIS) or within the next 25 hours TIS after the effective date of this AD, whichever occurs later, fluorescent penetrant inspect both wing front spar upper caps for cracks between the main landing gear actuating cylinder attachment and the front spar wing attach fittings in accordance with the instructions in Cessna Service Bulletin (SB) MEB91-7 or Cessna SB CQB91-8, both dated October 18, 1991, whichever is applicable.

(1) If any crack is found that is 2.5 inches or greater in length that is parallel to the top of the spar cap or any crack that is perpendicular to the top of the spar cap, prior to further flight, obtain a repair scheme from the manufacturer through the Wichita Aircraft Certification Office at the address specified in paragraph (b) of this AD, and reinspect thereafter at intervals not to exceed 300 hours TIS.

(2) If any crack is found that is less than 2.5 inches in length and is parallel to the top of the spar cap, return the airplane to service and reinspect thereafter at intervals not to exceed 25 hours TIS.

(3) If no cracks are found, return the airplane to service and reinspect thereafter at intervals not to exceed 300 hours TIS.

(b) Send the results of each inspection in writing to the Manager, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Room 100, Wichita, Kansas 67209, within 10 days after each inspection. State whether cracks were found, the location and length of any cracks, and the total hours TIS of the component at the time the crack was discovered. Reports may be submitted by filling out the form provided in the applicable service bulletin. (Reporting approved by the Office of Management and Budget under OMB No. 2120-0056.)

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Wichita Aircraft Certification Office at the address specified in paragraph (b) of this AD. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Wichita Aircraft Certification Office.

(e) The inspections required by this AD shall be done in accordance with Cessna Service Bulletin MEB91-7 or Cessna Service Bulletin CQB91-8, both dated October 18, 1991, whichever is applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies may be obtained from the Cessna Aircraft Company, Customer Service Department 753, P.O. Box 7704, Wichita, Kansas 67277. Copies may be inspected at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the Federal Register, 1100 L Street, NW; room 8401, Washington, DC. This amendment becomes effective on December 23, 1991.

Issued in Kansas City, Missouri, on November 29, 1991.

John E. Tigue,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 91-28413 Filed 11-26-91; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 39

[Docket No. 91-NM-221-AD; Amendment 39-8094; AD 91-24-08]

Airworthiness Directives; McDonnell Douglas Model MD-11 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to McDonnell Douglas Model MD-11 series airplanes, which requires a borescope inspection of the left and right outboard flap inboard and outboard closure rib spindle support fittings, and a visual inspection for cracks and delamination of the flap upper skin, and repair, if necessary. This amendment is prompted by reports of cracks in the outboard flap assembly inboard and outboard closure rib spindle support fittings and flap upper skin. This condition, if not corrected, could result in fatigue cracking and possible structural failure of the outboard flaps.

DATES: Effective December 12, 1991.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 12, 1991.

ADDRESSES: The applicable service information may be obtained from McDonnell Douglas Corporation, Technical Publications-Technical Administrative Support, C1-L5B, 3855 Lakewood Boulevard, Long Beach, California 90846. This information may be examined at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ms. Maureen Moreland, Aerospace Engineer, ANM-121L, FAA, Northwest Mountain Region, Transport Airplane Directorate, Los Angeles, California; telephone (213) 988-5238.

SUPPLEMENTARY INFORMATION: McDonnell Douglas has reported to the FAA findings of fatigue cracks in the outboard flap assembly on inboard and outboard closure rib spindle support fittings that were removed from three Model MD-11 flight test airplanes. Cracks were found in four outboard flap inboard and outboard spindle support fittings on two airplanes and in three fittings on the third airplane. The cracks were located in the upper and lower horizontal flanges of the fittings. In addition, cracks and delamination of the flap upper skin at the intersection/transition radius area of the outboard closure ribs were found on three flight test and four in-service airplanes. This condition, if not corrected, could result in fatigue cracking and possible structural failure of the outboard flaps.

The FAA has reviewed and approved McDonnell Douglas Alert Service Bulletin A57-15, Revision 2, dated October 28, 1991, which describes procedures for visual and borescope inspections for cracks, and necessary repair, of the outboard flap closure rib support fittings and upper and lower skin. The service bulletin also describes a modification of the closure rib spindle fittings and the addition of a doubler to the upper and lower flap skins.

Since this situation is likely to exist or develop on other airplanes of the same type design, this AD requires repetitive inspection of the left and right outboard flap inboard and outboard closure rib spindle support fittings and flap upper skin, and modification or repair, if necessary, in accordance with the service bulletin previously described.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable, and good cause exists for making this amendment effective in less than 30 days.

This is considered to be interim action. The FAA is considering further rulemaking to require the installation of a modification that will terminate the requirement for the repetitive inspections. However, the proposed compliance time is sufficiently long so that notice and public comment will not be impracticable.

The regulations adopted hereon will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—[AMENDED]

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

91-24-08. McDonnell Douglas: Amendment 39-8094. Docket No. 91-NM-221-AD.

Applicability: Model MD-11 series airplanes, certificated in any category.

Compliance: Required as indicated, unless previously accomplished.

To prevent fatigue cracking and possible structural failure of the outboard flaps, accomplish the following:

(a) Prior to the accumulation of 400 landings, or within 30 days after the effective date of this AD, whichever occurs later, perform a borescope inspection to detect cracks in the left and right outboard flap inboard and outboard closure rib spindle support fittings, in accordance with Paragraph 2, "Accomplishment Instructions," of McDonnell Douglas Alert Service Bulletin A57-15, Revision 2, dated October 28, 1991 (hereinafter referred to as the Service Bulletin).

(b) Within 30 days after the effective date of this AD, perform a visual inspection for cracks and delamination of the upper skin of the outboard flaps in accordance with the Service Bulletin.

(c) If no cracking or delamination is found as a result of the inspections required by paragraphs (a) and (b) of this AD, accomplish either subparagraph (c)(1) or (c)(2) of this AD:

(1) Repeat the borescope inspections of the spindle support fittings required by paragraph (a) of this AD at intervals not to exceed 400 landings; and repeat the visual inspections of the upper skin required by paragraph (b) of this AD at intervals not to exceed 60 days. In cases where no cracking is found, the accomplishment of the modification shown in Figures 3 and 4 and described in Tables I and II of the Service Bulletin constitutes terminating action for the repetitive inspections required by this paragraph. Or

(2) Prior to further flight, accomplish the modification shown in Figures 3 and 4 and described in Tables I and II of the Service Bulletin.

(d) If a crack with a length of less than 1 inch is found in the spindle support fitting as a result of the borescope inspections required by paragraphs (a) or (c)(1) of this AD, accomplish either subparagraph (d)(1) or (d)(2) of this AD:

(1) Prior to further flight, accomplish the modification shown in Figures 3 and 4 and described in Tables I and II of the Service Bulletin. In cases where such cracking is found, this modification is considered to be an interim (temporary) action only. Or

Note: The FAA is considering further rulemaking to require the accomplishment of a permanent repair.

(2) Prior to further flight, incorporate a permanent repair in a manner approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. The accomplishment of this permanent repair constitutes terminating action for the repetitive inspections required by paragraph (c)(1) of this AD.

(e) If a crack with a length of greater than 1 inch is found in the spindle support fitting as a result of the borescope inspections required by paragraph (a) or (c)(1) of this AD, prior to further flight, accomplish a permanent repair in a manner approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Accomplishment of this permanent repair constitutes terminating action for the repetitive inspections required by paragraph (c)(1) of this AD.

(f) If cracks or delamination are found in the skin as a result of the inspections required by paragraph (b) of this AD, prior to further flight, accomplish the modification shown in Figures 3 and 4 and described in Tables I and II of the Service Bulletin. Accomplishment of this modification constitutes terminating action for the repetitive inspections required by paragraph (c)(1) of this AD.

(g) An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate.

Note: The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who may concur or comment and then send it to the Manager, Los Angeles ACO.

(h) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the inspection requirements of this AD.

(i) The inspection and modification requirements shall be done in accordance with McDonnell Douglas MD-11 Alert Service Bulletin A57-15, Revision 2, dated October 28, 1991. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies may be obtained from McDonnell Douglas Corporation, Technical Publications-Technical Administrative Support, C1-L5B, 3855 Lakewood Boulevard, Long Beach, California 90846. Copies may be inspected at the FAA, Northwest Mountain Region, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California; or at the Office of the Federal Register, 1100 L Street NW., room 8401, Washington, DC.

This amendment (39-8094, AD 91-24-08) becomes effective on December 12, 1991.

Issued in Renton, Washington, on November 4, 1991.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 91-28412 Filed 11-26-91; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF COMMERCE

Technology Administration

15 CFR Part 1170

Productvity, Technology, and Innovation Metric Conversion Policy for Federal Agencies; Correction of Final Rule

AGENCY: Technology Administration, Commerce.

ACTION: Final rule; correction.

SUMMARY: The Department of Commerce's Technology Administration (hereinafter "TA") is correcting the table of contents pertaining to its regulations on Metric Conversion Policy for Federal Agencies, found at 15 CFR part 1170. TA published a Notice of Final Rule and Redesignation on Tuesday, August 20, 1991, which, *inter alia*, redesignated the section numbers for its regulations on Metric Conversion Policy for Federal Agencies from 15 CFR part 19 (subpart B) to 15 CFR part 1170. This is to correct the table of contents that was incorrectly listed in the Notice of Final Rule and Redesignation, published in the **Federal Register** on Tuesday, August 20, 1991 at page 41283.

EFFECTIVE DATE: November 27, 1991.

FOR FURTHER INFORMATION CONTACT: Philip J. Greene (202) 377-5394.

SUPPLEMENTARY INFORMATION: TA has promulgated regulations on Metric Conversion Policy for Federal Agencies to provide policy and guidelines for coordination for Federal agencies to deal with increasing use of the metric system within the Federal Government, consistent with voluntary conversion in State and local governments and in the private sector. These regulations were formerly found at 15 CFR part 19 (subpart B). On Tuesday, August 20, 1991, TA published a Notice of Final Rule and Redesignation which, *inter alia*, moved the above referenced regulations from 15 CFR part 19 (subpart B) to 15 CFR part 1170. In doing so, it published an incorrect table of contents. This is to correct the table of contents that was incorrectly listed in the above referenced Notice of Final Rule and Redesignation.

Dated: November 15, 1991.

Deborah Wince-Smith,

Assistant Secretary of Commerce for Technology Policy.

In the **Federal Register** issue of Tuesday, August 20, 1991, on page 41283, column one, the table of contents for 15 CFR part 1170 is correctly revised to read as follows:

Sec.
1170.1 Purpose.
1170.2 Definition.
1170.3 General policy.
1170.4 Guidelines.
1170.5 Recommendations for agency organization.
1170.6 Reporting requirement.
1170.7—1170.199 [Reserved].

[FR Doc. 91-28530 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 404

[Regulations No. 4]

RIN 0960-None Assigned

Federal Old-Age, Survivors and Disability Insurance; Determining Disability and Blindness; Extension of Expiration Date for Respiratory System Listings

AGENCY: Social Security Administration, HHS.

ACTION: Final rule.

SUMMARY: We are extending the expiration date of the respiratory system listings found in appendix I of part 404, subpart P, from December 6, 1991, to December 7, 1992. We have made no revisions in the medical criteria in the respiratory system listings; they remain the same as they now appear in the Code of Federal Regulations. We are presently considering revisions to update the medical criteria contained in part A and part B of the listings, and any revised criteria will be published as a proposed rule when we have completed our review.

EFFECTIVE DATE: This final rule will be effective November 27, 1991.

FOR FURTHER INFORMATION CONTACT: William J. Ziegler, Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (301) 965-1759.

SUPPLEMENTARY INFORMATION: On December 6, 1985, a revised Listing of Impairments in appendix 1 to subpart P of part 404 was published in the **Federal Register** (50 FR 50068). The Listing of Impairments describes, for each of 13 major body systems, impairments that are considered severe enough to preclude a person from engaging in any gainful activity (part A), or in the case of a child under the age of 18, impairments that are severe enough to prevent the child from functioning independently, appropriately, and effectively in an age-appropriate manner (part B). The Listing of Impairments is used for evaluating disability and blindness under the social security disability program and the supplemental security income program.

When the revised Listing of Impairments was published in 1985, we indicated that disability evaluation and treatment and program experience would require that the listings be periodically reviewed and updated. Accordingly, expiration dates were established ranging from 4 to 8 years for each of the specific body systems. A termination date of December 6, 1991, was established for part A of the respiratory system listings at that time. Part B of the listings has a termination date of December 6, 1993.

In May 1986, the Social Security Administration (SSA) asked several experts to review the current respiratory listings and propose revisions to SSA based upon advances in medical knowledge and technology. These experts included representatives from national medical professional groups and Federal and State representatives

with expertise in the evaluation of disability claims involving respiratory impairments. Three additional meetings were held over the next year, and the experts submitted their individual recommendations to SSA on May 20, 1988. These recommendations have required careful study as we have reviewed the existing listings and considered the development of new regulations.

As a result of our continuing and careful review of the listings, we now find that we will not have sufficient time to publish a notice of proposed rulemaking (with a 60-day period for public comment), setting out proposed revisions to the current listings and then publish a final regulation in the **Federal Register** by December 6, 1991. We have, therefore, decided to extend the current respiratory system listings without change for a period of 12 months and one day—from the present expiration date of December 6, 1991 to December 7, 1992. We would be extending the expiration date for one year, but December 6, 1992 is a Sunday. Under 20 CFR 404.3(c), the regulation would remain in effect through December 7, 1992. Therefore, we are extending the time period for an additional day. We believe this extension will give us sufficient time to publish any revised listings as a proposed rule (with a 60-day period for public comment), and then publish a final regulation in the **Federal Register** by December 7, 1992.

Regulatory Procedures

The Department, even when not required by statute, as a matter of policy, generally follows the Administrative Procedure Act notice of proposed rulemaking and public comment procedures specified in 5 U.S.C. 553 in the development of its regulations. The Administrative Procedure Act provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that, under 5 U.S.C. 553(b)(B), good cause exists for waiver of notice of proposed rulemaking and public comment procedures on this rule because it only extends the expiration date of part A of the respiratory system listings and makes no substantive changes to these listings. The current regulations expressly provide that the listings may be extended by the Secretary, as well as revised and promulgated again. Because we are not making any revisions to the current listings, use of public comment procedures is not contemplated by the existing regulations and is unnecessary under the Administrative Procedure Act. After our review of the existing respiratory system listings is completed, proposed revisions to the existing criteria will be published for public comment.

Executive Order 12291

The Secretary has determined that this is not a major rule under Executive Order 12291 because this regulation does not meet any of the threshold criteria for a major rule. Therefore, a regulatory impact analysis is not required.

Regulatory Flexibility Act

We certify that this regulation will not have a significant economic impact on a substantial number of small entities because it only affects disability claimants under titles II and XVI of the Act.

Paperwork Reduction Act

This regulation imposes no reporting or recordkeeping requirements necessitating clearance by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.802, Social Security Disability Insurance; No. 93.807, Supplemental Security Income Program)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: October 22, 1991.

Gwendolyn S. King,

Commissioner of Social Security.

Approved: November 12, 1991.

Louis W. Sullivan,

Secretary of Health and Human Services.

For the reasons set forth in the preamble, part 404, title 20 of the Code of Federal Regulations is amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950-)

1. The authority citation for subpart P of part 404 is revised to read as follows:

Authority: Secs. 202, 205 (a), (b), and (d)–(h), 216(i), 221 (a) and (i), 222(c), 223, 225, and 1102 of the Social Security Act; 42 U.S.C. 402, 405 (a), (b) and (d)–(h), 416 (i), 421 (a) and (i), 422 (c), 423, 425, and 1302.

2. Appendix 1 to subpart P, is amended by revising the third paragraph of the introductory text to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

The respiratory system (3.00) will no longer be effective on December 7, 1992.

* * * * *

[FR Doc. 91-28418 Filed 11-26-91; 8:45 am]

BILLING CODE 4190-29-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

Indiana Permanent Regulatory Program; Self-Bonding

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval of a proposed amendment to the Indiana permanent regulatory program (hereinafter referred to as the Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment (Program Amendment Number 91-7A) consists of proposed changes to the Indiana Surface Mining Statute provisions concerning self-bonding. The amendment is intended to adopt certain provisions of the 1990 Indiana Senate Enrolled Act 52.

EFFECTIVE DATE: November 27, 1991.

FOR FURTHER INFORMATION CONTACT: Mr. Richard D. Rieke, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, room 301, Indianapolis, IN 46204, telephone (317) 226-6166.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program
II. Submission of the Amendment
III. Director's Findings
IV. Summary and Disposition of Comments
V. Director's Decision
VI. Procedural Determinations

I. Background on the Indiana Program

On July 29, 1982, the Indiana program was made effective by the conditional approval of the Secretary of the Interior. Information pertinent to the general background on the Indiana program, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982 **Federal**

Register (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 914.15 and 914.16.

II. Submission of the Amendment

By letter dated June 4, 1991 (Administrative Record No. IND-0894), the Indiana Department of Natural Resources (IDNR) submitted a proposed amendment to the Indiana program at Indiana Code (IC) 13-4.1-1 through 13-4.1-6, 13-4.1-6.3 and 13-4.1-14. The proposed amendment consisted of Indiana's 1990 Senate Enrolled Act (SEA) 52, 1991 SEA 46, and 1991 SEA 154. These were received as a single proposed amendment. By letter dated June 5, 1991 (Administrative Record No. IND-0886), Indiana requested the OSM to separately process the statutes as three separate amendments. Consequently, this notice addresses the proposed amendments submitted under Indiana's SEA 52. SEA 52 was adopted during the 1990 Legislative Session and contains revisions to the self-bonding and bond pool fund provisions.

By letter dated March 18, 1988 (Administrative Record No. IND-0559A), Indiana submitted proposed amendments to IC 13-4.1-6.5 which propose to establish the Indiana surface coal mine reclamation bond pool. OSM is currently reviewing the proposed Indiana bond pool amendments. Therefore, the following proposed amendments which were submitted by Indiana under SEA 52, and which concern the proposed Indiana bond pool, have been transferred to and will be reviewed with the proposed bond pool amendment submitted under Administrative Record No. IND-0559A: IC 13-4.1-6.5-4 concerning participation in the bond pool; IC 13-4.1-6.5-6 concerning suspension from the bond pool; IC 13-4.1-6.5-9 concerning use of bond pool funds; and IC 13-4.1-6.5-11(e) concerning bond pool fund committee.

OSM announced receipt of the proposed amendment in the July 9, 1991, **Federal Register** (56 FR 31093), and in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period ended on August 8, 1991. The scheduled public hearing was not held as no one requested an opportunity to provide testimony.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment to the Indiana program.

1. IC 13-4.1-6.3-11, Indemnity Agreement

IC 13-4.1-6.3-11(2) currently requires that corporations applying for a self-bond or corporate guarantors guaranteeing a subsidiary's self-bond must submit an indemnity agreement signed by two corporate officers who are authorized to bind the corporation. Indiana proposes to amend the provision by deleting the "or" which follows "corporations applying for a self-bond" and by adding in its place the word "and," and to delete the word "subsidiary's." Indiana also proposes to add two requirements:

(1) That the director of IDNR must be given an affidavit certifying that the indemnity agreement is valid under all applicable State and Federal laws; and

(2) That a corporate guarantor must give the director of IDNR a copy of the corporate authorization demonstrating that the corporation may guarantee the self-bond and execute the indemnity agreement.

The proposed amendments render the IC 13-4.1-6.3-11(2) to be substantively identical to 30 CFR 800.23(e)(2) concerning self bonding. The Director notes that OSM has previously approved substantively identical amendments to IC 13-4.1-6.3-11(2) on April 23, 1990 (55 FR 15226). The Director finds the proposed amendments to be no less effective than the Federal regulations.

2. IC 13-4.1-6.3-13, Notice of Changes in Financial Condition

Indiana proposes to amend this provision by adding language which requires that if the applicant does not post an alternate form of bond within 90 days, the applicant must cease coal extraction and immediately begin reclamation. The approved Indiana program at 310 IAC 12-0.5-101 defines reclamation to mean those actions taken to restore mined land as required by IC 13-4.1, the Indiana surface coal mining and reclamation operations law, and 310 IAC 12, the Indiana surface coal mining and reclamation operations rules, to an approved postmining land use.

The Federal regulations at 30 CFR 800.16(e)(2) require that if an adequate bond is not posted by the end of the period allowed (not to exceed 90 days), the operator shall cease coal extraction and shall comply with the provisions concerning permanent cessation of operations at 30 CFR 816/817.132 and shall immediately begin to conduct reclamation operations in accordance with the reclamation plan. The Director notes that OSM has previously approved substantively identical amendments to IC 13-4.1-6.3-13 on April 23, 1990 (55 FR 15226). The Director finds that the proposed language is no less effective than the counterpart Federal regulations at 30 CFR 800.23(g).

IV. Summary and Disposition of Comments

Agency Comments

Pursuant to section 503(b) of SMCRA and 30 CFR 732.17(H)(11)(i), comments were solicited from various interested Federal agencies. The U.S. Environmental Protection Agency (EPA) responded that it had no comments and concurred on the proposed changes. The U.S. Fish and Wildlife Service and the U.S. Army Corps of Engineers, Management and Disposal Division responded but had no comments on the proposed amendments.

Public Comments

The public comment period and opportunity to request a public hearing was announced in the July 9, 1991, **Federal Register** (56 FR 31093). The comment period closed on August 8, 1991. No one requested an opportunity to testify at the scheduled public hearing so no hearing was held.

By letter dated August 3, 1991 (Administrative Record No. IND-0927), The Hoosier Environmental Council responded but had no specific comments related to the proposed amendments.

By letter dated August 6, 1991 (Administrative Record No. IND-0925), the Indiana Coal Council, Inc. responded and supported the proposed amendments and said they should be approved. In response, the Director notes that the proposed amendments concerning self-bonding are being approved and that the amendments submitted with SEA 52 that are related to Indiana's proposed bond pool at IC 13-4.1-6.5 have been transferred to and will be reviewed with the proposed bond pool amendment submitted under Administrative Record No. IND-0559A.

V. Director's Decision

Based on the above findings, the Director is approving proposed Program Amendment Number 91-7A as submitted by Indiana on June 4, 1991, with the exceptions of proposed amendments to IC 13-4.1-6.5 concerning the proposed Indiana bond pool. The proposed amendments to IC 13-4.1-6.5 have been transferred to and will be processed with the proposed bond pool amendment submitted under Administrative Record No. IND-0559A.

The Federal regulations at 30 CFR part 914 codifying decisions concerning the Indiana program are being amended to

implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage the states to conform their programs with the Federal standards without delay. Consistency of State and Federal standards is required by SMCRA.

EPA Concurrence

Under 30 CFR 732.17(h)(ll)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a State program amendment that relate to air or water quality standards promulgated under the authority of the Clear Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). The Director has determined that this amendment contains no provisions in these categories and that EPA's concurrence is not required. However, EPA responded to the Director's request for comments and stated that EPA had no comments and that it concurred on the proposed amendment (Administrative Record No. IND–0919).

VI. Procedural determinations

National Environmental Policy Act

The Secretary has determined that, pursuant to section 702(d) of SMCRA, 30 U.S.C. 1292(d), no environmental impact statement need be prepared on this rulemaking.

Exective Order 12291 and the Regulatory Flexibility Act

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Therefore, this action is exempt from preparation of a regulatory impact analysis and regulatory review by OMB.

The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule will not impose any new requirements; rather, it will ensure that existing requirements established by SMCRA and the Federal rules will be met by the State.

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under 44 U.S.C. 3507.

List of Subjects in 30 CFR Part 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 15, 1991.

Carl C. Close,

Assistant Director, Eastern Support Center.

For the reasons set out in the preamble, title 30, chapter VII, subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 914—INDIANA

1. The authority citation for part 914 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 914.15 is amended by adding a new paragraph (hh) to read as follows:

§ 914.15 Approval of regulatory program amendments.

* * * * *

(hh) The following amendments to the Indiana program as submitted to OSM on June 4, 1991 (under Program Amendment Number 91–7A), are approved effective November 27, 1991: IC 13–4.1–6.3–11 (2) concerning indemnity agreements; and IC 13–4.1–6.3–13 concerning notice of changes in financial condition.

[FR Doc. 91–28440 Filed 11–26–91; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Chapter I

Administrative Changes

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: The Department of Defense published a final rule revising the heading for subchapter R in title 32 of the Code of Federal Regulations. This document corrects the heading for subchapter R. This document also revises the heading for subchapters L and P.

EFFECTIVE DATE: July 11, 1991.

FOR FURTHER INFORMATION CONTACT: L. Bynum, 703–697–4111 in the **Federal Register** issue of Thursday, July 11, 1991, on page 31537, the heading for subchapter R is corrected to read as follows:

SUBCHAPTER R—ORGANIZATIONAL CHARTERS

SUBCHAPTER L—ENVIRONMENT [RESERVED]

The heading for subchapter L is added as set forth above and reserved.

SUBCHAPTER P—OBTAINING DOD INFORMATION

The heading for subchapter P is revised as set forth above.

Dated: November 20, 1991.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

November 20, 1991

[FR Doc. 91–28236 Filed 11–26–91; 8:45 am]

BILLING CODE 3810–01–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05–91–50]

Special Local Regulations for Marine Events; Holidays in the City Boat Parade; Town Point, Elizabeth River, Norfolk, VA

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation of 33 CFR 100.501.

SUMMARY: This notice implements 33 CFR 100.501 for the Holiday in the City Boat Parade and Fireworks Display. The event will consist of a boat parade with approximately 80 vessels and a fireworks display at the conclusion of the parade. The regulations in 33 CFR 100.501 are needed to control vessel traffic within the immediate vicinity of the event due to the confined nature of the waterway and the expected congestion at the time of the event. The regulations restrict general navigation in the area for the safety of life and property on the navigable waters during the event.

EFFECTIVE DATES: The regulations in 33 CFR 100.501 are effective from 4:30 p.m. to 8:30 p.m., November 30, 1991.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Phillips, Chief, Boating Affairs Branch, Boating Safety Division, Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004 (804) 398–6204, or Commander, Coast Guard Group Hampton Roads (804) 483–8559.

Drafting Information

The drafters of this notice are QM1 Kevin R. Connors, project officer,

Boating Affairs Branch, Boating Safety Division, Fifth Coast Guard District, and Lieutenant Monica L. Lombardi, project attorney, Fifth Coast Guard District Legal Staff.

Discussion of Regulation

The Downtown Norfolk Council submitted an application to hold the Holidays in the City Boat Parade and Fireworks Display. The boat parade will be held in the Elizabeth River in the Town Point area between the Banana Landmass and the Berkley Bridge. The fireworks display will be launched from Town Point Park, and will burst over the Elizabeth River. Since many spectator vessels are expected to be in the area to watch the boat parade and fireworks display, the regulations in 33 CFR 101.501 are being implemented for these events. The waterway will be closed during the fireworks display. Since the waterway will not be closed for an extended period, commercial traffic should not be severely disrupted. In addition to regulating the area for the safety of life and property, this notice of implementation also authorizes the Patrol Commander to regulate the operation of the Berkley drawbridge in accordance with 33 CFR 117.1007, and authorizes spectators to anchor in the special anchorage areas described in 33 CFR 110.72aa. The implementation of 33 CFR 100.501 also implements regulations in 33 CFR 110.72aa and 117.1007. 33 CFR 110.72aa establishes the spectator anchorages in 33 CFR 100.501 as special anchorage areas under Inland Navigation Rule 30, 33 U.S.C. 2030(g). 33 CFR 117.1007 closes the draw of the Berkley Bridge to vessels during and for one hour before and after the effective period under 33 CFR 100.501, except that the Coast Guard Patrol Commander may order that the draw be opened for commercial vessels.

Dated: November 20, 1991.

W.T. Leland,

Rear Admiral, U.S. Coast Guard Commander, Fifth Coast Guard District.

[FR Doc. 91-28489 Filed 11-26-91; 8:45 am]

BILLING CODE 4910-14-M

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33 CFR Part 117

[CGD1 91-004]

Drawbridge Operation Regulations, Saugus River, MA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: At the request of the Metropolitan District Commission (MDC) the Coast Guard is changing the regulations governing the General Edwards SR1A Bridge, mile 1.7, between Revere and Lynn, Massachusetts, over the Saugus River, by revising the hours when advance notice for an opening is required. This final rule will relieve the bridge owners of the burden of having persons constantly available to open the draws during periods of infrequent use and should still provide for the reasonable needs of navigation.

DATES: These regulations become effective on December 1, 1991.

FOR FURTHER INFORMATION CONTACT: William C. Heming, Bridge Administrator, First Coast Guard District, (212) 668-7170.

SUPPLEMENTARY INFORMATION: Drafting Information: The drafters of this notice are Mr. John McDonald, Project Officer, and Lieutenant Commander John Astley, project attorney.

Regulatory History

On 24 June, 1991, the Coast Guard published proposed rules in the **Federal Register** (56 FR 121), concerning this amendment. The Commander, First Coast Guard District, also published the proposal as a Public Notice dated July 3, 1991. In each notice interested persons were given until August 8, 1991, to submit comments.

Background and Purpose

The proposed regulations addressed the operation of all bridges over the Saugus River, including the MBTA/AMTRAK Bridge, mile 2.1 and the Belden Bly Bridge, mile 2.5, as well as the General Edwards SR1A Bridge. The Coast Guard received a number of adverse comments in opposition to this regulation. The District Commander has authorized a public hearing to collect data to resolve differences between various factions who support or oppose this regulation.

Mariners objected to having the bridges closed for any period of time because they could not pass under either the MBTA/AMTRAK or the Belden Bly Bridge at all stages of the tide. The mariners, however, did not submit adverse comments regarding the portion of the regulations pertaining to the General Edwards SR1A Bridge. This is primarily because the commercial and recreational vessels that use the Saugus River from December 1 to March 31, can pass under the General Edwards SR1A Bridge, which has a vertical clearance of 36' at mean low water (MLW) and 27' at mean high water (MHW).

In light of the above, as well as the fact that the issues to be resolved at the public hearing will not affect the implementation of that portion of the proposed regulation which pertains to the General Edwards SR1A Bridge, the Coast Guard has decided to promulgate that portion of the regulation regarding the General Edwards SR1A Bridge only. The final rule requires that mariners seeking to open the General Edwards SR1A Bridge must give an 8 hour advance notice from December 1 to March 31. This action will relieve the bridge owners of the burden of having persons constantly available to open the draws during periods of infrequent use, while at the same time still provide for the reasonable needs of navigation.

Discussion of Comments and Changes

The Coast Guard received a petition signed by 147 of the local mariners in opposition to the proposed regulation. Their opposition to the regulations was primarily directed at the portion of the proposed regulations that required the mariners to give advance notice for bridge openings at the MBTA/AMTRAK Bridge and the Belden Bly Bridge. This is because their vessels can not pass under these two bridges at all stages of the tide. However, all the mariners that use the Saugus River during the winter months can pass under the General Edwards SR1A Bridge at all times without a bridge opening. The vertical height of their boats is between 16' to 22', while the General Edwards SR1A Bridge has a clearance of 36' at MLW and 27' at MHW.

The enactment of this final rule should have no adverse impact on the mariners that use the Saugus River because the final rule will only implement the portion of the proposed rule that pertains to the General Edwards SR1A Bridge. The issues surrounding the proposed regulations for the MBTA/AMTRAK Bridge and the Belden Bly Bridge will be addressed at a public hearing and in subsequent rulemaking.

Regulatory Evaluation

These regulations are considered to be non-major under Executive Order 12291 on Federal Regulation, and nonsignificant under the Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). The economic impact is expected to be so minimal that a full regulatory evaluation is unnecessary. This opinion is based on the fact that the regulation will not prevent the mariners from transiting the bridges but shall just require advance notice for openings.

Small Entities

Because it expects the impact of these regulations to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) of the Regulatory Flexibility Act (5 U.S.C.

601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

This action has been analyzed under the principles and criteria in Executive Order 12612, and it has been determined that this rule does not have sufficient federalism implications to warrant preparation of a federal assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under section 2.B.2 of Commandant Instruction M16475.1B, this proposal is categorically excluded from further environmental documentation. A Categorical Exclusion Determination is available in the docket for inspection or copying at the John Foster Williams Building, room 628, 408 Atlantic Ave., Boston, Massachusetts.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

In consideration of the foregoing, part 117 of Title 33, Code of Federal Regulations, is amended as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05-1(g).

2. Section 117.618 is revised to read as follows:

§ 117.618 Saugus River.

(a) The following requirements apply to all bridges across the Saugus River:

(1) Public vessels of the United States, state or local vessels used for public safety, and vessels in distress shall be passed through the draw of each bridge as soon as possible at any time. The opening signal from these vessels is four or more short blasts of a whistle or horn or a radio request.

(2) The owners of these bridges shall provide and keep in good legible condition clearance gauges with figures not less than 12 inches high designed, installed and maintained according to provisions of § 118.160 of this chapter.

(3) Trains and locomotives shall be controlled so that any delay in opening the draw span shall not exceed seven minutes. However, if a train moving toward the bridge has crossed the home signal for the bridge before the signal requesting opening of the bridge is given, the train may continue across the bridge and must clear the bridge interlocks before stopping.

(b) The draw of the General Edwards SR1A Bridge, mile 1.7, between Revere and Lynn, Massachusetts, shall open on signal except that from December 1 through March 31 at least 8 hour advance notice shall be given by commercial and recreational vessels for an opening.

3. Appendix A to part 117 is amended to add the Saugus River listings under the State of Massachusetts between the listings for Merrimack River and the Taunton River to read as follows:

APPENDIX A TO PART 117.—DRAWBRIDGES EQUIPPED WITH RADIOTELEPHONES

Waterway	Mile	Location	Bridge name and owner	Call sign	Calling channel	Working channel
*	*	*	*	*		
Massachusetts						
*	*	*	*	*		
Saugus River	1.7	Lynn-Revere	General Edwards SR1A, MDC	WHV 992	16	13
	2.1	Saugus-Revere	Saugus/MBTA, MBTA	KVY 568	16	13
	2.7	Saugus-Revere	Belden Bly(Foxhill), MDPW	Pending	16	13
*	*	*	*	*		

Dated: November 18, 1991.

J.D. Sipes,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 91-28488 Filed 11-26-91; 8:45 am]

BILLING CODE 4910-14-M

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 202

[Docket No. 91-13]

Deposit of Foreign Works

AGENCY: Library of Congress, Copyright Office.

ACTION: File rule.

SUMMARY: The Copyright Office of the Library of Congress is issuing a final regulation which permits, in the case of works first published outside the United States, the deposit of either one complete copy or phonorecord of the work as first published or one complete copy of the best edition, for purposes of registration under 17 U.S.C. 408.

EFFECTIVE DATE: November 27, 1991.

FOR FURTHER INFORMATION CONTACT: Dorothy Schrader (202) 707-8380.

SUPPLEMENTARY INFORMATION: In the case of works first published outside the United States, Copyright Office regulations have required the deposit of one complete copy or phonorecord of the work as first published for registration of a claim to copyright under section 408 of the Copyright Act, title 17 of the United States Code. For works first published in the United States, the required deposit is the best edition. This difference in the regulations has led to confusion about the correct deposit. The best edition is often submitted for registration of foreign works.

The Copyright Office is amending § 202.20(c)(1)(iv) of its regulations to permit the deposit, in the case of registration for works first published outside the United States, of either one copy or phonorecord of the first published edition or one copy or phonorecord of the best edition. No change was necessary in § 202.19 of the regulations governing mandatory deposit under section 407 of the Act for the Library of Congress. Of course, deposits made under amended § 202.20(c)(1)(iv) for registration will continue to meet the deposit requirements of section 407 for the Library. Deposit for the Library, where the foreign work is published in the United States and no registration has been made, will continue to require the deposit of the best edition.

With respect to the Regulatory Flexibility Act, the Copyright Office takes the position that this Act does not

apply to Copyright Office rulemaking. The Copyright Office is a department of the Library of Congress, which is part of the legislative branch. Neither the Library of Congress nor the Copyright Office is an "agency" within the meaning of the Administrative Procedure Act of June 11, 1946, as amended (title 5, of U.S. Code, subchapter II and chapter 7). The Regulatory Flexibility Act consequently does not apply to the Copyright Office since that Act affects only those entities of the Federal Government that are agencies as defined in the Administrative Procedure Act.[1]

Alternatively, if it is later determined by a court of competent jurisdiction that the Copyright Office is an "agency" subject to the Regulatory Flexibility Act, the Register of Copyrights has determined and hereby certifies that this regulation will have no significant impact on small businesses.

List of Subjects in 37 CFR Part 202

Copyright registration.

Final Regulation

In consideration of the foregoing, part 202 of title 37 of the Code of Federal Regulations is amended in the manner set forth below.

PART 202—REGISTRATION OF CLAIMS TO COPYRIGHT

1. The authority citation for part 202 continues to read as follows:

Authority: Sections 702, 90 Stat. 2451; 17 U.S.C. 702. §§ 202.19, 202.20, and 202.21 are also issued under 17 U.S.C. 407 and 408.

2. In § 202.20, paragraph (c)(1)(iv) is revised to read as follows:

§ 202.20 Deposit of copies and phonorecords for copyright registration.

* * * * *

(c) * * *

(1) * * *

(iv) In the case of works first published outside of the United States, one complete copy or phonorecord of the work either as first published or of the best edition. For purposes of this section, any works simultaneously first published within and outside of the United States shall be considered to be first published in the United States.

* * * * *

Dated: November 12, 1991.

Ralph Oman,

Register of Copyrights.

Approved by:

James H. Billington,

The Librarian of Congress.

[FR Doc. 91-28423 Filed 11-26-91; 8:45 am]

BILLING CODE 1410-07-M

[1] The Copyright Office was not subject to the Administrative Procedure Act before 1978, and it is now subject to it only in areas specified by section 701(d) of the Copyright Act (i.e. "all actions taken by the Register of Copyrights under this title (17), except with respect to the making of copies of copyright deposits) (17 U.S.C. 706(b)). The Copyright Act does not make the Office an "agency" as defined in the Administrative Procedure Act. For example, personnel actions taken by the Office are not subject to APA-FOIA requirements.

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA 7528]

List of Communities Eligible for the Sale of Flood Insurance

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: This rule identifies communities participating in the National Flood Insurance Program (NFIP). These communities have applied to the program and have agreed to enact certain floodplain management measures. The communities' participation in the program authorizes the sale of flood insurance to owners of property located in the communities listed.

EFFECTIVE DATES: The dates listed in the third column of the table.

ADDRESSES: Flood insurance policies for property located in the communities listed can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the National Flood Insurance Program (NFIP) at: Post Office Box 457, Lanham, Maryland 20706, Phone: (800) 638-7418.

FOR FURTHER INFORMATION CONTACT: Frank H. Thomas, Assistant Administrator, Office of Loss Reduction, Federal Insurance Administration, (202) 646-2717, Federal Center Plaza, 500 C Street SW., room 417, Washington, DC 20472.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Since the communities on the attached list have recently entered the NFIP, subsidized flood insurance is now available for property in the community.

In addition, the Director of the Federal Emergency Management Agency has identified the special flood hazard areas in some of these communities by publishing a Flood Hazard Boundary Map (FHBM) or a Flood Insurance Rate Map (FIRM). The date of the flood map, if one has been published, is indicated in the fourth column of the table. In the communities listed where a flood map has been published, section 102 of the Flood Disaster Protection Act of 1973, as amended, requires the purchase of flood insurance as a condition of Federal or federally related financial assistance for acquisition or construction of buildings in the special flood hazard area shown on the map.

The Director finds that the delayed effective dates would be contrary to the public interest. The Director also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

The Catalog of Domestic Assistance Number for this program is 83.100 "Flood Insurance."

Pursuant to the provisions of 5 U.S.C. 605(b), the Administrator, Federal Insurance Administration, to whom authority has been delegated by the Director, FEMA, hereby certifies that this rule, if promulgated will not have a significant economic impact on a substantial number of small entities. This rule provides routine legal notice stating the community's status in the NFIP and imposes no new requirements or regulations on participating communities.

List of Subjects in 44 CFR Part 64

Flood insurance and floodplains.

1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*, Reorganization Plan No. 3 of 1978, E.O. 12127.

2. Section 64.6 is amended by adding in alphabetical sequence new entries to the table.

In each entry, a complete chronology of effective dates appears for each listed community. The entry reads as follows:

§ 64.6 List of Eligible Communities.

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date
New Eligibles—Emergency Program			
Oklahoma: Helena, town of, Alfalfa County	400388	October 1, 1991	Apr. 2, 1976.
Iowa:			
Kossuth County, unincorporated areas	190884	do	June 21, 1977.
Shell Rock, city of, Butler County	190338	do	Dec. 17, 1976.
Florida: San Antonio, city of, Pasco County	120634	October 10, 1991	
Louisiana: Greenwood, town of, Caddo Parish	220292	October 14, 1991	
Georgia: Charlton County, unincorporated areas	130292	do	May 14, 1976.
Nebraska: Dundy County, unincorporated areas	310432	October 25, 1991	
Mississippi: [1] Tishomingo County, unincorporated areas	280283	October 30, 1991	May 12, 1978.
New Eligibles—Regular Program			
Ohio: Lorain County, unincorporated areas	390346	October 14, 1991	Sept. 30, 1988.
Minnesota: Mantorville, city of, Dodge County	270585	Oct. 23, 1991	Feb. 3, 1982.
Georgia: Toombs County, unincorporated areas	130173	Oct. 31, 1991	May 2, 1991.
Ohio: Athens County, unincorporated areas	390760	Oct. 31, 1991	May 2, 1991.
Reinstatements—Regular Program			
Pennsylvania:			
Armstrong, Township of, Indiana County	421708	July 7, 1975, Emerg.; Apr. 16, 1990, Rein.; Apr. 16, 1990, Susp.; Oct. 1, 1991, Rein.	Apr. 16, 1990.
Marianna, Borough of, Washington County	420854	Jan. 21, 1975, Emerg.; June 19, 1989, Reg.; June 19, 1989, Susp.; Oct. 14, 1991, Rein.	June 19, 1989.
Pike, Township of, Potter County	421983	July 11, 1975, Emerg.; Aug. 19, 1991, Reg.; Aug. 19, 1991, Susp.; Oct. 14, 1991, Rein.	Aug. 19, 1991.
Wisconsin: Bloomer, City of, Chippewa County	550042	Mar. 20, 1975, Emerg.; Aug. 19, 1991, Reg.; Aug. 19, 1991, Susp.; Oct. 21, 1991, Rein.	Aug. 19, 1991.
Massachusetts: Russell, town of, Hampton County	250148	Aug. 8, 1975, Emerg.; Dec. 15, 1990, Reg.; July 16, 1991, Susp.; Oct. 31, 1991, Rein.	July 16, 1991.
Minimal Conversions			
Region V			
Michigan:			
Iron Mountain, city of, Isabella County	260063	Oct. 16, 1991, suspension withdrawn	Oct. 16, 1991.
Sherman, township of, Isabella County	260788	do	Oct. 16, 1991.

Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension; Rein.—Reinstatement.
[1] Declared disaster area.

Issued: November 18, 1991.

C.M. "Bud" Schauerte,

Administrator, Federal Insurance Administration.

[FR Doc. 91-28463 Filed 11-26-91; 8:45 am]

BILLING CODE 6718-21-M

DEPARTMENT OF DEFENSE

48 CFR Parts 208, 209, 211, 215, 219, 223, 225, 226, 231, 232, 233, 235, 237, 242, 243, 247, 249, 250, 252

[Defense Acquisition Circular (DAC) 88-19]

Department of Defense Acquisition Regulations; Miscellaneous Amendments

AGENCY: Department of Defense (DoD).

ACTION: Final rules.

SUMMARY: Defense Acquisition Circular (DAC) 88-19 amends the DoD FAR Supplement (DFARS) (1988 Edition) coverage on restriction on antifriction bearings, liquidated damages—Small Business Subcontracting Test Program, historically black colleges and universities and minority institutions, hazard warning labels, drugfree work force, logistics support for contractor personnel in Germany and Italy, Trade Agreements Act, duty-free entry, Indian Incentive Program, expedited payments to small disadvantaged businesses, GAO protest regulations, approval of fixed price development contracts, notification of substantial impact on employment, extraordinary contractual actions, and suspension and debarring officials.

EFFECTIVE DATE: November 15, 1991.

FOR FURTHER INFORMATION CONTACT: Ms. Lucile Hughes, Defense Acquisition Regulations System, OUSD(A), The Pentagon, Washington, DC 20301-3000, telephone (703) 697-7266.

SUPPLEMENTARY INFORMATION:

A. Background

The DoD FAR Supplement is codified in chapter 2 title 48 of the Code of Federal Regulations.

The October 1, 1990 revision of the CFR is the most recent edition of that title. It includes amendments to the 1988 edition of the DoD FAR Supplement made by Defense Acquisition Circulars 88-1 through 88-15.

The looseleaf version of Defense Acquisition Circular 88-19 contains 18 final rules, four interim rules, and two informational items (Items II and X). Of the 18 final rules, six finalize interim rules (Items V, IX, XI, XII, XIX, and XXII). Due to their previous publication in the **Federal Register**, Items III, IV, VII, XIII, XIV, XVII, and XX of DAC 88-19 appear in the looseleaf version of DAC 88-19 but not in the CFR amendments of this **Federal Register** notice.

The interim rules included in DAC 88-19 (Items III, IV, XIII, and XX) were published previously in the **Federal Register** for public comment. Their publication in the looseleaf version of DAC 88-19 does not constitute a request for comment.

Item III was published April 12, 1991 (56 FR 18610).

Item IV was published September 5, 1991 (56 FR 43986) and amended September 30, 1991 (56 FR 49506).

Item XIII was published July 25, 1991 (56 FR 34030).

Item XX was published October 18, 1991 (56 FR 52440).

Three of the final rules included in the looseleaf version of DAC 88-19 were finalized in previous **Federal Register** publications.

Item VII was published August 9, 1991 (56 FR 37963).

Item XIV was published September 12, 1991 (56 FR 46520).

Item XVII was published July 10, 1991 (56 FR 31341).

B. Regulatory Flexibility Act

DAC 88-19, Items I, VI, XV, XVI, XVIII, XXI and XXIV

These final rules do not constitute significant revisions within the meaning of FAR 1.501 and Public Law 98-577 and publication for public comment is not required. Therefore, the Regulatory Flexibility Act does not apply.

DAC 88-19, Item V

The Department of Defense certifies that this final rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., because the rule is being used under a test program which has very limited application. There were no comments received in response to the April 15, 1991 interim rule publication (56 FR 15162) which addressed the Regulatory Flexibility Statement.

DAC 88-19, Item VIII

The Department of Defense certifies that this final rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., because it requires offerors or contractors merely to generate and furnish before and with their product, a hazard warning label which they are already required to do under 29 CFR 1910.1200. Therefore, the time and financial resources necessary to comply with the proposed requirement are already invested prior to any involvement in contracting with the Government.

DAC 88-19, Item IX

The Regulatory Flexibility Act, 5 U.S.C. 601 et seq. applies to this final rule and a Final Regulatory Flexibility Analysis has been performed. A copy of the analysis may be obtained by writing Defense Acquisition Regulations System, Attn: Linda Neilson, OUSD(A), Pentagon, Washington, DC 20301-3000.

DAC 88-19, Item XI

The Department of Defense certifies that this final rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., because it provides more opportunity for participation of small firms by adopting the substantially transformed criteria of the Trade Agreements Act.

DAC 88-19, Item XII

The Department of Defense certifies that this final rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., because it merely adds one element of readily available information, contractor's address, to that already required.

DAC 88-19, Item XIX

The Department of Defense certifies that this final rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., because it implements GAO's revised protest procedures (4 CFR part 21) by incorporating those procedures which are essential information for contracting officers. It does not impact the involvement of small entities in the GAO protest process.

DAC 88-19, Item XXII

The Regulatory Flexibility Act, 5 U.S.C. 601 et seq. applies to this final rule and a Final Regulatory Flexibility Analysis has been performed. A copy of the analysis may be obtained by writing Defense Acquisition Regulations System, Attn: Eric Mens, OUSD(A), Pentagon, Washington, DC 20301-3000.

DAC 88-19, Item XXIII

The Regulatory Flexibility Act, 5 U.S.C. 601 et seq., applies to this final rule and a Final Regulatory Flexibility Analysis has been performed. A copy of the analysis may be obtained by writing Defense Acquisition Regulations System, Attn: Valorie Lee, OUSD(A), Pentagon, Washington, DC 20301-3000.

C. Paperwork Reduction Act

DAC 88-19, Items I, V, VI, VIII, XI, XV, XVI, XVIII, XIX, XXI, XXIII, and XXIV

The Paperwork Reduction Act does not apply because these rules do not contain information collection requirements which require the approval of OMB under 44 U.S.C. 3501 et seq.

DAC 88-19, Item IX

The Paperwork Reduction Act applies. OMB approval has been requested.

DAC 88-19, Item XII

The Paperwork Reduction Act applies. OMB has approved the information collection under Department of the Treasury clearance 1515-0170.

DAC 88-19, Item XXII

The Paperwork Reduction Act applies. OMB approved the information collection requirement on the interim rule (OMB 0704-0327) for the period ending September 30, 1991. OMB approval of the final rule has been requested.

List of Subjects in 48 CFR Parts 208, 209, 211, 215, 219, 223, 225, 226, 231, 232, 233, 235, 237, 242, 243, 247, 249, 250, and 252

Government procurement.

Claudia L. Naugle,

Executive Editor, Defense Acquisition Regulations System.

(Defense Acquisition Circular No. 88-19, dated November 15, 1991)

All DoD FAR Supplement and other directive material contained in this circular is effective November 15, 1991, unless otherwise specified in the Item summary.

Defense Acquisition Circular (DAC) 88-19 amends the DoD FAR Supplement (DFARS) 1988 edition, prescribes procedures to be followed, and provides informational interest items. The amendments, procedures, and information are summarized as follows:

Item I—Editorial Revision

DFARS 209.470(b) is amended to update the designation of Navy suspending and debarring official.

Item II—Restriction on Antifriction Bearings

The restriction in DFARS 208.7902 on the acquisition of antifriction bearings has been extended from September 30, 1991 until December 31, 1992. Except for the date, there is no change to the related policy, the clause at 252.208-7006, Required Sources for Antifriction Bearings, or to the clause prescription at 208.7905.

Item III—Acquisition and Distribution of Commercial Products

This interim rule was issued by Departmental Letter 91-007, effective for use April 30, 1991, as implementation of Section 824(b) of the FY 90-91 National Defense Authorization Act (Pub. L. 101-189). Section 824(b) requires that DoD establish a simplified uniform contract format for the acquisition of commercial items and require the use of such format to the maximum extent practicable. This interim rule added DFARS subpart 211.70, Acquisition and Distribution of Commercial Products, and added clauses at 252.211-7000 through 252.211-7021. It:

—Prohibits Government specified quality systems or quality programs.
—Restricts Government in-plant inspection. (Tailored inspection requirements are permitted for items having critical applications.
—Prohibits the use of Government specified designs, manufacturing processes or procedures.
—Prohibits the use of Military Standards or Military Specifications

that would impede a commercial supplier's ability to satisfy a DoD requirement.
—Requires packaging and marking in accordance with commercial practices.
—Limits the acquisition of technical data.
—Requires commercial computer software to be acquired under the same licensing agreements provided to the general public.
—Prohibits unilateral specification changes.
—Restricts the number of Government clauses contractors must flow down to their subcontractors or suppliers.
—Reduces the number of contract clauses that may be used in a DoD contract for commercial items.

The interim rule was modified by Departmental Letter 91-020, issued September 26, 1991, which advised that the clause at 252.211-7005, Limitation of Liability, may not be appropriate for use in all contracts for commercial items and shall not be used in part 211 contracts, pending issuance of the part 211 final rule. In the meantime, in contracts for commercial automatic data processing equipment, contracting officers are to follow the guidance in DFARS 270.310(a) and use the clause at 252.270-7001, Warranty Exclusion and Limitation of Damages, unless the contracting officer determines that a higher degree of protection is in the best interest of the Government. In contracts for all other commercial items, contracting officers are to follow the guidance at FAR Subpart 46.8, and may use the Limitation of Liability clauses at FAR 52.246-23 and 52.246-24 or other liability clauses authorized for use by a Military Department or Defense Agency.

Item IV—Evaluation of Acquisitions for Services and Uncompensated Overtime

Departmental Letter 91-017, dated August 19, 1991, revised DFARS subparts 215.6 and 237.1 and added a solicitation provision entitled "Identification of Uncompensated Overtime" as interim implementation of Section 834 of the FY 1991 DoD Authorization Act (Pub. L. 101-510). Section 834 requires the Secretary of Defense to issue regulations to ensure, to the maximum extent practicable, that professional and technical services are acquired on the basis of the task to be performed rather than on the basis of the number of hours provided. The DFARS revisions include guidance on evaluation of service acquisitions and on factors to consider in evaluating proposals to ensure that the use of uncompensated overtime does not degrade the level of technical expertise required. Language and a solicitation provision have been added on the use of uncompensated overtime. The new provision is to be used in all solicitations estimated at $100,000 or more for services to be acquired on the basis of the number of hours to be provided. These DFARS revisions were effective August 19, 1991.

Item V—Liquidated Damages—Small Business Subcontracting Test Program

This finalizes, without change, the interim revisions made to DFARS 219.702, 219.708, and 252.219-7016 by DAC 88-18, Item III. The revisions suspend application of liquidated damages to comprehensive subcontracting plans submitted under the test program described in DFARS 219.702. The revisions were effective March 4, 1991.

Item VI—Historically Black Colleges and Universities and Minority Institutions

DFARS 219.705-2, 226.7001, and 226.7003 are revised to implement section 832 of the FY 1991 DoD Authorization Act (Pub. L. 101-510). Section 832 provides for further enhancement of opportunities for participation of historically black colleges and universities and minority institutions in DoD programs.

Item VII—Pilot Mentor-Protege Program

Departmental Letter 91-016, dated July 31, 1991, revised DFARS 232.412 and added subpart 219.71 and the clause at 252.232-7009 to implement section 831 of the FY 1991 Defense Authorization Act (Pub. L. 101-510), as amended. Section 831 required that DoD establish a test program offering incentives to major contractors which provide developmental assistance to small disadvantaged businesses. Policy and procedures for operation of the test program are described in detail in a DoD policy document entitled "DoD Policy For the Pilot Mentor-Protege Program," a copy of which is included in this Defense Acquisition Circular. The DFARS amendments were effective October 1, 1991.

Item VIII—Hazard Warning Labels

DFARS subpart 223.72 is revised and a solicitation provision and clause are added as 252.223-7006 and 252.223-7007 to require that offerors identify hazardous materials which are not subject to the Hazard Communications Standard and to require that apparent successful offerors submit before award, labels for those materials which are subject to the Hazard Communications Standard.

IX—Drug-Free Work Force

This final rule replaces the interim rule published in DAC 88-2. It removes all language that duplicated the Drug-Free Workplace rule in FAR subpart 23.5 and it eliminates any ambiguity as to whether drug testing is required.

Item X—Logistics Support for Contractor Personnel in Germany and Italy

The United States Army, Europe (USAREUR) and Seventh Army grant logistics support and privileges to certain DoD contractor personnel under contracts performed in the Federal Republic of Germany and Italy. A USAREUR updated notice, superseding the notice published under Item I of DAC 88-11, of the support and privileges available is included as Attachment 2 to this DAC.

Item XI—Trade Agreements Act

This finalizes, without change, the interim revisions made by DAC 88-17, Item VII, to part 225, the clauses at 252.225-7001, Buy American Act and Balance of Payments Program, and 252.225-7006, Trade Agreements Act, and the provision at 252.225-7005, Buy American Act-Trade Agreements Act-Balance of Payments Program Certificate. The revision incorporated a definition of U.S. made end products that covers products substantially transformed in the United States but which do not qualify as domestic end products.

Item XII—Duty-Free Entry

This finalizes, without change, the interim revisions made by DAC 88-17, Item VIII, to DFARS 225.603-70, 252.225-7008, and 252.225-7014. The revisions added additional information necessary for processing duty-free certificates. Item VIII of DAC 88-17 mistakenly attributed the origin of this additional information requirement to a new paperless system of the U.S. Customs Service when in actuality the requirement is in support of the Defense Logistics Agency's Duty Free Entry Management System.

Item XIII—Offset Administrative Costs

DFARS 225.7304 was revised on an interim basis by Departmental Letter 91-015, dated July 15, 1991, to permit defense contractors to recover allowable offset administrative costs from foreign governments under foreign military sales contracts. This revision was effective July 15, 1991.

Item XIV—IR&D/B&P Costs

This final rule was effective August 19, 1991, upon issuance of Departmental Letter 91–018. DFARS Parts 225, 231, and 242 were revised to implement Section 824 of the FY 1991 DoD Authorization Act (Pub. L. 101–510) by incorporating the new, broader standard for IR&D/B&P projects which are of "potential interest to DoD" and to make other related changes. DFARS 225.7304(c)(2) was revised to remove an inconsistency that currently exists with 225.7304(c)(3). DFARS 225.7304(c)(3) was revised to incorporate the new 10 U.S.C. 2372 citation and to correct an erroneous reference to IR&D/B&P ceiling limitations or formula constraints as being contained in DFARS Part 231, rather than in FAR part 31. DFARS 231.205–18 incorporates the new, broader legislative standard for IR&D/B&P projects which are of "potential interest to DoD," including the specific examples of such projects listed in 10 U.S.C. 2372(c). DFARS 242.1005(a) was added to clarify that the DoD IR&D Technical Evaluation Group is responsible for providing appropriate guidance to contractors for submission of technical information to support IR&D proposals. DFARS 242.1005(b) was revised to clarify that the DoD IR&D Technical Evaluation Group is responsible for providing contracting officers with the required technical evaluation, including an opinion concerning the potential interest of the proposed IR&D projects to DoD. DFARS 242.1005(c), 242.1006, and 242.1007 were revised to incorporate the new standard of "potential interest to DoD" and to otherwise satisfy the requirements of 10 U.S.C. 2372. DFARS 242.1008 was revised to reflect current organizations and titles within DoD.

Item XV—Indian Incentive Program

DFARS Subpart 226.71 and the clause at 252.226–7002 are removed as they were incorporated in FAR Part 26 by FAC 90–07, Item VIII.

Item XVI—Foreign Selling Costs

This item is to clarify the effective date of Item K of DAC 88–18. The deletion of DFARS 231.205–1 and 231.205–38, accomplished under Item X of DAC 88–18, was effective May 15, 1991, upon effectivity of the comparable FAR language published as Item XVIII of FAC 90–04.

Item XVII—Customary Progress Payment Rates

This item was effective July 1, 1991, upon issuance of Departmental Letter 91–014. DFARS 232.5 is revised and a clause added at 252.232–7008 to implement DoD's customary uniform progress payment rates for contracts awarded on or after July 1, 1991 through March 31, 1992. Rates for subsequent years will be published in the first quarterly DAC for the calendar year. The customary uniform rates for July 1, 1991 through March 31, 1992, are 85 percent for large business, 90 percent for small business, and 95 percent for small disadvantaged business. This change does not affect progress payment rates for the repair, maintenance, or overhaul of naval vessels which are governed by rates established by the Secretary of the Navy in accordance with 10 U.S.C. 7312, as amended. For flow-down to subcontractors, refer to (j)(4) of the progress payments clause at FAR 52.232–16. Implement the revised rates as follows:

1. *Existing Contracts.* In no event will an existing contract be modified to incorporate the revised rates.

2. *Contract Awards in Process.* If a contract price has been agreed to and the contract is scheduled for award on or after July 1, 1991, you may include a revised rate in the contract if the contract price is reduced to reflect the price consideration received from the contractor for the revised rate. However, in competitive procurements where "Best and Final" offers or sealed bids have been received, no change should be made to the financing terms contained in the solicitation or invitation for bid.

3. *Modifications to Existing Contracts.* Contract modifications (e.g., supplemental agreements, changes, exercise of priced options, definitization of letter contracts, etc.) to existing contracts for inscope effort will be financed at the rate established in the existing contract.

4. *Basic Ordering Agreements.* Prompt action should be taken by the contracting officer to modify basic ordering agreements to incorporate the new contract financing rates for orders issued on or after July 1, 1991.

5. *Letter Contracts.* You may include a revised rate in the contract if the price is negotiated on or after July 1, 1991, based on the revised rate.

Item XVIII—Expedited Payments to Small Disadvantaged Businesses

This final rule adds DFARS 232.903 and 232.905–70 to implement a decision by the Under Secretary of Defense for Acquisition to assist small disadvantaged business concerns by authorizing and encouraging DoD payment offices to pay such concerns as quickly as possible after invoices are received and prior to payment due dates.

Item XIX—GAO Protest Regulations

This finalizes, without change, the interim rule that was published in Departmental Letter 91–019 and was effective August 23, 1991. The interim rule added DFARS 233.104, implementing the General Accounting Office's (GAO) revised protest procedures (4 CFR part 21), which went into effect on April 1, 1991. The DFARS language covers only those portions of GAO's revised rules which pertain to contracting officers and is to be used until a permanent FAR change is made.

DFARS 233.104, which is a substantial rewrite and is to be used in lieu of FAR 33.104, implements GAO's revised procedures, presents procedures in a more logical order, and makes other editorial improvements. The most significant procedures address the information an agency is required to provide to GAO, protective orders issued by GAO, and formal fact-finding hearings.

Agency reports to the GAO must now include all evaluation documents. In addition, agencies must also make available to GAO any document specifically requested by the protestor. GAO's new rules provide interested parties with easier access to documents. Accordingly, DFARS 233.104(a)(5) addresses requests for, and GAO issuance of, protective orders to limit the right to use and disclose released documents. DFARS 233.104(e) gives notice of GAO's formal fact-finding hearings, with minimal discussion of the detailed procedures.

Item XX—Contracting Officer Final Decisions

This interim rule was effective October 4, 1991, upon issuance of Departmental Letter 91–021. The interim rule adds Section 233.211 to require contracting officers to insert a "note" in all contracting officer final decisions, immediately following the paragraph required by FAR 33.211(a)(4)(v). The note advises the contractor to refer to a recent Circuit Court decision which may affect the contractor's choice of a forum for appeal.

Item XXI—Approval of Fixed-Price Development Contracts

DFARS 235.006 was revised by Departmental Letter 91–009, dated May 2, 1991, to require a determination by the

Under Secretary of Defense for Acquisition (USD(A)) before award, using FY 1991 funds, of a fixed price type contract over $10 million for development of a major system, or subsystem thereof. We previously published a revision to DFARS 235.006 in DAC 88-16 that requires a determination by the USD(A) before 1990 funds can be obligated on a fixed-price development contract in excess of $10 million for development of a major system or subsystem. Section 8038 of the FY 1991 DoD Appropriations Act (Public Law 101-511) contains the same requirement before FY 1991 funds can be obligated.

Item XXII—Notification of Substantial Impact on Employment

This final rule supersedes the interim rule published in Departmental Letter 91-011 on May 14, 1991. DFARS subparts 243, 249, and 252 are revised to implement section 4201 of the FY 1991 DoD Authorization Act (Pub. L. 101-510). Section 4201 requires the Secretary of Defense to notify the Secretary of Labor if the modification or termination of a major defense contract or subcontract will have a substantial impact on employment.

The rule requires reporting on modifications or convenience terminations of prime contracts valued at $5 million or more, or subcontracts of $500,000 or more, which will have a substantial impact on employment. Contracting officers must either modify existing contracts to incorporate the clause at 252.249-7001, Notification of Substantial Impact on Employment, or tailor any termination notices that are subsequently issued against these contracts to request the contractor to provide a statement of impact on employment.

The final rule differs from the interim rule in that:

1. The phrase "for convenience" has been added to DFARS 243.107(S-70), 249.102(a)(5), 249.7003(a), the title at 249.7003, and 252.249-7001 (b) and (c), to make it clear that the notification requirement applies to terminations for convenience and not to terminations for default.

2. Time frames for notification have been added to the text and clause. The contractor must notify the contracting officer within 30 calendar days if the proposed modification or termination for convenience will have a substantial impact on employment (249.102(a)(5) and 252.249-7001(c)). The head of the contracting activity must provide the notification to the Office of Economic Adjustment (OEA) within ten work days (249.7003(b)).

3. DFARS 249.7003(b)(1) has been added to require that the contractor notices include the data elements specified in paragraph (c) of the clause at 252.249-7001. As an option, contractors may use a new DD Form 2604, Notification of Substantial Impact, to provide the requisite notice (252.249-7001(c)).

4. DFARS 249.7003(b)(2) has been added to provide contracting activities with the appropriate mail and telefax address for the submission of notices to OEA.

5. DFARS 252.249-7001(a)(1)(ii) has been revised to remove the phrase "awarded under the prime" to make it consistent with the prescriptive language at 249.7003(c) and to make it clear that the text and clause apply to all subcontracts of $500,000 or more.

Item XXIII—Liability for Personal Property Shipments

DFARS 247.271-4(b)(9) and the clause at 252.247-7110 are revised to modify the contractor's liability for loss or damage to personal property picked up or delivered under Schedule III, Intra-City and Intra-Area, of the Personal Property Management Regulation, DoD 4500.34-R. Under this modification, the contractor must be notified within 75 days (instead of a year) following delivery and the contractor is liable for depreciated value (rather than replacement value) but the maximum liability is increased from $.60 per pound per article to $1.25 per pound times the net weight of the shipment.

Item XXIV—Extraordinary Contractual Actions

DFARS 250.103, Deviations, is deleted as unnecessary because FAR subpart 1.4 and DFARS subpart 1.4 provide adequate policies and procedures for deviations. The language in FAR 50.103 was deleted by FAC 90-07, Item XII.

Interim Rules Adopted as Final Without Change

PARTS 219 AND 252 [AMENDED]

219.702, 219.708, 252.219-7016 [Amend]

1. Accordingly, the interim rules amending sections 219.702, 219.708, and 252.219-7016 which were published at 56 FR 15162 on April 15, 1991 are adopted as final rules without change.

225.000-70, 225.000-71, 225.105-70, 225.109, 225.401, 225.402, 225.407, 252.225-7001, 252.225-7005, 252.225-7006 [Amended]

2. The interim rules amending sections 225.000-70, 225.000-71, 225.105-70, 225.109, 225.401, 225.402, 225.407, 252.225-7001, 252.225-7005, and 252.225-7006 which were published at 56 FR 9082 on March 4, 1991 are adopted as final rules without change.

225.603-70, 252.225-7008, 252.225-7014 [Amended]

3. The interim rules amending sections 225.603-70, 252.225-7008, and 252.225-7014 which were published at 56 FR 9082 on March 4, 1991 are adopted as final rules without change.

233.104 [Amended]

4. The interim rule amending section 233.104 which was published at 56 FR 45832 on September 6, 1991 and amended at 56 FR 49506 on September 30, 1991 is adopted as a final rule without further change.

Amendments to DoD FAR Supplement

Therefore, the DoD FAR Supplement is amended as set forth below.

5. The authority for 48 CFR parts 209, 219, 223, 225, 226, 232, 233, 235, 243, 247, 249, 250, and 252 continues to read as follows:

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, and FAR subpart 1.3.

PART 209—CONTRACTOR QUALIFICATIONS

209.470 [Amended]

6. Section 209.470 is amended by revising paragraph (b) to read as follows:

209.470 Authorized representatives.

* * * * *

(b) In the Navy, the General Counsel of the Department of the Navy;

* * * * *

PART 219—SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS CONCERNS

219.705-2 [Amended]

7. Section 219.705-2 is revised to read as follows:

(d) For research and development acquisitions, major systems acquisitions, and other complex or sensitive acquisitions involving formal or alternative source selection procedures, the extent to which offerors specifically identify, and commit to, SDB, HBCU or MI participation in performance of the contract (whether as joint venture, teaming arrangement, or traditional subcontracting arrangement) shall be an evaluation factor for source selection.

PART 223—ENVIRONMENT, CONSERVATION, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE

223.7202 [Amended]

8. Section 223.7202 is amended by revising paragraph (b) and paragraph (e) to read as follows:

* * * * *

(a) * * *

(b) To accomplish this objective, it is necessary to obtain certain information relative to the hazards which may be introduced into the workplace by the supplies being acquired. Accordingly, offerors and contractors are required to submit information on hazardous materials under the clause at 252.223-7004, Hazardous Material Identification and Material Safety Data, and under the provisions at 252.223-7006, Pre-Award Submission of Hazardous Material Labels. The latest version of Federal Standard No. 313 (Material Safety Data Sheet, Preparation and Submission of) includes criteria for identification of hazardous materials.

* * * * *

(e) The contracting officer shall provide a copy of MSDSs and hazard warning labels received from apparently successful offerors to the cognizant safety officer and/or other designated official, in order to facilitate:

(1) Inclusion of relevant data in an agency MSDS information system or label information system, if applicable; and

(2) Other control, safety, or information purposes, as applicable.

223.7203 [Amended]

9. Section 223.7203 is revised to read as follows:

223.7203 Solicitation provision and contract clauses.

When one or more of the circumstances listed in 223.7202(c) exists, the contracting officer shall insert—

(a) The provision at 252.223-7006, Pre-Award Submission of Hazardous Material Labels, in the solicitation; and

(b) The clauses at 252.223-7004, Hazardous Material Identification and Material Safety Data, and at 252.223-7007, Hazard Warning Labels, in solicitations and contracts.

10. Subpart 223.75 is revised to read as follows:

Subpart 223.75—Drug-Free Work Force

Sec.
223.7500 Policy.
223.7501 Definitions.
223.7502 Contract clause.

223.7500 Policy.

The unlawful use by contractor employees of controlled substances threatens national security and the safety of personnel and equipment. Therefore, DoD policy is to ensure that DoD contractors have a program for eliminating the unlawful use of controlled substances by employees whose duties affect health, safety, national security, or accomplishment of the DoD mission.

223.7501 Definitions.

As used in this section—

Controlled substance and *employee* are as defined in FAR 23.503.

Employee in a sensitive position is as defined in the clause at 252.223-7500, Drug-Free Work Force.

223.7502 Contract clause.

(a) Use the clause at 252.223-7500, Drug-Free Work Force, in all solicitations and contracts that require contractor employees to perform in sensitive positions.

(b) Do not use the clause in solicitations and contracts—

(1) Below the small purchase limitation in FAR part 13;

(2) For performance or partial performance (but only to the extent of the partial performance) outside the United States, its territories, and its possessions, unless the contracting officer determines inclusion to be in the best interest of the Government; or

(3) For law enforcement agencies, and the head of such agency or designee determines that application of the requirements of this section would be detrimental to the law enforcement agency's undercover operations.

PART 226—OTHER SOCIOECONOMIC PROGRAMS

226.7001 [Amended]

11. Section 226.7001 is revised to read as follows:

226.7001 Scope of Subpart.

This subpart implements certain provisions of section 1207 of Public Law 99-661, section 806 of Public Law 100-180, section 831 of Public Law 101-189, and section 832 of Public Law 101-510 which establish for DoD an objective of awarding a combined total of five percent of its total contract dollars during each of fiscal years 1987-93 to Historically Black Colleges and Universities (HBCUs), Minority Institutions (MIs), and to Small Disadvantaged Business (SDB) Concerns (see 219.201). Section 1207 also provided certain discretionary authority to the Secretary of Defense for achievement of that objective.

226.7003 [Amended]

12. Section 226.7003 is revised to read as follows:

226.7003 General Policy.

In furtherance of the Government policy of placing a fair proportion of its acquisitions with HBCUs, MIs and SDBs, Section 1207 of Public Law 99-661, Section 806 of Public Law 100-180, section 831 of Public Law 101-189, and section 832 of Public Law 101-510 established an objective for the Department of Defense of awarding a combined total of five percent of its total contract dollars during each of fiscal years 1987-93 to HBCUs, MIs and SDBs (see 219.201) and of maximizing the number of such entities participating in Defense prime contracts and subcontracts. Executive Order 12320 contains additional guidance concerning HBCUs. It is the policy of the Department of Defense to strive to meet these objectives through the enhanced use of outreach efforts, technical assistance programs, and the special authorities conveyed by these laws (e.g., through a total set-aside for HBCUs and MIs) to acquire research and studies normally acquired from Higher Education Institutions (HEIs). In addition, DoD will establish "infrastructure assistance" (e.g., scholarships, faculty development, training agreements with defense laboratories, and laboratory renovation) at colleges, universities, and institutions that agree to bear a substantial portion of the costs associated with the programs. (For reporting requirements see 219.202-5.) With regard to technical assistance programs, it is the Department's policy to provide HBCUs and MIs technical assistance, to include information about the Department's HBCU and MI Program, advice about acquisition procedures, instructions on preparation of proposals, and such other assistance as is consistent with the Department's mission. In the event an HBCU or MI submits an offer under an unrestricted acquisition that offers an evaluation preference for SDBs, the HBCU or MI offer shall be evaluated as if it had been submitted by an SDB concern (see 252.219-7007(d)).

226.71 [Removed]

13. Subpart 226.71 is removed.

PART 232—CONTRACT FINANCING

14. Section 232.903 is added to read as follows:

232.903 Policy.

DoD policy is to assist small disadvantaged business concerns by paying such concerns as quickly as possible after invoices are received and prior to normal payment due dates established in the contract (see 232.905-70).

15. Section 232.905-70 is added to read as follows:

232.905-70 Additional Invoice Payment Procedures.

Designated payment offices are encouraged to pay small disadvantaged business (SDB) concerns as quickly as possible after invoices are received and prior to normal payment due dates established in the contract (see 232.903). The restrictions of FAR 32.903 prohibiting early payment do not apply to invoice payments made to SDBs. Contractors shall not, however, be entitled to interest penalties if invoice payments are not made prior to the normal payment due dates established in the contract.

PART 235—RESEARCH AND DEVELOPMENT CONTRACTING

235.006 [Amended]

16. Section 235.006 is revised to read as follows:

235.006 Contracting Methods and Contract Type.

(S-70) *Fixed-Price Type Development Contracts.*

(1) A fixed-price type contract shall not be awarded for a development program effort unless:

(i) The level of program risk permits realistic pricing;

(ii) The use of a fixed-price type contract permits an equitable and sensible allocation of program risk between the Government and the contractor; and

(iii) A written determination, that the criteria of paragraphs (S-70)(1) (i) and (ii) of this section have been met, is properly executed—

(A) By the Under Secretary of Defense for Acquisition (USD(A)), for—

(*1*) Research and development for non-major systems, if the contract is over $25 million;

(*2*) The lead ship of a class;

(*3*) The development of a major system (as defined in FAR 34.001) or subsystem thereof, if the contract is over $25 million, or is over $10 million and is funded with FY 90 funds (Pub. L. 101-165, section 9048)) or FY 91 funds (Pub. L. 101-511).

(B) By the contracting officer for all fixed-price type contracts for all development not covered by paragraph (S-70)(1)(iii)(A) of this section.

(2) Before award, submit the Government's prenegotiation position, and the proposed (and unexecuted) agreement with the contractor to the USD(A) for any action which is—

(i) An increase of more than $250 million in the price of a fixed-price type development contract, or a fixed-price type contract for the lead ship of a class;

(ii) A reduction in the amount of work under a fixed-price type development contract or a fixed-price type contract for the lead ship of a class, when the contract action is valued at more than $100 million;

(iii) A repricing of fixed-price type production options to a development contract, or a contract for the lead ship of a class, which increases the price by more than $250 million for equivalent quantities.

(3) Notify the USD(A) of an intent not to exercise a fixed-price production option on a development contract for a major weapon system reasonably in advance of the expiration of the option exercise period.

PART 243—CONTRACT MODIFICATIONS

17. Section 243.107 is revised to read as follows:

243.107 Contract Clause.

(S-70) The Secretary of Defense is required to notify the Secretary of Labor if the modification or termination for convenience of a major defense contract or subcontract will have a substantial impact on employment. See 249.7003(c) for the prescribed contract clause, which defines "substantial impact on employment."

PART 247—TRANSPORTATION

247.271-4 [Amended]

18. Section 247.271-4 is amended by revising paragraph (b)(9) to read "252.247-7110, Contractor Liability for Loss or Damage."

PART 249—TERMINATION OF CONTRACTS

249.102 [Amended]

19. Section 249.102 is revised to read as follows:

249.102 Notice of Termination.

(a) *General.* See 243.301 for use of the Standard Form 30 (SF 30), Amendment of Solicitation/Modification of Contract, in providing notice of termination and amendment of the termination notice.

(5) Include a statement that, if a termination for convenience will have a substantial impact on employment, as defined in the clause at 252.249-7001, Notification of Substantial Impact on Employment, the contractor must provide the required notice to the contracting officer within 30 calendar days.

20. Subpart 249.70 is amended by revising 249.7003 to read as follows:

249.7003 Contract Modifications and Terminations For Convenience Having a Substantial Impact on Employment.

(a) Section 4201(a)(1)(B) of the National Defense Authorization Act for Fiscal Year 1991 (Pub. L. 101-510, Division D, Title XLII; Defense Economic Adjustment, Diversification, Conversion, and Stabilization Act of 1990), requires the Secretary of Defense to notify the Secretary of Labor if a modification or termination for convenience of a major defense contract or subcontract will have a substantial impact on employment, as defined in the clause at 252.249-7001, Notification of Substantial Impact on Employment.

(b) Within ten work days after the contractor provides the notification required under the clause at 252.249-7001, the head of the contracting activity shall notify the Office of Economic Adjustment (OEA), Assistant Secretary of Defense (Force Management and Personnel), in accordance with department/agency procedures.

(1) The notice to OEA shall include the data elements set forth in 252.249-7001(c).

(2) Notices may be mailed or telefaxed to OEA at: Office of Economic Adjustment, 400 Army-Navy Drive, Suite 200, Arlington, VA 22202-2884, Attention: Division D Notification, Telefax: (703) 697-3021.

(c) Use the clause at 252.249-7001, Notification of Substantial Impact on Employment, in all contracts of $5 million or more and all contracts with subcontracts of $500,000 or more.

PART 250—EXTRAORDINARY CONTRACTUAL ACTIONS

250.103 [Removed]

21. Section 250.103 is removed.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

22. Sections 252.223-7006 and 252.223-7007 are added to read as follows:

252.223-7006 Pre-Award Submission of Hazardous Material Labels.

As prescribed in 223.7203, insert the following provision:

Pre-Award Submission of Hazardous Material Labels (Nov. 1991)

(a) *Hazardous material,* as used in this provision, includes any material defined as hazardous under the version of Federal Standard 313, current at the time of submission of this offer.

(b) All hazardous material, to be delivered, or otherwise furnished under the resultant contract, requires labeling in accordance with either the Hazard Communication Standard (29 CFR 1910.1200 et seq.) or one of the statutes in paragraph (b) (1) through (5) of the Hazard Warning Labels clause of this solicitation.

(1) *Hazardous material not subject to Hazard Communication Standard labeling.* The offeror shall identify in the following spaces the hazardous material, to be delivered or otherwise furnished under the resultant contract, that requires labeling in accordance with one of the statutes in paragraphs (b)(1) through (5) of the Hazard Warning Labels clause of this solicitation. Use additional sheets, if necessary, and title them "Identification of Hazardous Material Not Subject to the Hazard Communication Standard—Continuation Sheet."

Material (Enter "NONE" if none exists)	Statute
.....	
.....	
.....	

(2) *Hazardous material subject to Hazard Communication Standard labeling.* The apparent successful offeror shall submit before award of the contract a copy of the hazard warning label for any hazardous material which is proposed to be delivered, or otherwise furnished, under any resultant contract and which is subject to the labeling requirements of the Hazard Communication Standard (29 CFR 1910.1200 et seq.). The offeror shall submit the labels with the material data sheets being furnished under the Hazardous Material Identification and Material Safety Data clause of this solicitation.

(End of provision)

252.223-7007 Hazard Warning Labels.

As prescribed in 223.7203, insert the following clause:

Hazard Warning Labels (Nov 1991)

Hazardous material, as used in this clause, includes any material defined as hazardous under the latest version of Federal Standard 313 (including revisions adopted during the term of this contract).

(b) The Contractor shall label the individual item package (unit container) of any hazardous material to be delivered under this contract. The labeling shall conform to the requirements of the Hazard Communication Standard, unless the hazardous material is otherwise subject to the labeling requirements of one of the following statutes, in which case, the labeling shall conform to the statute:

(1) Federal Insecticide, Fungicide and Rodenticide Act;

(2) Federal Food, Drug and Cosmetics Act;

(3) Consumer Product Safety Act;

(4) Federal Hazardous Substances Act;

(5) Federal Alcohol Administration Act.

(c) The Contractor shall also comply with MIL-STD-129, Marking for Shipment and Storage (including revisions adopted during the term of this contract).

(End of clause)

23. Section 252.223-7500 is revised to read as follows:

252.223-7500 Drug-Free Work Force.

As prescribed in 223.7502, insert the following clause:

Drug-Free Work Force (Nov 1991)

(a) Definitions.

As used in this clause—

(1) *Controlled substance,* "employee," and "criminal drug statute" have the meanings given in the Drug-Free Workplace clause of this contract.

(2) *Employee in a sensitive position* means an employee whose duties could reasonably be expected to affect health, safety, or national security, including, but not limited to, duties involving—

(i) Access to classified information;

(ii) Possession or use of firearms;

(iii) Design, manufacture, test and evaluation, or maintenance of aircraft, vessels, vehicles, heavy equipment, munitions, toxic materials, weapons, weapons systems, potentially dangerous equipment/materials/or applications (such as lasers, explosives, unstable chemicals, or medical equipment with potentially life threatening consequences), or major components of the foregoing which are directly contracted for by the Department of Defense;

(iv) Control, operation or use of aircraft, vessels, vehicles, heavy equipment, toxic or nuclear materials, munitions, weapons, weapon systems, or potentially dangerous equipment/materials/or applications (such as lasers, explosives, unstable chemicals, or medical equipment with potentially life threatening consequences);

(v) Transportation, storage, or protection of toxic or nuclear materials, or munitions, or potentially dangerous materials (such as explosives or unstable chemicals);

(vi) Direct treatment or rehabilitation of employees for unlawful use or abuse of controlled substances; or

(vii) Air traffic control.

(b) The Contractor shall institute and maintain a program for achieving a drug-free work force. As a minimum, the program shall provide for the random drug testing of Contractor employees working in sensitive positions. The Contractor's drug testing program shall conform to the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" published by the Department of Health and Human Services (53 FR 11970), April 11, 1988.

(c) The Contractor shall not permit an employee to work in a sensitive position in the performance of a Department of Defense contract if—

(1) The employee tests positive for the use of a controlled substance during a test pursuant to this clause or a test based on reasonable suspicion of drug use; and

(2) The use is determined to be unlawful; or

(3) The employee is convicted of violating a criminal drug statute.

(d) The Contractor may permit an employee covered by paragraph (c) of this clause to work in a sensitive position on a Department of Defense contract only—

(1) With the approval of the Contracting Officer; and

(2) After the employee has successfully completed a supervised rehabilitation program.

(e) The requirements of this clause take precedence over any State and local laws to the contrary.

(End of clause)

252.226-7002 [Removed]

24. Section 252.226-7002 is removed.

252.247-7110 [Amended]

25. Section 252.247-7110 is revised to read as follows:

252.247-7110 Contractor Liability for Loss or Damage.

As prescribed in 247.271-4(b)(9), use the following clause:

Contractor Liability for Loss or Damage (Nov 1991)

(a) *Definitions.* As used in this clause—

Article means any shipping piece or package and its contents.

Schedule means the level of service for which specific types of traffic apply as described in DoD 4500.34-R, Personal Property Traffic Management Regulation.

(b) For shipments picked up under Schedule I, Outbound Services, or delivered under Schedule II, Inbound Services—

(1) If notified within one year after delivery that the owner has discovered loss or damage to the owner's property, the Contractor agrees to indemnify the Government for loss or damage to the property which arises from any cause while it is in the Contractor's possession. The Contractor's liability is—

(i) *Non-negligent damage.* For any cause, other than the Contractor's negligence, indemnification shall be at a rate not to exceed sixty cents per pound per article.

(ii) *Negligent damage.* When loss or damage is caused by the negligence of the Contractor, the liability is for the full cost of satisfactory repair or for the current replacement value of the article.

(2) The Contractor shall make prompt payment to the owner of the property for any loss or damage for which the Contractor is liable.

(3) In the absence of evidence or supporting documentation which places liability on a carrier or another contractor, the destination contractor shall be presumed to be liable for the loss or damage, if timely notified.

(c) For shipments picked up or delivered under Schedule III, Intra-City and Intra-Area—

(1) If notified of loss or damage within 75 days following delivery, the Contractor agrees to indemnify the Government for loss or damage to the owner's property.

(2) The Contractor's liability shall be for the full cost of satisfactory repair, or for the

current replacement value of the article less depreciation, up to a maximum liability of $1.25 per pound times the net weight of the shipment.

(3) The Contractor has full salvage rights to damaged items which are not repairable and for which the Government has received compensation at replacement value.

(End of clause)

26. Section 252.249-7001 is revised to read as follows:

252.249-7001 Notification of Substantial Impact on Employment.

As prescribed in 249.7003(c), use the following clause:

Notification of Substantial Impact on Employment (Nov. 1991)

(a) *Definitions.*

(1) "Major defense contract or subcontract" means—

(i) All prime contracts of $5 million or more; and

(ii) All subcontracts of $500,000 or more.

(2) "Substantial impact on employment" means—

(i) A reduction of—

(A) 2,500 or more employee positions, in the case of a Metropolitan Statistical Area (MSA) or similar area. MSAs are identified in FIPS Publication 8-5, Metropolitan Statistical Areas, which is available from the U.S. Department of Commerce, National Technical Information Service, Springfield, VA 22161, Tel. (703) 487-4650. Telephone inquiries concerning MSAs may also be directed to the Bureau of the Census, Population Division, Population Distribution Branch, Washington, DC, Tel. (301) 763-5158;

(B) 1,000 or more employee positions, in the case of a labor market area outside an MSA, or

(C) One percent of the total number of civilian jobs in that area; or

(ii) A reduction, or the threat of a reduction, of—

(A) 25 percent or more in sales or production of the contractor or subcontractor; or

(B) 80 percent or more of the workforce of the contractor or subcontractor in any division of such contractor or such subcontractor or at any plant or other facility of such contractor or subcontractor; or

(iii) Any group of 100 or more workers at a defense facility who are, or who are threatened to become, eligible to participate in the Defense Conversion Adjustment Program under section 325 of the Job Training Partnership Act (29 U.S.C. 1662-1662c, as amended).

(b) This clause applies only if a modification or termination for convenience of a major defense contract or subcontract will have a substantial impact on employment.

(c) The Contractor shall notify the Contracting Officer within 30 calendar days if the proposed modification or termination for convenience of this contract or a major defense subcontract under this contract will have a substantial impact on employment. The Contractor may use DD Form 2604, Notification of Substantial Impact. If the form is not used, the notice shall include:

(1) Contract number;

(2) Contractor name and division name;

(3) Type of business (e.g. small disadvantaged business, small business, large business, etc.);

(4) Address of affected work location, including county;

(5) Contract price of items cancelled or terminated;

(6) Number of employees affected;

(7) Percentage reduction in sales or production;

(8) Percentage of contractor workforce at affected work location;

(9) Title and signature of the reporting official; and

(10) The information required by (1) through (9) for each subcontract.

(d) The Contractor shall include the substance of this clause in all subcontracts of $500,000 or more under this contract.

(End of Clause)

[FR Doc. 91-28287 Filed 11-26-91; 8:45 am]

BILLING CODE 3810-01-M

Proposed Rules

Federal Register
Vol. 56, No. 229
Wednesday, November 27, 1991

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 630

RIN 3206-AE53

Absence and Leave; Voluntary Leave Transfer and Voluntary Leave Bank Programs

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management (OPM) proposes to amend its regulations on the use of annual leave by leave recipients under the voluntary leave transfer or leave bank programs. The proposed regulations would provide that donated annual leave used by a leave recipient under the voluntary leave transfer program or annual leave received from a leave bank under the voluntary leave bank program may be used only for the purpose of the medical emergency for which the leave recipient was approved. In addition, the proposed regulations would permit an employee's leave bank membership to transfer to another leave bank within the same agency. This would eliminate the need for employees who transfer within their employing agency to make an additional contribution to a leave bank for the year in which the transfer occurs.

DATES: Comments must be submitted on or before December 27, 1991.

ADDRESSES: Comments may be sent or delivered to Barbara L. Fiss, Assistant Director for Pay Policy and Programs, Personnel Systems and Oversight Group, U.S. Office of Personnel Management, room 7H28, 1900 E Street, NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Martha Hoehn, (202) 606-2858 or (FTS) 266-2858.

SUPPLEMENTARY INFORMATION: Public Law 100-566, the "Federal Employees Leave Sharing Act of 1988," directed OPM to establish by regulation a 5-year experimental voluntary leave transfer and leave bank program. OPM published final regulations governing these programs in the **Federal Register** on December 28, 1989 (54 FR 53303). As part of OPM's responsibility to monitor and evaluate the operation of the voluntary leave transfer and leave bank programs, we have determined that certain technical changes are necessary. These changes are based on agency comments received during the preparation of a report to Congress on first-year operation of the programs.

OPM proposes to revise 5 CFR 630.909(a) and 630.1009(a) to provide that annual leave used by leave recipients under the voluntary leave transfer program and annual leave received by leave recipients under the voluntary leave bank program may be used only for the purpose of the medical emergency for which the leave recipient was approved. This proposed change will help agencies administer their programs and prevent abuse of the program.

Also, in response to a request from the Internal Revenue Service, OPM proposes to revise 5 CFR 630.1004(h) by giving a leave bank board the authority to eliminate the minimum contribution required to become a leave bank member if a leave bank member transfers within his or her employing agency to an organization covered by a different leave bank. The proposed change would permit an employee to "transfer" his or her leave bank membership to a different leave bank within the same agency and eliminate the necessity for the employee to make an additional minimum contribution to a leave bank during the same year. This change will help agencies, such as the Internal Revenue Service, that established several leave banks within the agency and that experience significant employee mobility within the agency.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will affect only Federal employees and agencies.

List of Subjects in 5 CFR Part 630

Government employees.

U.S. Office of Personnel Management.

Constance Berry Newman,

Director.

Accordingly, OPM proposes to amend part 630 of title 5 of the Code of Federal Regulations as follows:

PART 630—ABSENCE AND LEAVE

1. The authority citation for part 630 continues to read as follows:

Authority: 5 U.S.C. 6311; § 630.303 also issued under 5 U.S.C. 6133(a); § 630.501 and subpart F also issued under E.O. 11228; subpart G also issued under 5 U.S.C. 6305; subpart H issued under 5 U.S.C. 6326; subpart I also issued under 5 U.S.C. 6332 and Public Law 100-566; subpart J also issued under 5 U.S.C. 6362 and Public Law 100-566; subpart K also issued under Public Law 102-25.

2. Section 630.909(a) is revised to read as follows:

§ 630.909 Use of transferred annual leave.

(a) A leave recipient may use annual leave transferred to his or her annual leave account under § 630.906 of this part only for the purpose of the medical emergency for which the leave recipient was approved.

* * * * *

3. Section 630.1004(h)(3) is added to read as follows:

§ 630.1004 Application to become a leave contributor and leave bank member.

* * * * *

(h) * * *

(3) Eliminate the requirement for a minimum contribution under paragraph (g) of this section when a leave bank member transfers within his or her employing agency to an organization covered by a different leave bank.

* * * * *

4. Section 630.1009(a) is revised to read as follows:

§ 630.1009 Use of annual leave withdrawn from a leave bank.

(a) A leave recipient may use annual leave withdrawn from a leave bank only for the purpose of the medical emergency for which the leave recipient was approved.

* * * * *

[FR Doc. 91-28438 Filed 11-27-91; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 91-CE-71-AD]

14 CFR Part 39

Airworthiness Directives; Piper PA34 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to adopt a new airworthiness directive (AD) that would supersede AD 90-17-04, which currently requires the replacement of the rudder torque tube fitting and attaching hardware on Piper PA34 series airplanes. Parts are currently not available to accomplish the modification required by AD 90-17-04. The proposed action would allow continued operation of the affected airplanes until parts become available provided repetitive inspections are performed. The actions specified by the proposed AD are intended to prevent failure of the torque tube fitting and possible loss of rudder control while also preventing inadvertent grounding of the affected airplanes.

DATES: Comments must be received on or before January 31, 1992.

ADDRESSES: Piper Service Bulletin No. 899, dated February 10, 1989, that is discussed in this AD may be obtained from the Piper Aircraft Corporation, Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960. This information also may be examined at the Rules Docket at the address below. Send comments on the proposal in triplicate to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 91-CE-71-AD, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

FOR FURTHER INFORMATION CONTACT: Mr. David Cundy, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, 1669 Phoenix Parkway, suite 210C, Atlanta, Georgia 30349; Telephone (404) 991-2910; Facsimile (404) 991-3606.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 91-CE-71-AD, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

Airworthiness Directive (AD) 90-17-04, Amendment 39-6674 (55 FR 3238 August 9, 1990) currently requires a one-time inspection of any steel rudder torque tube fitting for proper attachment and the replacement of any aluminum rudder torque tube fitting with one made of steel on Piper Models PA34-200, PA34-200T, and PA34-220T airplanes. The inspection or replacement must be done in accordance with Piper Service Bulletin No. 899, dated February 10, 1989.

It has been reported to the FAA that parts are presently not available to perform the replacement that is required by AD 90-17-04, Amendment 39-6674. The FAA has determined that the requirements of AD 90-17-04 are still valid but, to avoid inadvertent grounding of the affected airplanes, the airplane operators should be allowed to continue operating the affected airplanes provided (1) The parts have been ordered from the manufacturer; (2) repetitive inspections of the aluminum rudder torque tube fitting are performed; and (3) cracked or corroded aluminum rudder torque tube fittings are replaced.

Since the condition described is likely to exist or develop in other Piper Models PA34-200, PA34-200T, and PA34-220T airplanes of the same type design, the proposed AD would require a one-time inspection of any steel rudder torque tube fitting and the replacement of any aluminum rudder torque tube fitting with one made of steel in accordance with Piper Service Bulletin No. 899, dated February 10, 1989; or continued operation of the airplane if parts are not available provided (1) The airplane operator has ordered the parts from the manufacturer; (2) the airplane operator performs repetitive inspections of the aluminum rudder torque tube fitting; and (3) cracked or corroded aluminum rudder torque fittings are replaced.

It is estimated that 2,500 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 4 hours per airplane to accomplish the proposed action, and that the average labor rate is approximately $55 an hour. Parts cost approximately $150 per airplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $925,000. The above cost analysis is the same as AD 90-17-04, which would be superseded by this proposed action. This proposed action would provide an alternative method that would avoid the impact associated with removing the affected airplanes from service if replacement parts were not immediately available.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "ADDRESSES".

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—[Amended]

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing AD 90-17-04, Amendment 39-6674 (55 FR 3238 August 9, 1990), and adding the following new AD:

Piper Aircraft Corporation: docket No. 91-CE-71-AD. Applicability: Model PA34-200 airplanes (serial numbers (S/N) 34-7250001 through 34-7450220), Model PA34-200T airplanes (S/N 34-7570001 through 34-8170092), and Model PA34-220T airplanes (S/N 34-8133001 through 34-8533012), certificated in any category.

Compliance: Required as indicated, unless already accomplished.

To prevent failure of the torque tube fitting and possible loss of rudder control, accomplish the following:

(a) Within the next 50 hours time-in-service (TIS) after September 14, 1990 (the effective date of AD 90-17-04, Amendment 39-6674), inspect to determine whether the rudder torque tube fitting is steel or aluminum.

(1) If steel, inspect for proper attachment, and check the bolt torque in accordance with the criteria and instructions in Piper Service Bulletin No. 899, dated February 10, 1989.

(i) If fitting is properly attached and bolt torque is correct, return the airplane to service and the requirements of this AD have been accomplished.

(ii) If fitting is improperly attached and/or bolt torque is incorrect, properly attach fitting and/or torque to proper criteria as specified in and in accordance with the instructions in Piper SB No. 899, dated February 10, 1989. Return the airplane to service and the requirements of this AD have been accomplished.

(2) If aluminum, replace with steel fitting in accordance with the instructions in Piper SB No. 899, dated February 10, 1989, return the airplane to service, and the requirements of this AD have been accomplished.

(b) If the steel fitting required by paragraph (a)(2) of this AD has been ordered but is not available, prior to further flight, accomplish the following:

(1) Visually inspect the aluminum fitting for corrosion. If any evidence of corrosion is found, remove and treat the corroded area in accordance with AC 43-13.1A.

(2) Dye penetrant inspect the aluminum fitting for cracks. If found cracked, replace with an aluminum fitting found to be free from cracks and corrosion.

(3) Return the airplane to service and visually inspect the aluminum fitting for proper attachment, cracks, and/or corrosion, at intervals not to exceed 50 hours TIS.

(i) If fitting is found improperly attached or hardware is found loose, properly attach fitting in accordance with the instructions in Piper SB No. 899, dated February 10, 1989.

(ii) If any evidence of corrosion is found, remove and treat the corroded area in accordance with AC 43-13.1A.

(iii) If found cracked, replace with aluminum fitting found to be free from cracks and corrosion in accordance with the installation instructions in Piper SB No. 899, dated February 10, 1989.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Atlanta Aircraft Certification Office, 1669 Phoenix Parkway, suite 210C, Atlanta, Georgia 30349. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta Aircraft Certification Office.

(e) All persons affected by this directive may obtain copies of the document referred to herein upon request to the Piper Aircraft Corporation, Customer Services, 2926 Piper Drive, Vero Beach, Florida 32960; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street; Kansas City, Missouri 64106.

This amendment supersedes AD 90-17-04, Amendment 39-6674.

Issued in Kansas City, Missouri, on November 21, 1991.

John E. Tigue,

Acting Manager, Small Airplane Directorate Aircraft Certification Service.

[FR Doc. 91-28460 Filed 11-26-91; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[INTL-965-86]

RIN 1545-AM12

Calculation of Currency Gain or Loss on Transfers From Qualified Business Unit Branches Using the Profit and Loss Method of Accounting; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains corrections to the notice of proposed rulemaking (INTL-965-86), which was published on Wednesday, September 25, 1991, (56 FR 48457). The proposed Income Tax Regulations relate to the calculation of income (including currency gain or loss on remittances) attributable to a qualified business unit (QBU) of a taxpayer that uses the profit and loss method of accounting.

FOR FURTHER INFORMATION CONTACT: Carol Murphy (202-566-6795, not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking that is the subject of these corrections contains proposed regulations under section 987 of the Internal Revenue Code of 1986 (including currency gain or loss on remittances and terminations) attributable to a QBU branch of a taxpayer that uses profit and loss method of accounting.

Need for Correction

As published, the proposed regulations contain errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the proposed regulations (INTL-965—86), which was the subject of FR Doc. 91-22854, is corrected as follows:

§ 1.987-3 [Corrected]

Par. 1. On page 48464, column one, in § 1.987-3, paragraph (h)(1), line 9, the language "includes any exchange or loss" is corrected to read "includes any exchange gain or loss".

Par. 2. On page 48464, column three, in § 1.987-7(j), paragraph (iii) of *Example 2*, is corrected to read as follows:

§ 1.987-3 Termination of a QBU branch.

* * * * *

(j) * * *

Example. 2. * * *

(iii) Under Step 3, X is deemed to transfer 4LC to A. This results in an equity pool of O, and a basis pool of $2 ($1 + $1 (4LC at 4LC:$1)). Therefore, X recognizes section 987 loss of $2, which is the positive amount of the basis pool.

Dale D. Goode,

Federal Register Liasion Officer Assistant Chief Counsel (Corporate).

[FR Doc. 91-28397 Filed 11-26-91; 8:45 am]

BILLING CODE 4830-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 925

Missouri Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Missouri permanent regulatory program (hereinafter, the "Missouri program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment revises State statutes pertaining to penalties. The amendment was submitted on the State's own initiative and is intended to revise the State program to be consistent with other programs in the Missouri Department of Natural Resources.

This notice sets forth the times and locations that the Missouri program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m., c.s.t. December 27, 1991. If requested, a public hearing on the proposed amendments will be held on December 23, 1991. Requests to present oral testimony at the hearing must be received by 4 p.m., c.s.t. on December 12, 1991.

ADDRESSES: Written comments should be mailed or hand delivered to Jerry R. Ennis at the address listed below.

Copies of the Missouri program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Kansas City Field Office.

Jerry R. Ennis, Director, Kansas City Field Office, Office of Surface Mining Reclamation and Enforcement, 943 Wyandotte, room 500, Kansas City, MO 64105, Telephone: (816) 374-6405.

Missouri Department of Natural Resources, Land Reclamation Program, 205 Jefferson Street, P.O. Box 176, Jefferson City, MO 65102, Telephone: (314) 751-4041.

FOR FURTHER INFORMATION CONTACT: Jerry R. Ennis, Director, Kansas City Field Office, (816) 374-6405.

SUPPLEMENTARY INFORMATION:

I. Background on the Missouri Program

On November 21, 1980, the Secretary of Interior conditionally approved the Missouri program. General background information on the Missouri program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Missouri program can be found in the November 21, 1980, **Federal Register** (45 FR 77017). Subsequent actions concerning Missouri's program and program amendments can be found at 30 CFR 925.12, 925.15, and 925.16.

II. Proposed Amendment

By letter dated November 8, 1991, (Administrative Record No. MO-541) Missouri submitted a proposed amendment to its program pursuant to SMCRA. Missouri submitted the proposed amendment at the State's own initiative to improve its program.

Missouri proposes to amend the Revised Statutes of Missouri (MO. Rev. Stat.) at sections: 444.870.1 through 444.870.8, Penalties.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is now seeking comment on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Missouri program.

Written Comments

Written comments should be specific, pertain only to the issue proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under "DATES" or at locations other than the Kansas City Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

Public Hearing

Persons wishing to testify at the public hearing should contact the person listed under "**FOR FURTHER INFORMATION CONTACT**" by 4:00 p.m., c.s.t. December 12, 1991. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to testify at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested, as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to testify and persons present in the audience who wish to testify have been heard.

Public Meeting

If only one person requests an opportunity to testify at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under "**FOR FURTHER INFORMATION CONTACT.**" All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under "**ADDRESSES.**" A written summary of each meeting will be made a part of the administrative record.

List of Subjects in 30 CFR Part 925

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 20, 1991.

Raymond L. Lowrie,

Assistant Director, Western Support Center.

[FR Doc. 91-28439 Filed 11-26-91; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900-AE85

Election of Subsistence Allowance at the Chapter 34 Rate Under the Vocational Rehabilitation Program

AGENCY: Department of Veterans Affairs.

ACTION: Proposed regulatory amendments.

SUMMARY: This proposed change would eliminate provisions under which a service-disabled veteran in the vocational rehabilitation program with remaining eligibility and entitlement to educational assistance benefits could elect payment of chapter 31 subsistence allowance at the chapter 34 educational assistance rate. No veterans are currently eligible to receive educational assistance benefits under chapter 34 since the law barred provision of those benefits after December 31, 1989. Therefore, no one presently qualifies to make the election to receive benefits at chapter 34 rates. The intended effect of this change is to update VA regulations by removing all provisions for election

of subsistence allowance at the chapter 34 rate or payment at that rate.

DATES: Comments must be received on or before December 27, 1991. All comments received will be available for public inspection until January 6, 1992. It is proposed that this change be effective January 1, 1990.

ADDRESSES: Interested persons are invited to submit written comments, suggestions, or objections regarding these changes to the Secretary of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC, 20420. All written comments will be available for public inspection only in the Veterans Services Unit, room 170 of the above address, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays) until January 6, 1992.

FOR FURTHER INFORMATION CONTACT: Morris Triestman, (202) 233-6496, Rehabilitation Consultant, Policy and Program Development, Vocational Rehabilitation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington DC 20420.

SUPPLEMENTARY INFORMATION: A veteran with remaining eligibility for the entitlement to educational assistance benefits under the noncontributory educational assistance program authorized under chapter 34, title 38, United States Code, if eligible to receive a subsistence allowance under the chapter 31 vocational rehabilitation program, could formerly elect to receive chapter 31 subsistence payments at the educational assistance rate payable under the chapter 34 program under certain conditions. However, effective December 31, 1989, no further benefits could be afforded any eligible veteran under the chapter 34 program. As a result no one presently has any remaining eligibility for or entitlement to such benefits upon which to base an election to receive chapter 31 benefits at chapter 34 rates. Therefore we are deleting all references to this option from the regulations.

In addition we are making other changes which update the pages being revised to remove references to chapter 34. For example, 38 CFR 21.134 is revised to delete a reference to the applicability of chapter 34 regulations to the pursuit of flight training under chapter 31. This change does not affect VA policy under which vocational rehabilitation participants are only furnished flight training as a part of training which leads to a standard college degree.

These regulatory amendments are retroactively effective. These are interpretive rules which implement statutory provisions. Moreover, VA finds that good cause exists for making these rules retroactively effective. A delayed effective date would be contrary to statutory design and would complicate implementation of this provision of law.

These proposed regulations do not contain a major rule as that term is defined in Executive Order 12291, Federal Regulations. The proposal will not have a $100 million annual effect on the economy, will not cause a major increase in costs or prices, and will not have any other significant adverse effects on the economy. The Secretary certifies that these amendments will not, if promulgated, have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA) 5 U.S.C. 601-612. Pursuant to 5 U.S.C. 605(b), these rules are therefore exempt from the initial and final flexibility analyses requirements of sections 603 and 604. The reasons for this certification are that the amendments only affect the rights of individual beneficiaries. No new regulatory burdens are imposed on small entities by these amendments.

(The Catalog of Federal Domestic Assistance number is 64.116.)

List of Subjects in 38 CFR Part 21

Civil rights, Claims, Education, Grant programs, Loan programs, Reporting requirements, Schools, Veterans, Vocational education, Vocational rehabilitation.

Approved: October 25, 1991.

Edward J. Derwinski,

Secretary of Veterans Affairs.

PART 21—VOCATIONAL REHABILITATION AND EDUCATION

For the reasons set forth in the preamble, 38 CFR part 21 is proposed to be amended as follows:

1. The authority citation for part 21, subpart A continues to read as follows:

Authority: 38 U.S.C. 210(C).

1A. Section 21.21 is amended by revising paragraph (a) and its authority citation to read as follows:

§ 21.21 Election of benefits under education programs administered by the Department of Veterans Affairs.

(a) *Election of benefits required.* A veteran must make an election of benefits among the programs of education administered by VA for which he or she may be eligible. A veteran who has basic entitlement to rehabilitation under chapter 31 and is also eligible for assistance under any of the other education programs administered by VA must make an election of benefits between chapter 31 and any other VA program of education for which he or she may be eligible. The veteran may reelect at any time if he or she is otherwise eligible. (See §§ 21.264 and 21.334.)

(Authority: 38 U.S.C. 1781(b))

* * * * *

§ 21.22 [Amended]

2. Section 21.22, paragraph (a) is amended by removing the words "or chapter 34" wherever they appear.

§ 21.78 [Amended]

3. In § 21.78, the first sentence of the introductory text to paragraph (b)(4) is amended by removing the words "or chapter 34" wherever they appear; in paragraph (b)(4)(i) remove the words "under § 21.4235, or" and add "under § 21.4235 before December 31, 1989, or"; in paragraph (b)(4)(ii) remove the words "or 45 month limitation on chapter 34 entitlement".

4. Section 21.134 and its authority citation are revised to read as follows:

§ 21.134 Limitation on flight training.

Flight training approved under chapter 31 may only be authorized in degree curriculums in the field of aviation that include required flight training. This type of training is otherwise subject to the same limitations as are applicable to flight training under chapter 30.

(Authority: 38 U.S.C. 1504(c), 1515(b))

§ 21.148 [Amended]

5. Section 21.148, paragraph (d) is amended by removing the words "or chapter 34" wherever they appear.

§ 21.254 [Amended]

6. Section 21.254, paragraph (b)(1) is amended by removing the words "or chapter 34" whichever they appear.

7. Section 21.256, paragraph (e)(2) and its authority citation are revised to read as follows:

§ 21.256 Incentives for employers.

* * * * *

(e) *Benefits and services.* * * *

(2) Notwithstanding any other provisions of these regulations, if the program in which the veteran is participating meets the criteria for approval of on-job training under chapter 30, the veteran may be paid at educational assistance rates provided for this type of training under chapter 30 to the extent that he or she has remaining eligibility and entitlement under chapter 30 and has elected to receive a subsistence allowance in accordance with § 21.7136.

(Authority: 38 U.S.C. 1508(f), 1516,(b), 1662(e))

* * * * *

§ 21.264 [Amended]

8. Section 21.264 is amended by removing the words "or chapter 34" and the words "and chapter 34" wherever they appear.

21.268 [Amended]

9. Section 21.268, paragraph (b) is amended by removing the words "or chapter 34" wherever they appear.

21.272 [Amended]

10. Section 21.272, paragraph (b)(1) is amended by removing the words "or chapter 34" wherever they appear.

21.276 [Amended]

11. Section 21.276, paragraph (g) is amended by removing the words "or chapter 34" wherever they appear.

21.320 [Amended]

12. Section 21.320, paragraph (b)(3) and (d)(3) are amended by removing the words "or chapter 34" wherever they appear.

21.330 [Amended]

13. Section 21.330, paragraph (a) is amended by removing the second sentence.

21.334 [Amended]

14. Section 21.334 is amended by removing the words "or chapter 34" and the words "and chapter 34" wherever they appear.

15. Section 21.334 is amended by revising paragraphs (a) and its authority citation, (b)(1), and (e)(2) and its authority citation to read as follows:

§ 21.334 Election of payments at the chapter 30 rate.

(a) *Election.* When the veteran elects payment of an allowance at the chapter 30 rate, the effective dates for commencement, reduction and termination of the allowance shall be in accordance with §§ 21.7130 through 21.7135 and § 21.7050 of this part under chapter 30.

(Authority: 38 U.S.C. 1808(f), 1780)

(b) *Election of payment at the chapter 30 rate subsequent to induction into a rehabilitation program.* * * *

(1) The commencing date determined under § 21.7131 of this part in the case of a veteran who has elected payment at the chapter 30 rate; or

* * * * *

(e) *Effect of chapter 34 program termination.* * * *

(2) A veteran entitled to chapter 30 benefits based on his or her chapter 34 eligibility as of December 31, 1989, and whose election of (payment of subsistence allowance at) chapter 34 rates (was) terminated as of that date under paragraph (1) must, if the individual desires payment (of subsistence allowance) at the chapter 30 rate, elect such payment.

(Authority: 38 U.S.C. 1411(a))

16. Section 21.340, paragraph (c) and its authority citation are revised to read as follows:

§ 21.340 Introduction.

* * * * *

(c) *Election of benefits at the chapter 30 rate.* If a veteran elects to receive a subsistance allowance paid at the chapter 30 rate, the effect of absences is determined under §§ 21.7139 and 21.7154 of this part.

(Authority: 38 U.S.C. 1508(f), and 1510)

[FR Doc. 91-28447 Filed 11-26-91; 8:45 am]

BILLING CODE 8320-01-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 91-314; FCC 91-335]

Radio Broadcast Services

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Notice of Proposed Rule Making seeks to develop a rule regarding broadcast hoaxes, which would codify licensee obligations and would permit the Commission to levy fines in order to address harmful hoaxes. The Notice proposes that any hoax rule include three elements: (1) False information; (2) public harm; and (3) foreseeability. As a framework for comment, the Notice includes a model hoax rule incorporating these three elements.

DATES: Comments must be submitted on or before January 2, 1992; reply comments must be submitted on or before February 3, 1992.

ADDRESSES: Federal Communication Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jane Hinckley, Mass Media Bureau, Policy and Rules Division, (202) 632-7792.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making in MM Docket No. 91-314, adopted October 24, 1991, and released November 14, 1991.

The complete text of this Notice of Proposed Rule Making is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street NW., Washington, DC, and also may be purchased from the Commission's copy contractor, Downtown Copy Center, at (202) 452-1422, 1919 M Street NW., room 246, Washington, DC 20554.

Synopsis of Notice of Proposed Rule Making

1. In several recent incidents, stations have broadcast seemingly accurate programming that later proved to be a hoax. In those instances, the hoax resulted in the use of what may have been substantial public safety resources. The Notice proposes adoption of a rule prohibiting harmful hoaxes. Such a rule would permit the Commission to fine stations that perpetrate harmful hoaxes, thus allowing a sanction less drastic than license revocation but with more deterrence value than admonition. At the same time, however, the rule must not cause an undue chilling effect on broadcasters' speech.

2. With these factors in mind, the Notice proposes a hoax rule that includes three elements. First, the Notice proposes that to be held liable, a licensee must have known that the material was false. Second, the Notice proposes that the hoax must have directly caused immediate, substantial and actual public harm, and seeks comment on what types of harm should be considered. Third, the Notice proposes that the public harm must have been foreseeable. The Notice seeks comment regarding these three elements and asks some additional questions concerning the proper scope of any hoax rule. For example, the Notice asks whether the rule should prohibit only the broadcast of false reports of crimes or catastrophes rather than any false material. The Notice also notes that some hoaxes have the potential for substantial public harm but, fortunately, cause little quantifiable harm. The Notice questions whether the rule should cover these types of hoaxes by including the threat of harm, rather than actual harm, as one element. In addition, the Notice seeks comment regarding factors to be considered in determining whether the harm is foreseeable. To help guide and structure comments received in this proceeding, the Notice includes the following example of a possible hoax rule that incorporates the three elements described above:

No licensee of any broadcast station shall broadcast information or other material it knows to be false if it is foreseeable that broadcast of the information could cause substantial

public harm, and if broadcast of the information does in fact directly cause substantial public harm.

Note 1: For purpose of this rule, "public harm" is immediate, substantial and actual damage to the health and safety of the general public or to property, or substantial diversion of law enforcement or other public safety authorities from their duties.

Note 2: The public harm will be deemed foreseeable if the licensee could expect with a significant degree of certainty that public harm would occur. Foreseeability will not be inferred from warnings or disclaimers associated with the broadcast. Lack of foreseeability may be determined in light of factors such as the content of the broadcast or the timing of the broadcast (*e.g.*, April Fool's Day or Halloween).

Ex Parte Rules—Non-Restricted Proceeding

3. This is a non-restricted notice and comment rulemaking proceeding. See generally 47 CFR 1.1202, 1.1203 and 1.1206(a).

Comment Information

4. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, interested parties may file comments on or before January 2, 1992, and reply comments on or before February 3, 1992. All relevant and timely comments will be considered by the Commission before final action is taken in this proceeding.

Initial Regulatory Flexibility Analysis

5. We certify that the Regulatory Flexibility Act of 1980 does not apply to this rulemaking proceeding because if the proposed rule amendments are promulgated, there will not be a significant economic impact on a substantial number of small business entities, as defined by section 601(3) of the Regulatory Flexibility Act. Broadcasters will not be liable for a monetary forfeiture unless the Commission determines that the hoax rule has been violated and that a monetary forfeiture is warranted. The Secretary shall send a copy of this notice of Proposed Rule Making, including the certification, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act. Public Law No. 96–354, 94 Stat. 1164, 5 U.S.C. 601 *et seq.* (1981).

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 91–28515 Filed 11–26–91; 8:45 am]

BILLING CODE 6712-01-M

Notices

Federal Register
Vol. 56, No. 229
Wednesday, November 27, 1991

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Solicitation of Recommendations for Nominees to the Alternative Agricultural Research and Commercialization Board

AGENCY: Office of the Secretary, Department of Agriculture.

ACTION: Solicitation of recommendations for nominees to the Alternative Agricultural Research and Commercialization Board.

SUMMARY: The U.S. Department of Agriculture is soliciting recommendations for nominees to the Alternative Agricultural Research and Commercialization Board (Board). The Board is to be appointed by the Secretary and is to be responsible for the general supervision and policy control of the Alternative Agricultural Research and Commercialization Center (Center) consistent with provisions of sections 1657–64 of Public Law No. 101–624, (7 U.S.C. 5901–5908).

DATES: Recommendations for nominees must be received on or before January 11, 1992.

SEND NOMINATIONS TO: Mark Dungan, room 200A, Office of the Secretary, USDA, Administration Building, Washington, DC 20250.

DOCUMENTATION REQUIRED: Please submit a resume addressing one or more of the categories set forth below. It is not expected that each nominee have education and work experience in each area. However, the Board, as a whole, should reflect the required experience and expertise.

MEMBERSHIP: 7 U.S.C. 5903 states that the Board shall consist of nine members:

1. One member who shall be an employee of the U.S. Department of Agriculture;
2. At least one member representative of the leading scientific disciplines relevant to the activities of the Center;
3. At least one member who is a producer or processor of agricultural commodities;
4. At least one member who is engaged privately in the commercialization of new nonfood, nonfeed products from agricultural commodities;
5. Two members who have expertise in areas of applied research relating to the development or commercialization of new nonfood, nonfeed products, appointed from a list of at least four persons nominated by the Director of the National Science Foundation; and
6. Two members who have expertise in financial and managerial matters, appointed from a list of at least four persons nominated by the Secretary of Commerce.

RESPONSIBILITIES: The Board shall:

1. Be responsible for the general supervision and policy control of the Center and any Regional Centers created under 7 U.S.C. 5907;
2. Determine (in consultation with the advisory council appointed under 7 U.S.C. 5905 and those Regional Centers established under 7 U.S.C. 5907) high priority commercialization areas to receive assistance under 7 U.S.C. 5905;
3. Review any grant, contract, or cooperative agreement to be made by the Center under 7 U.S.C. 5904 and any financial assistance to be provided under 7 U.S.C. 5905;
4. Make the final decision, by majority vote, on whether and how to provide assistance to an applicant;
5. Establish program policy, objectives, research and development, and commercialization priorities to implement sections 1657–64 of Public Law No. 101–624, through a process of public hearings to be initiated as soon as practicable after the establishment of the Board; and
6. Using the results of such hearings and other information and data collected under paragraph 5, develop and establish a budget plan and a long-term operating plan to implement sections 1657–64 of Public Law No. 101–624.

COMPENSATION AND TERM: The term of office of a Board member shall be four years, except that the members initially appointed shall be appointed to serve staggered terms. Board members who are officers or employees of the United States shall not receive any additional compensation by reason of service on the Board. Other members of the Board shall receive, for each day (including travel time) they are engaged in the performance of the functions of the Board, compensation at a rate not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule. All Board members shall be reimbursed for travel, subsistence, and other necessary expenses incurred by them in performance of their duties to the limit allowed by the Department's Travel Regulations.

RESTRICTIONS: Nominees selected for further consideration will be required to submit financial and organizational affiliation disclosure statements.

ADDITIONAL INFORMATION: The Department of Agriculture has special interest in assuring that women, minority groups, and the physically handicapped are adequately represented on the Board and, therefore, extends particular encouragement for recommendations for nominees that are appropriately qualified female, minority, or physically handicapped candidates.

Dated: November 21, 1991.

Edward Madigan,

Secretary of Agriculture.

[FR Doc. 91–28410 Filed 11–26–91; 8:45 am]

BILLING CODE 3410-01-M

Federal Grain Inspection Service

Invitation To Serve on Federal Grain Inspection Service Advisory Committee

Under authority of section 20 of the United States Grain Standards Act (Act), the Secretary of Agriculture established the Federal Grain Inspection Service (FGIS) Advisory Committee (Advisory Committee) on September 29, 1981, to provide advice to the FGIS Administrator on inplementation of the Act. Public Law 100–518 extended the authority for the Advisory Committee through September 30, 1993. The Advisory Committee was renewed by the Secretary of Agriculture on January 16, 1991.

The Advisory Committee presently consists of 15 members, appointed by the Secretary, who represent the interests of grain producers, processors, handlers, merchandisers, consumers, and exporters, including scientists with expertise in research related to the policies in section 2 of the Act (7 U.S.C. 74). Members of the Committee serve

without compensation. They are reimbursed for travel expenses, including per diem in lieu of subsistence, for travel away from their homes or regular places of business in performance of Committee service, as authorized under section 5703 of title 5, United States Code.

Nominations are being sought for persons to serve 3-year terms on the Advisory Committee to replace the five members and five alternate members whose terms expire in February 1992.

Persons interested in serving on the Advisory Committee, or in nominating individuals to serve, should contact: John C. Foltz, Administrator, FGIS, room 1094-S, P.O. Box 96454, Washington, DC 20090-6454, in writing and request Form AD-755, which must be completed and submitted to the Administrator at the above address not later than January 27, 1991.

Nominations are open to all individuals without regard to race, color, religion, sex, national origin, age, mental or physical handicap, or marital status.

The final selection of Advisory Committee members and alternates will be made by the Secretary.

Dated: November 10, 1991.

John C. Foltz,

Administrator, Federal Grain Inspection Service.

[FR Doc. 91-28246 Filed 11-26-91; 8:45 am]

BILLING CODE 3410-EN-M

Rescission of Type Evaluation Handbook

AGENCY: Federal Grain Inspection Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the rescission of the FGIS Type Evaluation Handbook.

EFFECTIVE DATE: November 27, 1991.

ADDRESSES: David B. Funk, Chief, Quality Control and Testing Branch, Quality Assurance and Research Division, Federal Grain Inspection Service, USDA, Box 20285, Kansas City, MO 64195.

FOR FURTHER INFORMATION CONTACT: David B. Funk, address as above, telephone (816) 374-6518.

SUPPLEMENTARY INFORMATION: This action has been reviewed and determined not to be a rule or regulation as defined in Executive Order 12291 and Departmental Regulation 1512-1; therefore, the Executive Order and Departmental Regulation do not apply to this action.

Section 7B of the U.S. Grain Standards Act, as Amended (Act) specifies that the Administrator shall provide for testing of all equipment used in the sampling, grading, inspection, and weighing for the purpose of official inspection, official weighing, or supervision of weighing. Notwithstanding any other provision of law, no person shall use for the purpose of the Act any such equipment not approved by the Administrator.

On November 22, 1988, the Federal Grain Inspection Service published a handbook (Type Evaluation Handbook) pertaining to prototype equipment used for official purposes. The handbook contains criteria and performance standards, and sets forth procedures for submitting, evaluating, and approving such equipment. Since the handbook was published, there has been a considerable increase in the amount and types of prototype equipment submitted for evaluation. Due to that fact, the 1988 handbook is no longer suitable for further use in testing and evaluating equipment in a way which avoids unnecessary duplication of officially approved inspection equipment and which promotes uniform inspection of grain. For these reasons, the 1988 Type Evaluation Handbook is hereby rescinded and will no longer be used in evaluating and approving prototype equipment. In its place, FGIS is presently drafting a new publication regarding equipment evaluation procedures.

The rescission of the handbook does not affect the current regulations which provide for evaluation of prototype equipment upon a determination of need by FGIS. When an application is received, and it is determined that evaluation of a particular piece of equipment would be appropriate, FGIS will develop or recommend testing and evaluation procedures on a case-by-case basis.

Authority: Pub. L. 94-582, 90 Stat. 2867, as amended (7 U.S.C. 71 et seq.)

Dated: November 19, 1991.

John C. Foltz,

Administrator.

[FR Doc. 91-28247 Filed 11-26-91; 8:45 am]

BILLING CODE 3410-EN-M

Food Safety and Inspection Service

[Docket No. 91-033N]

Hazard Analysis and Critical Control Point (HACCP) Workshop—Solicitation of Participants; In-Plant Testing—Solicitation of Volunteers

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food Safety and Inspection Service (FSIS) intends to assist the meat and poultry industries in developing generic model Hazard Analysis and Critical Control Point (HACCP) plans. This notice solicits participation by technical experts from the meat and poultry industries at the workshop on Fresh Ground Beef to include the following 9 CFR 319.15 Miscellaneous Beef Products: Chopped beef, ground beef, hamburger, and beef patties. This workshop will be held December 3-5, 1991, at the Pointe on South Mountain, Phoenix, Arizona.

In addition, this notice also extends the deadline for volunteers for in-plant testing of the generic HACCP model for fresh ground beef as provided in the Agency's January 18, 1991, **Federal Register** notice. The notice provided that plants interested in participating in in-plant testing must notify FSIS by February 15, 1991. Potential volunteers for Fresh Ground Beef testing have requested that the Agency extend the entry deadline for participation in the in-plant testing program. This notice extends the deadline to January 6, 1992.

DATES: Interested participants for the workshop on Fresh Ground Beef to include the following 9 CFR 319.15 Miscellaneous Beef Products: Chopped beef, ground beef, hamburger, and beef patties should supply the requested information no later than November 29, 1991.

Letters of inquiry from persons interested in volunteering a plant for the in-plant testing study of the generic HACCP model for Fresh Ground Beef to include the following 9 CFR 319.15 Miscellaneous Beef Products: Chopped beef, ground beef, hamburger, and beef patties should be submitted by January 6, 1992.

FOR FURTHER INFORMATION CONTACT: Dr. Dorothy Stringfellow, Acting Director, HACCP Special Team, United States Department of Agriculture, Food Safety and Inspection Service, Room 2915, South Building, 14th and Independence Avenue, SW., Washington, DC 20250, (202) 690-2087.

SUPPLEMENTARY INFORMATION: FSIS recognizes the merits of HACCP as a system for sanitation and process control. The industries have expressed an interest in incorporating HACCP into the production of meat and poultry products. It is the intention of FSIS to assist the industries by conducting product specific workshops at which the industries will develop generic HACCP models. For this purpose, technical experts from the meat and poultry industries are being sought to work on

the development of a generic HACCP model for Fresh Ground Beef to include the following 9 CFR 319.15 Miscellaneous Beef Products: Chopped beef, ground beef, hamburger, and beef patties. Individuals or companies volunteering to participate in the development of the model during the workshop need not have previous experience in HACCP-based operations. In fact, it is desirable to include firms with varying degrees of prior HACCP experience.

The workshop on Fresh Ground Beef to include the following 9 CFR 319.15 Miscellaneous Beef Products: Chopped beef, ground beef, hamburger, and beef patties will be held on December 3–5, 1991, at the Pointe on South Mountain, 7777 S. Pointe Parkway, Phoenix, Arizona 85044.

Anyone interested in participating in the workshop on Fresh Ground Beef to include the following 9 CFR 319.15 Miscellaneous Beef Products: Chopped beef, ground beef, hamburger, and beef patties should submit a written request noting the following:

(1) Organization affiliation, i.e., national and/or local trade association(s), if any;

(2) Company, corporation, or independent operation represented by participant;

(3) Plant size, i.e., small, medium, or large; and

(4) Major product lines and approximate volumes.

The number of industry participants involved in the development of the generic HACCP models may have to be limited. If anyone is interested in participating in the workshop on Fresh Ground Beef to include the following 9 CFR 319.15 Miscellaneous Beef Products: Chopped beef, ground beef, hamburger, and beef patties and/or receiving technical information on the Agency's HACCP initiative, please submit written requests to Dr. Dorothy Stringfellow at the above address.

The workshop on Fresh Ground Beef to include the following 9 CFR 319.15 Miscellaneous Beef Products: Chopped beef, ground beef, hamburger, and beef patties will also be open to the public for observation. Space available for observers may be limited and seating will be based on a first come, first served basis. Therefore, those desiring to attend the workshop as observers are asked to submit requests in writing, indicating the following:

(1) Name, address, and phone number; and

(2) Name of company or corporation the observer is representing, if applicable.

Observers will be given an opportunity to comment during the course of the workshop session.

There is no registration fee, but transportation and per diem expenses must be borne by the participant or his/her sponsor.

A future **Federal Register** notice will be issued regarding site location, confirmation of time and date, and participation in the remaining workshop(s). The tentative schedule is as follows:

Month	Region	Product
March 1992	North Central	Swine slaughter (market hogs).

On January 18, 1991, FSIS published a notice in the **Federal Register** (56 FR 1972) soliciting volunteers for in-plant testing of the generic HACCP models developed at these workshops. The notice provided that plants interested in volunteering for in-plant testing must notify FSIS by February 15, 1991. Potential volunteers for Fresh Ground Beef to include the following 9 CFR 319.15 Miscellaneous Beef Products: Chopped beef, ground beef, hamburger, and beef patties have requested that the Agency extend the deadline for participation in the in-plant testing program. This notice extends the deadline to January 6, 1992.

Plants interested in volunteering as a test plant for the Fresh Ground Beef HACCP model or receiving more information on the in-plant test study should submit a written request to Dr. Stringfellow at the above address and note the following:

(1) Name, address, phone number, and establishment number;

(2) Affirmation that the plant is volunteering to test the Fresh Ground Beef HACCP model;

(3) Types of beef slaughtered;

(4) Affiliation, i.e., national and/or local trade association(s), if any;

(5) Fresh ground beef volume per year; and

(6) Type(s) of operation, e.g., New Line Speed Inspection System (NELS) or Streamlined Inspection System (SIS), and number of shifts.

Done at Washington, DC, on: November 7, 1991.

Ronald J. Prucha,

Acting Administrator.

[FR Doc. 91-28381 Filed 11-26-91; 8:45 am]

BILLING CODE 3410-DM-M

Forest Service

Main Bay Fish Hatchery Expansion, Chugach National Forest, Glacier Ranger District, Girdwood, AK

AGENCY: USDA, Forest Service.

ACTION: Notice of intent to prepare an environmental impact statement

SUMMARY: The Department of Agriculture, Forest Service, will prepare an Environmental Impact Statement (EIS) to analyze effects of doubling the size of the Main Bay Fish Hatchery on the Glacier Ranger District to increase sockeye salmon smolt releases to 20 million. The Record of Decision (ROD) will decide if the hatchery should be expanded and identify the conditions by which the expansion would be permitted. A ROD and Final Environmental Impact Statement (FEIS) was issued in April, 1980 by the Chugach National Forest Supervisor for the existing special use permit. The permit allowed the Alaska Department of Fish & Game (ADF&G) to construct and operate a salmon fish hatchery at Main Bay, Alaska.

DATES: Comments concerning the scope of the analysis should be received by December 16, 1991.

ADDRESSES: Written comments and suggestions concerning the scope of analysis must be sent to District Ranger, Glacier Ranger District, Chugach National Forest, P.O. Box 129, Girdwood, AK 99587.

FOR FURTHER INFORMATION CONTACT: Questions about the proposed action and EIS should be directed to Elaine Gross, Glacier Ranger District, Chugach National Forest, phone 907-783-3242.

SUPPLEMENTARY INFORMATION: The ADF&G Fisheries Rehabilitation, Enhancement and Development (F.R.E.D.) Division, proposes developing and implementing an expanded production program at the Main Bay Fish Hatchery. The proposed expansion would increase production capacity of the hatchery from the existing 5.1 million sockeye smolts to 20 million sockeye smolts. The proposed production capacity of Main Bay Fish Hatchery would produce about 4 million adult sockeye salmon.

Numerous facility improvements are needed to support the proposed expanded production capacity of Main Bay Fish Hatchery. The proposed improvements are the expansion of the hatchery rearing/incubation space, an increase in salt water rearing space, improvements to capacity and flexibility of the hatchery fresh water supply system, expanded staff housing

accommodations, and a new power generation facility. Fresh water requirements will double with expansion. Fresh water is obtained from Main Lake. The expansion would occur completely within the area currently under special use permit to the State of Alaska for the Main Bay Fish Hatchery.

The Responsible Official for the EIS is Regional Forester, Michael A. Barton, Alaska Region, Juneau, Alaska. He will select from a full array of alternatives presented in the EIS, including the alternative of "no action". At this early stage, possible alternatives to the proposed action are not known. Specific alternatives will be generated through public involvement.

Preliminary issues for the project are expected to include:

1. What effect will the expanded hatchery have on the character of the Nellie Juan-College Fjord wilderness study area?

2. What effect will increased numbers of sockeye salmon have on the commercial fishing industry in Prince William Sound?

3. What effect will hatchery expansion and increased sockeye salmon production have on subsistence resource use in Prince William Sound?

4. Will hatchery-raised Sockeye Salmon have a negative impact on Native fish stocks in Prince William Sound?

5. What effect will the hatchery and associated increased commercial fishing have on the recreation opportunities of western Prince William Sound?

The Alaska Department of Fish and Game, F.R.E.D. Division, will participate as a cooperating agency to evaluate compatibility of the proposed expansion on the overall goals and plans developed for Prince William Sound.

Public participation is very important throughout this analysis process. Key times for public involvement include the scoping process when input will be used to prepare the Draft Environmental Impact Statement (DEIS) and again after issuance of the DEIS before preparation of the Final Environmental Impact Statement (FEIS). The Forest Service will be seeking information, comments, and assistance from Federal, State, and local agencies, and other individuals or organizations who may be interested in or affected by the proposed action. Scoping is to begin in November, 1991. No public hearings or meetings are scheduled at this time. The public will be notified in advance when any public hearings and meetings are scheduled. The DEIS should be filed with EPA in May, 1992, and the final EIS filed in November, 1992.

The comment period on the DEIS will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of the DEIS must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the DEIS stage but that are not raised until after completion of the FEIS may be waived or dismissed by the courts. *City of Angoon* v. *Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1988) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the FEIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the DEIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the DEIS or the merits of the alternatives formulated and discussed in the statement. (Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points).

Permits required for implementation include the following:

1. U.S. Army Corps of Engineers:

Approval of the discharge of dredged or fill materials into waters of the United States, under section 404 of the Clean Water Act.

Approval of the construction of structures or work in navigable waters of the United States, under section 10 of the River and Harbor Act of 1899.

2. U.S. Environmental Protection Agency:

National Pollutant Discharge Elimination System (402) permit for discharge of wastewater into waters of the United States.

3. U.S. Federal Energy Regulatory Commission:

License for the generation of electric power.

4. State of Alaska, Department of Environmental Conservation:

Certificate of Reasonable Assurance for the discharge of wastewater into the ocean.

5. State of Alaska, Department of Natural Resources:

Permit to place structures in streams or wetlands (Form 10–106).

Water use permit for use of fresh water (Form 10–102).

Site grading permit.

6. State of Alaska, Department of Fish and Game:

Anadromous fish protection permit.

Permit to alter a natural stream channel or stream bank.

Hatchery permit.

Explosives permit.

Michael A. Barton, Regional Forester, USDA Forest Service, Box 21628, Juneau, Alaska, 99802, is the responsible official. The responsible official will consider the comments, responses, disclosure of environmental consequences, and applicable laws, regulations, and policies in making a decision regarding this proposal. The responsible official will document the decision and rationale in the ROD.

Dated: November 15, 1991.

Michael A. Barton,

Regional Forester.

[FR Doc. 91–28419 Filed 11–26–91; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Action Affecting Export Privileges; Delft Instruments Defense BV; et al.

In the Matter of:

Delft Instruments Defense BV, Van Miereveltlaan 9, P.O. Box 72, Delft, Netherlands

Instrubel NV, Westerring 19, B–9700 Oudenaarde, Belgium

OIP NV, Westerring 21, B–9700 Oudenaarde, Belgium

Franke Systemtechnik GmbH, Philosophenstrasse 116, Postfach 5420, 6300 Giessen/Lahn, Germany

Odelft Electronic Instruments SRI, Via C. Armellini 20, 00143 Rome, Italy

BV Delft Electronische Producten, Dwazziewegen 2, P.O. Box 60, 9300 AB Roden, The Netherlands

Delft Instruments Electro-Optics BV, Van Miereveltlaan 9, P.O. Box 5083, 2600 GB Delft, The Netherlands

Respondents

Decision and Order

On February 22, 1991, then Assistant Secretary for Export Enforcement, Quincy M. Krosby, issued a temporary denial order (TDO) for 180 days naming Delft Instruments N.V., located in the Netherlands, also known as Oldelft, Old Delft, Olde Delft, Oude Delft (hereinafter referred to as Delft); Delft Instruments Electro-Optics, Delft Electronische Products and Optische Industrie Oude Delft; OIP Instrubel, a Delft subsidiary located in Belgium, and Franks & Co. Optik GmbH,[1] a Delft subsidiary located in Germany, as persons temporarily denied all U.S. export privileges. 56 FR 8321 (February 28, 1991). On August 21, 1991, then-Acting Assistant Secretary for Export Enforcement, Kenneth A. Cutshaw, renewed that TDO for 90 days and modified it to name specifically all of Delft's 47 subsidiaries as persons related to Delft and, as such, also denied export privileges. 56 FR 42977 (August 30, 1991).[2] Without renewal, the TDO will expire on November 19, 1991.

On October 30, 1991, the Office of Export Enforcement, Bureau of Export Administration, United States Department of Commerce (Department), filed a request with me asking me to renew again the TDO against Delft and all of its subsidiaries for 180 days. Since then, I have reviewed the Department's request and Delft's opposition thereto. I have also had discussions with representatives of the Department and Delft. Based thereon, I have decided to renew the TDO for 90 days with regard to Delft's defense-related entities because I find that such a renewal is necessary in the public interest to prevent an imminent violation of the Export Administration Regulations (currently codified at 15 CFR parts 768–799 (1991)) (the Regulations), issued pursuant to the Export Administration Act of 1979, as amended (currently codified at 50 U.S.C.A. app. 2401–2420 (1991)) (Act).[3] However, with regard to Delft's civil-sector entities, I find that such a renewal is not warranted.

Accordingly, it is hereby Ordered:

I. Effective November 19, 1991, the TDO in effect against Delft and certain related parties shall expire and have no effect, except that, it shall continue in effect with regard to those Delft subsidiaries with a significant involvement in defense-related business. Accordingly, all outstanding validated export licenses in which Delft Instruments Defense BV, Van Miereveleltlaan 9, P.O. Box 72, Delft, Netherlands; INSTRUBEL NV, Westerring 19, B–9700 Oudenaarde, Belgium; OIP NV Westerring 21 B–9700 Oudenaarde, Belgium; Franke Systemtechnik GmbH Philosophenstrasse 116 Postfach 5420, 6300 Giessen/Lahn Germany; Odelft Electronic Instruments SRI Via G. Armellini 20, 00143 Rome, Italy; Delft Electronische Producten, Dwazziewegen 2, P.O. Box 60 9300 AB Roden, Netherlands; and Delft Instruments Electro-Optics BV Van Miereveltlaan 9, P.O. Box 5083, 2600 GB Delft, Netherlands, appear or participate, in any manner or capacity, are hereby revoked and shall be returned forthwith to the Office of Export Licensing for cancellation. Further, all of respondents' privileges of participating, in any manner or capacity, in any special licensing procedure, including, but not limited to, distribution licenses, are hereby revoked.

II. Respondents Delft Instruments Defense BV, Instrubel NV, OIP NV, Franke Systemtechnik GmbH, Odelft Electronic Instruments SRI, Delft Electronische Producten and Delft Instruments Electro-Optics BV, their successors, assignees, officers, partners, representatives, agents, and employees, hereby are denied all privileges of participating, directly or indirectly, in any manner or capacity, in any transaction in the United States or abroad involving commodities or technical data exported or to be exported from the United States, in whole or in part and subject to the Regulations. Without limiting the generality of the foregoing, participation, either in the United States or abroad, shall include participation, directly or indirectly, in any manner or capacity: (a) As a party or as a representative of a party to any export license application submitted to the Department; (b) in preparing or filing with the Department any export license application or reexport authorization, or any document to be submitted therewith; (c) in obtaining from the Department or using any validated or general export license, reexport authorization or other export control document; (d) in carrying on negotiations with respect to, or in receiving, ordering, buying, selling, delivering, storing, using, or disposing of, in whole or in part, any commodities or technical data exported or to be exported from the United States subject to the Regulations; and (e) in financing, forwarding, transporting, or other servicing of such commodities or technical data. Such denial of export privileges shall extend only to those commodities and technical data which are subject to the Act and the Regulations.

III. After notice and opportunity for comment, such denial may be made applicable to any person, firm, corporation, or business organization with which either Delft Instruments Defense BV, Instrubel NV, OIP NV, Franke Systemtechnik GmbH, Odelft Electronic Instruments SRI, Delft Electronische Producten or Delft Instruments Electro-Optics BV, is now or hereafter may be related by affiliation, ownership, control position of responsibility, or other connection in the conduct of trade or related services.

IV. As provided for in section § 787.12(a) of the Regulations, without prior disclosure of the facts to and specific authorization of the Office of Export Licensing, in consultation with the Office of Export Enforcement, no person may directly or indirectly, in any manner or capacity, with respect to U.S.-origin commodities and technical data: (i) Apply for, obtain, or use any license, Shipper's Export Declaration, bill of lading, or other export control document relating to an export or reexport of commodities or technical data by, to, or for another person then subject to an order revoking or denying his export privileges or then excluded from practice before the Bureau of Export Administration; or (ii) order, buy, receive, use, sell, deliver, store, dispose of, forward, transport, finance, or otherwise service or participate (a) in any transaction which may involve any commodity or technical data exported or to be exported from the United States, (b) in any reexport thereof, or (c) in any other transaction which is subject to the Export Administration Regulations, if the person denied export privileges may obtain any benefit or have any interest in, directly or indirectly, any of these transactions.

V. In accordance with the provisions of Section 788.19(e) of the Regulations, any respondent may, at any time, appeal this temporary denial order by filing with the Office of the Administrative Law Judge, U.S. Department of Commerce, room H–6716, 14th Street and Constitution Avenue, NW., Washington, DC, 20230, a full written statement in support of the appeal.

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[1] Since the time the TDO was originally issued, I have learned that the correct spelling of "Franks & Co. Optik GmbH" is "Franke & Co. Optik GmbH."

[2] The TDO was modified again on October 18, 1991 to delete B.V. Enraf-Nonius Ermelo as a person related to Delft, based on evidence proffered by Delft that it had sold that entity. 56 FP 55491 (October 28, 1991).

[3] The Act expired on September 30, 1990. Executive Order 12730 (55 FR 40373, October 2, 1990) continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C.A. 1701–1706 (1991)).

VI. This order is effective immediately and shall remain in effect for 90 days.

VII. In accordance with the provisions of § 788.19(d) of the Regulations, the Department may seek renewal of this temporary denial order by filing a written request not later than 20 days before the expiration date. Any respondent may oppose a request to renew this temporary denial order by filing a written submission with the Assistant Secretary for Export Enforcement, which must be received not later than seven days before the expiration date of this order.

A copy of this order shall be served on each respondent and this order shall be published in the **Federal Register**.

Entered this 19th day of November, 1991.

Douglas E. Lavin,

Acting Assistant Secretary for Export Enforcement.

[FR Doc. 91-28454 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-01-M

Foreign-Trade Zones Board

[Docket No. 75-91]

Foreign-Trade Zone 54—Portland, Oregon Application for Subzone Tofle Stainless Steel Tubing Plant Tualatin, OR (Portland Port of Entry)

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Port of Portland, grantee of FTZ 45, Portland, Oregon, requesting special-purpose subzone status for export manufacturing at the stainless steel tubing plant of Tofle U.S.A., Inc. (subsidiary of Tofle Co., Japan), located in Tualatin, Oregon. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on November 6, 1991.

The plant (3.2 acres, 10,000 sq. ft.) is located at 10850 S.W. Leveton Dr., Tualatin, Oregon, some 4 miles southwest of Portland. The facility is used to manufacture flexible, stainless steel tubing (⅜-inch to 12 inches in diameter). The majority of the materials and components are purchased from abroad, including stainless steel sheet, stainless steel wire and cast iron fittings. All of the products manufactured under zone procedures would be exported.

Zone procedures would exempt Tofle from Customs duty payments on the foreign materials and components used in its export production. The applicant indicates that zone savings will improve the plant's competitiveness in international markets.

In accordance with the Board's regulations, an examiners committee has been appointed to investigate the application and report to the Board. The committee consists of: Dennis Puccinelli (Chairman), Foreign-Trade Zones Staff, U.S. Department of Commerce, Washington, DC 20230; Thomas W. Hardy, District Director, U.S. Customs Service, Pacific Region, 511 N.W. Broadway Federal Bldg., Portland, Oregon 97209; and, Major General Ernest J. Harrell, District Engineer, U.S. Army Engineer District Portland, P.O. Box 2870, Portland, Oregon 97208–2870.

Comments concerning the proposed foreign-trade subzone are invited from interested parties. They should be addressed to the Board's Executive Secretary at the address below and postmarked on or before January 10, 1992.

A copy of the application and accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce District Office, Suite 242, One World Trade Center, 121 SW Salmon Street, Portland, Oregon 97204

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 3716, 14th Street and Constitution Avenue, NW., Washington, DC 20230

Dated: November 19, 1991.

Dennis Puccinelli,

Acting Executive Secretary.

[FR Doc. 91-28524 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DS-M

[Docket No. 76-91]

Foreign-Trade Zone 39—Dallas/Fort Worth, TX; Application for Expansion

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Dallas/Fort Worth International Airport Board, grantee of FTZ 39, requesting authority to expand its zone at the Dallas/Fort Worth International Airport. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on November 6, 1991.

FTZ 39 was approved on August 17, 1978 (Board Order 133, 43 FR 37478, 8/23/78). It currently consists of three parcels (250 acres) located within the northeastern portion of the Dallas/Fort Worth International Airport complex.

The grantee is now requesting authority to expand the zone to include additional facilities (2,150 acres) within the 18,000-acre airport complex, such as industrial park sites and the airport's aviation fuel storage and distribution facility. The zone project is operated by Sekin Transport International, Inc. No manufacturing requests are being made at this time. Such approvals would be requested from the Board on a case-by-case basis.

In accordance with the Board's regulations, an examiners committee has been appointed to investigate the application and report to the Board. The committee consists of: John J. Da Ponte, Jr. (Chairman), Director, Foreign-Trade Zones Staff, U.S. Department of Commerce, Washington, DC 20230; Donna De La Torre, Director, Office of Inspection and Control, U.S. Customs Service, Southwest Region, 5850 San Felipe Street, Suite 500, Houston, Texas 77057–3012; and, Colonel John A. Mills, District Engineer, U.S. Army Engineer District Fort Worth, P.O. Box 17300, Fort Worth, Texas 76102–0300.

Comments concerning the proposed expansion are invited in writing from interested parties. They should be addressed to the Board's Executive Secretary at the address below and postmarked on or before January 13, 1991.

A copy of the application is available for inspection at each of the following locations:

U.S. Department of Commerce, District Office, room 7A5, 1100 Commerce Street, Dallas, Texas 75242.

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, room 3716, 14th & Pennsylvania Avenue NW., Washington, DC 20230.

Dated: November 20, 1991.

Dennis Puccinelli,

Acting Executive Secretary.

[FR Doc. 91-28525 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DS-M

International Trade Administration A-428-602

Brass Sheet and Strip From the Federal Republic of Germany; Final Results of Antidumping Duty Administrative Review

AGENCY: International Trade Administration/Import Administration, Department of Commerce.

ACTION: Notice of final results of antidumping duty administrative review.

SUMMARY: On July 10, 1990, the Department of Commerce (the Department) published the preliminary results of its administrative review of the antidumping duty order on brass sheet and strip from the Federal Republic of Germany (Germany). The review covers five manufacturers and/or exporters of this merchandise for the period August 22, 1986 through February 29, 1988. Three of these five firms, Wieland Werke AG and its wholly-owned subsidiaries, Langenberg Kupfer- und Messingwerke GmbH KG and Metallwerke Schwarzwald GmbH, had shipments to the United States during the period of review (POR). Another firm, William Prym, failed to respond to the Department's antidumping questionnaire. For this firm we used the best information available (BIA) for assessment and cash deposit purposes. We determined the BIA to be the highest rate for a responding firm during this review period. One firm, Schwermetall Halbzeugwerke, had no shipments to the United States during the POR. For this firm, we used the "all other" rate established during the LTFV investigation.

We gave interested parties an opportunity to comment on the preliminary results. Based on our analysis of the comments received and the correction of certain clerical errors, we have changed the margins for Wielamd-Werke AG and its wholly-owned subsidiaries, Langenberg Kupfer- und Messingwerke GmbH KG and Metallwerke Schwarzwald GmbH, hereinafter collectively referred to as "the Weiland Group", from 7.94 percent to 19.59 percent.

EFFECTIVE DATE: November 27, 1991.

FOR FURTHER INFORMATION CONTACT: J. David Dirstine, Michael Diminich, or Richard Rimlinger, Office of Antidumping Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230, telephone: (202) 377-4733.

SUPPLEMENTARY INFORMATION:

Background

On July 10, 1990, the Department published in the **Federal Register** (55 FR 28264) the preliminary results of its administrative review of the antidumping duty order on brass sheet and strip from the Federal Republic of Germany (52 FR 6997, March 6, 1987). The Department has now completed that administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (Tariff Act) 19 U.S.C. 1675).

Scope of Review

Imports covered by the review are shipments of brass sheet and strip, other than leaded brass and tin brass sheet and strip, from Germany. The chemical composition of the products covered is currently defined in the Copper Development Association (C.D.A.) 200 series of the Unified Numbering System (U.N.S.) C20000 series. Products whose chemical composition are defined by other C.D.A. or U.N.S. series are not covered by this review. The physical dimensions of the products covered by this review are brass sheet and strip of solid rectangular cross section over 0.006 inches (0.15 millimeters) through 0.188 inches (4.8 millimeters) in finished thickness or gauge, regardless of width. Coiled, wound on reels (traverse wound) and cut-to-length products are included. During the review period, such merchandise was classified under item numbers 612.3960, 612.3982, 612.3986 of the Tariff Schedules of the United States Annotated (TSUSA). This merchandise is currently classifiable under Harmonized Tariff Schedule (HTS) item numbers 7409.21.00 and 7409.29.00. The TSUSA and HTS item numbers are provided for convenience and for Customs purposes. The written descriptions remain dispositive.

The review covers five manufacturers and/or exporters of this merchandise for the period August 22, 1986 through February 29, 1988.

Analysis of Comments Received

We gave interested parties an opportunity to comment on the preliminary results. We received comments from the petitioner and the Wieland Group, respondent.

Comment 1: Respondent asserts that some of the made-to-order merchandise it sells in both the home market and the United States differs in specific physical characteristics (*i.e.*, camber, suitability for electropolishing, etc.) even within the product groupings established by the Department. Therefore, respondent claims that in comparing U.S. merchandise to its similar home market merchandise, an adjustment should be made to account for these cost-based differences.

Department's Position: The Department matched categories of "such or similar" merchandise based on the primary characteristics of material (sheets or strips), coating (tinned/non-tinned), grade (alloy composition), and dimensions (gauge and width). In the April 21, 1988 questionnaire, and in the supplemental questionnaire, the Department requested information on costs reflecting the differences in merchandise (difmer) for the primary characteristics of gauge and width. The Wieland Group failed to provide this information. The Wieland Group did provide difmer data for "special characteristics" which, as secondary characteristics, are not considered in determining the product matching hierarchy. Respondent, however, provided standard cost data, not actual cost data, to support this difmer claim. In addition, the Wieland Group failed to segregate the total material cost segment, the direct labor cost segment, and the direct factory overhead cost segment of each of these claims, as requested by the Department in both the questionnaire and the supplemental request for information.

Because of these reporting deficiencies with respect to differences attributable to "special characteristics" and the Wieland Group's failure to report the requested difmer data for the primary characteristics of gauge and width, the Department has denied respondent's difmer claim for "special characteristics".

Comment 2: Respondent claims that the Department should grant a cost-based quantity discount adjustment on its home market sales, because there is a significant difference between the average order size in the United States and the home market. Respondent states that, consistent with the initial LTFV investigation, it conservatively calculated only the cost differences that are attributable to quantity. Respondent further asserts that it carefully and correctly calculated the cost savings for different production quantities, with all other variables held constant.

Respondent further contends that the Department's preliminary decision not to accept its cost-based quantity adjustment was based on its erroneous perception that there was no direct correlation between prices and quantities sold. Respondent asserts that a correlation between price and quantity is unnecessary to establish a valid claim to a cost-based quantity adjustment. See 19 CFR 353.55(b)(2) (1990). Assuming, *arguendo*, that such a correlation is necessary, however, respondent claims that it has demonstrated that one exists.

Petitioner counters that respondent's contention that a difference in average order size between the two markets entitles it to a cost-based quantity adjustment is erroneous. Petitioner states that respondent has chosen an improper basis upon which to claim this adjustment and that the regulations clearly state that the differences in cost incurred must be attributable to the production of the different quantities

involved. Petitioner asserts that respondent failed to provide a detailed breakout of its production planning, data processing, and shipping documentation costs. Petitioner further asserts that the production costs reported by respondent appear to be fixed costs and, thus, not directly related to the production of the subject merchandise.

With respect to respondent's contention that it has demonstrated that a correlation between price and quantity exists, petitioner responds that respondent failed to hold all variables, except the quantity variable, constant. It adjusted its analysis for differences in so-called special characteristics or secondary matching criteria, and failed to adjust its analysis for differences in primary physical characteristics such as alloy, gauge and width. Respondent merely grouped all alloys, gauges and widths—regardless of the date of sale—in each of its five product categories to arrive at its reported weighted-average unit price, by quantity grouping.

Department's Position: As stated in Brass Sheet and Strip from the Netherlands, 53 FR 2341 (1988), "the controlling requirement of § 353.14 (353.55(a) under the new antidumping regulations) is that, to be eligible for a quantity-based adjustment, a respondent must demonstrate a clear and direct correlation between price differences and quantities sold or costs incurred." The exporter must clearly demonstrate that discounts are warranted on the basis of savings which are specifically attributable to longer production runs. The Department maintains that respondent failed to take into account price differences due to differences in alloy composition and gauge and width. In addition to failing to hold all variables, except the quantity variable, constant, the Wieland Group has not adequately demonstrated a correlation between prices and savings specifically attributable to different production quantities.

Comment 3: Respondent asserts that the Department improperly compared further-processed exporter's sales price (ESP) prices, reduced by the amount of value added by further United States processing, to the price of further-processed products in the home market not similarly reduced for value added. Respondent contends that this resulted in the unfair comparison of the ESP price of an unprocessed product to the home market price of a processed product. The Wieland Group claims that because the processed product is more costly to produce and commands a higher price, the Department's comparison unfairly skews the results. Respondent contends that the Department should either not deduct U.S. value added from exporter's sales price or should compare the adjusted ESP sales to appropriate, adjusted home market sales.

Department's Position: Section 772(e)(3) of the Tariff Act mandates that we calculate the price and compare ESP sales in the form in which the merchandise enters the United States. In both the original questionnaire and the request for supplemental information, the Department requested the Wieland Group to report the form in which products used for further processing are imported. The Wieland Group failed to report this information and reported specifications for value added merchandise on an "as sold" basis only. Because respondent did not report the information required by the Department to match further-processed U.S. sales on an "as imported" basis, we deducted the U.S. value added to further-processed merchandise and, as BIA, made comparisons on an "as sold" basis.

Comment 4: Respondent claims that the Department's failure to adjust reasonably for the effect of dramatic metal price fluctuations that occurred during the POR created fictitious margins. It contends that because metal prices varied widely on a daily basis and are entirely outside its pricing control, it is impossible to compare U.S. and home market sales made on different dates without some adjustment.

Department's Position: We are not convinced by information on the record that we should alter our position here from that of the preliminary results. Circumstance of sale adjustments are normally only allowed for differences in selling expenses related to sales being compared, not differences in raw material costs, and would therefore be inappropriate in this case. Difference in merchandise adjustments would also be inappropriate unless there is a physical difference in merchandise being compared. Furthermore, for the majority of the POR (August 22, 1986 through February 29, 1988), metal values were relatively stable. Significant fluctuations in metal values did not occur until the latter part of 1987. However, when the Department compares U.S. sales to monthly weighted-average contemporaneous home market sales, the weighting process itself reduces the potential for distortion in price comparisons. Also, our use of only contemporaneous sales for comparison purposes further reduces the potential for such distortion. Therefore, for the above reasons, we do not believe there is need for any other metal price fluctuation adjustments.

Comment 5: Petitioner contends that the Department erred when it used as BIA the weighted-average margin of reviewable sales for those sales in which respondent failed to provide cost adjustment information for difmer adjustments. For such sales, petitioner asserts that the Department should use either the highest transaction margin or the difmer data submitted by petitioner in its submission of February 17, 1989.

Department's Position: In accordance with Section 776(c) of the Tariff Act, the Department has applied BIA for those sales for which we did not have matches. Normally, the Department will make difference in merchandise (difmer) adjustments in order to compare non-identical merchandise. Because the Wieland Group failed to report difmer information to allow the Department to make comparisons on the unmatched sales, for the final results of this review we have used the highest weighted-average margin for any member of the Wieland Group as BIA for the unmatched sales.

Comment 6: Petitioner contends that the Department failed to adjust accurately for differences in merchandise due to differences in alloys. Petitioner asserts that the Department should have compared transactions on the basis of an exact alloy match. Petitioner states, for example, that a comparison of C.D.A. alloy 260 with C.D.A. alloys 270 and 274, without an adjustment to account for differences in metal content, will result in inaccurate comparisons.'

Department's Position: We maintain our position that, in formulating such or similar product groupings, it is appropriate to group alloys according to their copper content. Of the two metals which comprise brass, copper and zinc, copper generally constitutes the larger input in an alloy, and is also more expensive than zinc. However, for non-identical product comparisons within a such or similar group, we did make an adjustment for physical differences in alloy composition based on London Metal Exchange settlement prices.

Comment 7: Petitioner contends that the Department incorrectly understated the Wieland Group's U.S. value-added amount for sales it further processed in the United States, and that respondent did not supply the Department with information on the following four value-added components: (1) U.S. manufacturing costs incurred by the Wieland Groups's U.S. production affiliate, Wieland-Metals, to roll the

brass merchandise; (2) an allocated portion of the general and administrative expenses incurred by the Wieland Group's U.S. sales affiliate, Wieland-America; (3) an allocated portion of Wieland-Metals' and Wieland-America's general, selling and administrative expenses incurred in Germany in association with U.S. value-added operations; and (4) an allocated portion of profit. Petitioner contends that since the Wieland Group failed to provide U.S. rolling costs, the Department should use BIA to determine the U.S. processing amount on the Wieland Group's rerolled sales. Petitioner has provided data for use as BIA in a February 17, 1989 letter to the Department.

Respondent contends that it rolled only a very small quantity of the total merchandise under review. Moreover, because of its start-up nature, the production costs associated with the fledgling reroll operations were not kept in normal cost records. Given the insignificant amount of rerolled material and the nonrepresentative nature of rerolling costs during testing, respondent asserts that the Department correctly decided not to adjust the prices of these sales. Respondent further states that the Department should not double count U.S. selling expenses by including them in the value added calculation.

Department's Position: With respect to U.S. manufacturing costs incurred by Wieland Metals to roll the brass merchandise, respondent did not provide the Department, as requested, with its reroll processing costs, nor did it identify those rerolled sales which were not subject to slitting and traverse winding. Therefore, for purposes of these final results, we have used BIA for those sales that were rerolled. We determine BIA to be the highest weighted-average margin for any member of the Wieland Group. With respect to those U.S. sales for which there was further processing but not rerolling, we did not allocate a portion of Wieland America's general, selling and administrative expenses because those sales were not made through Wieland America. Since Wieland Metals handled all such U.S. sales, a portion of that firm's general, selling and administrative expenses was allocated to the total U.S. value-added amount. In addition, any general, selling and administrative expenses incurred in Germany in support of U.S. sales were not included because, under section 772(e)(3) of the Tariff Act, we can only deduct any increase in value resulting from a process of manufacture or assembly performed on the imported merchandise after its importation. Finally, with respect to profit, we did not include profit in the total value-added amount because respondent's data indicated that Wieland Metals had not profit during the POR.

Comment 8: Petitioner argues that respondent failed to substantiate its home market credit claim and, therefore, the Department should not adjust for home market credit. Petitioner further argues that the Department incorrectly calculated respondent's U.S. purchase price credit expense claim based on a higher interest rate than was used to calculate the home market credit expense.

Department's Position: Respondent did not furnish actual credit interest rates applicable to home market sales or U.S. sales. In its response, the Wieland Group submitted a range of short-term interest rates offered by its banks during the POR. Since we do not have actual interest rates identified for sales to each market, for purposes of these final results, as BIA for the credit expense adjustments, we have used the highest interest rate in the range for home market sales and the lowest interest rate in the range for U.S. sales.

Comment 9: Petitioner asserts that respondent failed to explain why the interest rate associated with its consignment credit claim is a higher percentage than the interest rate associated with its home market claim.

Respondent argues that the direct credit expenses associated with its post-sale consignment arrangements are properly calculated using the company's long-term borrowing rate, which is higher than the short-term borrowing rate.

Department's Position: We agree with respondent for the reasons outlined in a proprietary memorandum to the file dated November 8, 1991, from Michael Diminich, Analyst, Office of Antidumping Compliance.

Comment 10: Petitioner argues that the Department should be consistent in its treatment of inventory expenses because these expenses are identical in each market. In its preliminary analysis, the Department treated the home market inventory expenses as direct selling expenses and the U.S. inventory expenses as indirect selling expenses. Petitioner claims that, whether incurred on behalf of a home market customer or on behalf of a U.S. customer, expenses associated with inventory were incurred for identical reasons. Petitioner asserts that the only difference between the home market and U.S. inventory expenses was the label respondent assigned to these expenses. Respondent characterized its U.S. inventory expenses as "buffer stocks" and claimed that they were indirect selling expenses. In contrast, it characterized its home market buffer stocks as "consignment" sales and claimed they constituted direct selling expenses.

Department's Position: The Department recognizes these credit expenses on consignment inventory as post-sale, direct expenses because these expenses are directly related to individual sales to a specific customer. Such consignment sales, however, exist only in the home market. In contrast, pre-sale credit expenses for buffer stock arrangements on the U.S. sales are not related to specific sales or specific customers. In buffer stock arrangements, a potential customer is not obligated to purchase the products and the Wieland Group can withdraw merchandise from buffer stocks and ship it to any customer. Credit expenses associated with buffer stock arrangements are, therefore, indirect pre-sale warehousing expenses.

Comment 11: Petitioner argues that the Department neglected to make an adjustment for respondent's inventory holding period for U.S. sales. The inventory holding period for these sales should represent the period between the time that the brass merchandise was shipped from respondent's German facility and the time that the merchandise was shipped from respondent's U.S. facility. Respondent reported that the holding period for merchandise shipped to the U.S. is 14 weeks. Therefore, petitioner argues, in the final results, the Department should calculate respondent's indirect credit expense adjustment based on an inventory period of 98 days.

Department's Position: We agree. In cases involving ESP transactions, we include the costs of financing inventory in our calculation of indirect selling expenses. (See, *e.g.*, Antifriction Bearings from the Federal Republic of Germany, 54 FR 18992, App. B; Sect. 12 (1989)). We calculated respondent's indirect credit expense adjustment based on an inventory period of 98 days.

Comment 12: Petitioner contends that the Department incorrectly accepted hypothetical sales prices, as opposed to actual selling prices, for certain home market sales made under one of respondent's two split-pricing billing options which are offered to certain home market customers. Under these split-pricing billing options, participating customers purchase metal from respondent, who establishes a metal account against which customers can draw for future orders. Split-pricing

entails breaking down the total price paid into that portion of the price attributable to metal costs and that attributable to fabrication costs. Respondent reports that it bills its split-pricing customers' accounts in one of two methods. Under the first method, respondent bills the customer at the time of delivery of the merchandise for both the metal and fabrication portions of the price. Under the second method, respondent bills the participating customer separately for fabrication and for metal, as the latter is credited to the customer's metal account.

Respondent states that under the second billing method it cannot match the actual metal price, *i.e.*, the metal price at the time the participating customers' accounts are credited, to specific sales. Therefore, to calculate the total sales price for the split-pricing sales under this method, respondent added to the fabrication price the official German metal price in effect on the date of sale.

Respondent further explained that it reduced these date-of-sale metal prices by a customary metal discount and an early payment discount that the Wieland Group receives. Petitioner argues that respondent, under the second billing method, constructed a metal price that does not reflect the actual metal price its customer paid for the metal. Further, petitioner states that respondent not only failed to report its actual metal prices for these subject split-priced sales, but also did not demonstrate that it received a metal discount or early payment discount on all of its split-pricing metal purchases. Therefore, petitioner contends that the Department should add the reported metal discount and early payment discount to each home market sale.

Department's Position: The Department requested that respondent provide the actual metal price charged to home market customers purchasing on a split-priced basis who were billed separately for the metal value portion of the sale. Respondent failed to provide the requested information and failed to provide an acceptable constructed price that was representative of actual prices charged. In addition, the Wieland Group reported early payment and metal discounts on all split-pricing metal purchases. However, the Wieland Group failed to demonstrate that it actually received these discounts on all split-pricing metal purchases. Therefore, we accepted information submitted by petitioner as BIA with respect to the total sale price and adjusted all home market prices to levels applicable to home market sales not covered by split-pricing agreements by adding the metal discount and early payment discount to each home market sale.

Comment 13: Petitioner argues that the Department should not have accepted the Wieland Group's home market commission claim. According to petitioner, the Wieland Group failed to state whether the actual amount of the commission varied from product to product. Petitioner further asserts that the Wieland Group did not offer an explanation as to whether or how the commission varied from customer to customer, nor has the Wieland Group properly explained the terms and conditions of its home market commission claim. Petitioner contends that because respondent has not documented that it paid commissions on sales of such or similar merchandise, the Department should reject this home market commission claim in its final analysis.

The respondent responds that petitioner erroneously states that commissions are not tied to sales of such or similar merchandise and that commissions are firmly tied to sales of such or similar merchandise.

Department's Position: According to the Wieland Group's response, the firm sells through unrelated agents who, in turn, each sell in certain assigned territories. Respondent claims that because commissions do not vary by product or customer within a territory, a commission will necessarily apply to the products under investigation if sold in an area in which the respondent uses unrelated agents. The commission is only deducted from home market sales of covered merchandise made in one of these "commission" areas. Therefore, the Department has accepted the Wieland Group's home market commission claim for purposes of the final results.

Comment 14: Petitioner asserts that respondent's reported early payment discount claim was based on its total home market sales of all products and not just on the discounts granted on the subject merchandise. Respondent reported that early payment discounts are not granted on split-pricing sales that feature separate billing for metal costs and fabrication costs. Thus, respondent does not grant early payment discounts for certain split-pricing sales and failed to segregate its reported early payment discount claim on either a sales-specific or customer-specific basis. Therefore, petitioner argues, the Department should reject this claim.

Department's Position: The Department generally makes an adjustment if discounts, granted pursuant to accurately and adequately described programs, are properly reported on a sale or customer-specific basis and are directly associated with the products or sales under consideration. Although the Department has the discretion to allow adjustments based on allocations rather than invoice-specific adjustments where the allocation methods were reasonable and consistent, we are disallowing this claim (See Department's Position, Comment 12).

Comment 15: Both respondent and petitioner alleged that the Department made certain clerical and calculation errors.

Department's Position: Based on our analysis of the comments received and the correction of certain inadvertent programming and clerical errors, we have changed the preliminary results.

Final Results of Review

As a result of our review of the comments received, we have determined that the following weighted-average margins exist for the period August 22, 1986, through February 29, 1988:

Manufacturer/exporter	Margin (Percent)
Wieland Group (Wieland-Werke AG) (Langenberg Kupfer-und Messingwerke GmbH KG) (Metallwerke Schwarzwald GmbH)	19.59
William Prym	19.59
Schwermetall Halbzeugwerke	*7.30

*No shipments during the period. Rate is from the LTFV investigation.

The Department will instruct the Customs Service to assess antidumping duties on all appropriate entries. Individual differences between U.S. price and foreign market value may vary from the percentages stated above. The Department will issue appraisement instructions directly to the Customs Service.

Furthermore, the following deposit requirements will be effective upon publication of these final results of this administrative review for all shipments of the subject merchandise from Germany entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided in section 751(a)(1) of the Tariff Act: (1) The cash deposit rate for any shipments of this merchandise manufactured or exported by manufacturers/exporters not covered by this review, but specifically covered in the final determination of sales at LTFV, will continue to be the rate published in that

final determination; (2) the cash deposit rate for William Prym, Schwermetall Halbzeugwerke, and the Wieland Group (Wieland-Werke AG, Langenberg Kupfer-und Messingwerke GmbH KG and Metallwerke Schwarzwald GmbH) will be 19.59 percent; and (3) the cash deposit rate for all other exporters/producers shall be 19.59 percent for shipment of the subject merchandise. These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

We have determined that the cash deposit rate applies to all entries from the former German Democratic Republic entered or withdrawn from warehouse for consumption on or after October 3, 1990.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. section 1675(a)(1)) and 19 CFR 353.22.

Dated: November 14, 1991.

Marjorie A. Chorlins,

Acting Assistant Secretary for Import Administration.

[FR Doc. 91-28526 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DS-M

[A-614-801]

Preliminary Determination of Sales at Less Than Fair Value: Fresh Kiwifruit From New Zealand

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: November 27, 1991.

FOR FURTHER INFORMATION CONTACT: Erik Warga, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 377-8922.

PRELIMINARY DETERMINATION: We preliminarily determine that fresh kiwifruit from New Zealand is being, or is likely to be, sold in the United States at less than fair value, as provided in section 773 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice..

Case History

Since the publication of our notice of initiation on June 14, 1991, (56 FR 20023), the following events have occurred.

On June 19, 1991, the U.S. International Trade Commission (ITC) issued an affirmative preliminary injury determination in this case (56 FR 28171).

On August 21, 1991, the Department of Commerce (the Department) determined that this investigation was extraordinarily complicated, and postponed the preliminary determination from October 1, 1991, until November 21, 1991, in accordance with section 733(c)(1) of the Act (56 FR 41507).

On July 1, 1991, the Department presented sections A, B, and C of its questionnaire to the New Zealand Kiwifruit Marketing Board (NZKMB). As the entity through which, by law, all New Zealand kiwifruit for export must pass, with the exception of kiwifruit destined for export to Australia, the NZKMB is the only respondent in this investigation.

We received the NZKMB's response to section A of the questionnaire on July 29, 1991; on August 19, 1991, we received responses to sections B & C. Based on these responses, we issued a deficiency questionnaire on October 2, 1991, to which the NZKMB responded on October 16, 1991.

In its petition filed March 25, 1991, petitioners alleged that the NZKMB was selling kiwifruit in the home market and third country markets at prices below the cost of production. After an analysis of petitioners' allegations, the Department initiated a cost of production (Cop) investigation (56 FR 20023). Accordingly, a COP (section D) questionnaire was issued to the NZKMB, including growers, on July 22, 1991. Responses were received form 19 of 20 growers on September 12, 1991. On October 11, 1991, a deficiency questionnaire was issued with respect to the section D responses. Responses were received on October 30, 1991, but seven of the 19 were not accompanied by company certifications, as required by 19 CFR 353.31(i)(l). The uncertified responses were returned to the respondent. We used the September 12, 1991, responses and the 12 certified October 30, 1991, responses which were received in a timely manner for purposes of this preliminary determination. We subsequently received complete deficiency responses from six of the remaining seven growers, through not in time for use in this preliminary determination. Those certified responses will be considered for our final determination.

In their petition filed March 25, 1991, petitioners alleged the existence of critical circumstances. The Department requested shipment information from respondents in its questionnaire issued July 1, 1991. See the "Critical Circumstances" section of this notice below.

Scope of the Investigation

The product covered by this investigation is fresh kiwifruit from New Zealand. Processed kiwifruit, including fruit jams, jellies, pastes, purees, mineral waters, or juices made from or containing kiwifruit, are not within the scope of this investigation.

Fresh kiwifruit is currently classifiable under subheading 0810.90.20.60 of the Harmonized Tariff Schedule (HTS). Although the HTS subheading is provided for convenience and customs purposes, or written description of the scope of this proceeding is dispositive.

Period of Investigation

The period of investigation (POI) is April 1, 1990, through March 31, 1991. The "standard" six-month POI defined under 19 CFR 353.42(b) did not fall entirely within the normal selling season, failed to capture the bulk of kiwifruit sales in the United States, and would have been represented disproportionately by sales of kiwifruit nearing the end of its useful commercial life. In order to gain a more accurate picture of NZKMB pricing practices in the normal course of trade, and to more adequately address possible seasonal price patterns and questions of product perishability, the POI was extended to a one-year period encompassing a complete crop year an entire selling season.

Such or Similar Comparisons

We have determined that fresh kiwifruit constitutes one such or similar category of merchandise. The period of investigation was segmented according to the pricing periods utilized by respondent in the third country market (see "Market Viability" section of this notice below). Product comparisons within each pricing period were made according to count size (the number of kiwifruit contained on a single tray of a standard weight), and, when possible, pack form. In instances where we were able to make comparisons by count size but not by pack form, kiwifruit of identical count sizes were compared without regard to pack form. Because cost differences between trays of different count sizes are not quantifiable, and because other methods of calculating differences in merchandise were deemed inappropriate, we made no adjustments for differences in the physical characteristics of the merchandise; therefore, when there were no sales of merchandise of identical count size in the third country during a given pricing

period, the U.S. sale was not considered in our analysis.

Fair Value Comparisons

To determine whether sales of fresh kiwifruit from New Zealand to the United States were made at less than fair value, we compared the United States price to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

We based United States price on exporter's sales price (ESP), in accordance with section 772(c) of the Act, because virtually all sales to unrelated parties occurred after importation into the United States. We omitted from our analysis the purchase price sales (those made to unrelated parties prior to importation into the United States) because these sales constituted an extremely small percentage of total sales volume. Their inclusion would have had no meaningful impact on the calculation of estimated dumping margins.

We calculated ESP based on packed F.O.B. (ex-New Zealand coolstore), and packed F.O.B., freight prepaid prices. We made deductions, where appropriate, for New Zealand inland freight (coolstore to port), loading charges in New Zealand, ocean freight, basic marine insurance, charter insurance, U.S. import duties, U.S. brokerage and handling, U.S. inland freight (decreased to account for prepaid freight where applicable), and price discounts (*i.e.*,) advertising allowances, special advertising allowances, market adjustment discounts, advertising rebates which actually constituted discounts, and discounts for quality problems). In accordance with section 772(e)(1) and (2) of the Act, we made additional deductions, where appropriate, for agent commissions, broker commissions, credit, direct advertising, and indirect selling expenses. Indirect selling expenses included inventory carrying costs, repacking, U.S. primary and U.S. satellite coolstore charges, New Zealand and U.S. instore insurance, fire insurance, product liability and tamper insurance, earthquake insurance, indirect advertising, quality control expenses, miscellaneous selling-agent-related charges, U.S. incurred indirect expenses, and New Zealand incurred indirect selling expenses associated with selling in the United States. We increased the U.S. price to account for post sale price adjustments not reflected in the gross price.

Foreign Market Value

Market Viability

In order to determine whether there were sufficient sales of fresh kiwifruit in the home market to serve as a viable basis for calculating FMV, we compared the volume of home market sales of fresh kiwifruit to the volume of third country sales of fresh kiwifruit in accordance with section 773(a)(1) of the Act. We found that the home market was not viable for sales of fresh kiwifruit.

In selecting which third country market to use for comparison purposes, we first determined which third country markets had "adequate"sales volumes, within the meaning of 19 CFR 353.49(b)(1). We determined that the volume of sales to a third country market was adequate if the sales of such or similar merchandise exceeded, or was equal to, five percent of the volume sold to the United States.

In selecting which third country market of those having an adequate sales volume was the most appropriate for comparison purposes, we selected Japan, in accordance with CFR 353.49(b). In determining the most appropriate third country market for calculating foreign market value, we evaluated fruit age, count size, distribution systems, and market organization.

With respect to the criteria listed above, we did not find significant differences between the United States and Japan. Therefore, we have determined that Japan, the largest single third-country market is the appropriate third country market to be used for calculating foreign market value. Memorandum to Francis J. Sailer dated August 9, 1991.

Cost of Production

Petitioners alleged that respondent's home market and third country sales of fresh kikifruit were made at prices below COP. Since there are approximately 4,000 kiwifruit growers in New Zealand, the Department determined that sampling was necessary and appropriate to arrive at a representative cost for purposes of our analysis. Based on comments received from petitioner and respondent, we determined that the most significant factors influencing the cost of producing kiwifruit are farm location and farm size. We therefore stratified our sample into eight classifications using two regions and four size ranges. We chose farms from within the Bay-of-Plenty region, and elsewhere in New Zealand, and within the size ranges of less than two hectares, two to five hectares, five to 10 hectares, and greater than 10 hectares. All parties to the proceeding believe that the Bay-of-Plenty region has superior growing conditions compared to other regions of the country. COP questionnaires were issued through the NZKMB to 20 kiwifruit growers. Nineteen kiwifruit growers responded to the Department's questionnaire. We analyzed the 19 questionnaire responses received, and those deficiency responses which were certified within the deadline for submission, and have used this information in reaching our preliminary determination.

For purposes of calculating the COP of kiwifruit we relied upon the 19 grower submissions where such information was appropriately quantified or valued.

For the one grower that did not respond to our questionnaire, we used petitioner's cost information as best information available (BIA).

For grower number three, we calculated per unit costs based on the actual production quantity, rather than expected quantity.

For grower number nine, we allowed the offset of interest income against interest expense only to the extent of interest expense.

Grower number 17 stated that the cost of a full-time manager was reported in direct labor costs, however, no amount for labor was included in the COP. Therefore, we included the average cost for a full-time manager as submitted by the NZKMB.

Because grower number 18 reported no direct labor for its kiwifruit operations, we included the average direct labor cost per tray of all growers as BIA.

Since complete information regarding kiwifruit start-up costs was not provided by the growers, we used petitioner's information as BIA to value the start-up costs. We adjusted the farms' reported number of trays sold by the percentage fruit loss of 13 percent, which was disclosed by the NZKMB in its financial statement. Each farm's total costs were then allocated over the adjusted quantity sold to determine the cost per tray.

Individual grower costs were simple-average within each classification. These costs included the cost of materials, farm labor, farm overhead, and packing. A weighting factor was calculated for each classification based upon New Zealand production statistics regarding farm output by size and location. The simple-average grower costs by classification was multiplied by this weighting factor to arrive at the overall weighted-average farm cost per tray. We added the NZKMB's cool storage and selling, general and

administrative expenses to the weighted average farm cost per tray. We did not include the NZKMB's other expenses in the calculation of selling, general and administrative expenses (SG&A) as it was primarily comprised of foreign exchange losses. The total cost of production was calculated on a New Zealand dollar per single-layer tray equivalent basis (NZ$/SLT).

We compared third country weighted-average prices within each selling period (see FMV section below) to the calculated COP. We did not make adjustments to the cost of production based on the fruit size because we have preliminarily determined that there are no quantifiable cost differences associated with production of different fruit sizes.

Since over 90 percent of the NZKMB's sales were at prices above the total COP of fresh kiwifruit, we did not disregard any below-cost sales since the respondent's below-cost sales were not made in substantial quantities.

Foreign Market Value

We calculated FMV based on C&F prices to unrelated customers in Japan. We made deductions, where appropriate, for rebates, New Zealand inland freight, New Zealand inland freight insurance, New Zealand port loading expenses, ocean freight and charter insurance. Direct advertising, imputed credit, and letter of credit charges were also deducted. Where appropriate, we deducted third country packing costs and added U.S. packing costs. We rejected the NZKMB's reported packing figures because they represented an estimate of the cost to the packhouses of packing, not the cost to growers. We instead based packing on an average of packing costs reported by growers in their COP responses. We also deducted indirect selling expenses including inventory carrying costs, New Zealand instore and fire insurance, product liability and tamper insurance, indirect advertising, and other indirect selling expenses. This deduction for third country indirect selling expenses was capped by the amount represented by U.S. indirect selling expenses plus U.S. commissions, in accordance with 19 CFR 353.56(b).

Date of Sale

Respondent reported the date of sale as the first date of the pricing period during which each sale was made. However, at the beginning of a pricing period, only price had been determined; quantities assigned to each importer for a given shipment changed even after the date of departure. The invoice is the first written document in which both price and quantity sold to each importer in Japan for a given shipment are indicated. Since it is the Department's practice to assign the date of sale to the date of the earliest written evidence that firmly establishes the material terms of sale (price and quantity) (see Antifriction Bearings (Other Than Tapered Roller Bearings) From the Federal Republic of Germany, France, Italy, Japan, Romania, Singapore, Sweden, Thailand and the United Kingdom, 54 FR 18992, May 3, 1989), we elected to use the invoice date as the date of sale.

Critical Circumstances

Petitioners allege that "critical circumstances" exist with respect to imports of fresh kiwifruit from New Zealand. Section 733(e)(1) of the Act provides that critical circumstances exist when we determine that there is a reasonable basis to believe or suspect the following:

(1) That there is a history of dumping of the same class or kind of merchandise, or that the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the merchandise at less than fair market value, and

(2) That there have been massive imports of the subject merchandise over a relatively short period.

To determine whether imports have been massive over a relatively short period, we based our analysis on respondents' shipment data for equal periods immediately preceding and following the filing of the petition. Based on this analysis, we find that imports of the subject merchandise from New Zealand during the period subsequent to receipt of the petition did increase significantly. However, this increase in imports is a cyclical occurrence due to the seasonal nature of the subject merchandise. Therefore, after considering seasonal trends pursuant to 19 CFR 353.16(f)(ii), we do not find that there have been massive imports of the subject merchandise.

Since we do not find that there have been massive imports, we need not consider whether there is a history of dumping or whether importers of this merchandise knew or should have known that such merchandise was being sold at less than fair value. Therefore, we find that there is no reasonable basis to believe or suspect that critical circumstances exist with respect to imports of fresh kiwifruit from New Zealand.

Currency Conversion

When calculating foreign market value, we made currency conversions in accordance with 19 CFR 353.60 by using the exchange rates certified by the Federal Reserve Bank of New York.

Verification

As provided in section 776(b) of the Act, we will verify the information used in making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of fresh kiwifruit from New Zealand, that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register.** The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins, as shown below. This suspension of liquidation will remain in effect until further notice.

Producer/ manufacturer/ exporter	Weighted-average margin percentage	Critical circumstances
NZKMB	78.38	No
All Others	78.38	No

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine whether these imports are materially injuring, or threaten material injury to, the U.S. industry before the later of 120 days after the date of this preliminary determination or 45 days after our final determination.

Public Comment

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than January 10, 1992, and rebuttal briefs no later than January 15, 1992. In accordance with 19 CFR 353.38(b), we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Tentatively, the hearing will be held on January 20, 1992, at 10 a.m. at the U.S. Department of Commerce, room 3708, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Import

Administration, U.S. Department of Commerce, room B-099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

This determination is published pursuant to section 733(f) of the Act and 19 CFR 353.15.

Dated: November 21, 1991.

Eric I. Garfinkel,

Assistant Secretary for Import Administration.

[FR Doc. 91-28527 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DS-M

Export Trade Certificate of Review

ACTION: Notice of application for an amendment to an Export Trade Certificate of Review.

SUMMARY: The Office of Export Trading Company Affairs (OETCA), International Trade Administration, Department of Commerce, has received an application for an amendment to an Export Trade Certificate of Review. This notice summarizes the amendment and requests comments relevant to whether the Certificate should be amended.

FOR FURTHER INFORMATION CONTACT: George Muller, Director, Office of Export Trading Company Affairs, International Trade Administration, 202/377-5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001-21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. A Certificate of Review protects the holder and the members identified in the Certificate from State and federal government antitrust actions and from private, treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Act and 15 CFR 325.7, 325.6(a) require the Secretary to publish a notice in the **Federal Reigster** identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination of whether the Certificate should be amended. An original and five (5) copies should be submitted no later than 20 days after the date of this notice to: Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, room 1800H, Washington, DC 20230. Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). Comments should refer to this application as "Export Trade Certificate of Review, application number 83-2A028."

OETCA has received the following application for an amendment to Export Trade Certificate of Review No. 83-00028, which was issued on April 13, 1984 (49 FR 15596, April 19, 1984).

Summary of the Application

Applicant: Carpenter Body Works, Inc., 1500 West Main Street, Mitchell, Indiana 47446.

Contact: Thomas R. Haley III, Attorney, Telephone: (317) 636-8000.

Application No.: 83-2A028.

Date Deemed Submitted: November 21, 1991.

Request For Amended Conduct: Carpenter Body Works, Inc. seeks to change the name of its current Export Trade Certificate of Review from "Carpenter Body Works, Inc." to "Carpenter Manufacturing, Inc." The Export Trade, Export Trade Facilitation Services, Export Markets, Export Trade Activities, and Methods of Operation covered by the certificate of review are unchanged.

Dated: November 21, 1991.

George Muller,

Director, Office of Export Trading Company Affairs.

[FR Doc. 91-28528 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DR-M

Export Trade Certificate of Review

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of initiation of process to revoke Export Trade Certificate of Review No. 84-00013.

SUMMARY: The Department of Commerce had issued an export trade certificate of review to Equinomics, Inc. Because this certificate holder has failed to file an annual report as required by law, the Department is initiating proceedings to revoke the certificate. This notice summarizes the notification letter sent to Equinomics, Inc.

FOR FURTHER INFORMATION CONTACT: George Muller, Director, Office of Export Trading Company Affairs, International Trade Administration 202/377-5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 ("the Act") (15 U.S.C. 4011-21) authorized the Secretary of Commerce to issue export trade certificates of review. The regulations implementing title III ("the Regulations") are found at 15 CFR part 325. Pursuant to this authority, a certificate of review was issued on June 25, 1984 to Equinomics, Inc.

A certificate holder is required by law (section 308 of the Act, 15 U.S.C. 4018) to submit to the Department of Commerce annual reports that update financial and other information relating to business activities covered by its certificate. The annual report is due within 45 days after the anniversary date of the issuance of the certificate of review (§ 325.14 (a) and (b) of the Regulations). Failure to submit a complete annual report may be the basis for revocation (§§ 325.10(a) and 325.14(c) of the Regulations).

The Department of Commerce sent to Equinomics, Inc. on July 17, 1991, a letter containing annual report questions with a reminder that its annual report was due on August 9, 1991. Additional reminders were sent on August 22, 1991 and on October 10, 1991. The Department has received no written response to any of these letters.

On November 19, 1991, and in accordance with § 325.10(c)[2] of the Regulations, a letter was sent by certified mail to notify Equinomics, Inc. that the Department was formally initiating the process to revoke its certificate. The letter stated that this action is being taken for the certificate holder's failure to file an annual report.

In accordance with § 325.10(c)(2) of the Regulations, each certificate holder has thirty days from the day after its receipt of the notification letter in which to respond. The certificate holder is deemed to have received this letter as of the date on which this notice is published in the **Federal Register**. For good cause shown, the Department of Commerce can, at its discretion, grant a thirty-day extension for a response.

If the certificate holder decides to respond, it must specifically address the Department's statement in the notification letter that it has failed to file an annual report. It should state in detail why the facts, conduct, or circumstances described in the notification letter are not true, or if they are, why they do not warrant revoking the certificate. If the certificate holder does not respond within the specified period, it will be considered an admission of the statements contained in the notification letter (§ 325.10(c)[2] of the Regulations)

If the answer demonstrates that the material facts are in dispute, the Department of Commerce and the

Department of Justice shall, upon request, meet informally with the certificate holder. Either Department may require the certificate holder to provide the documents or information that are necessary to support its contentions (§ 325.10(c)[3] of the Regulations).

The Department shall publish a notice in the **Federal Register** of a revocation or modification or a decision not to revoke or modify (§ 325.10(c)[4] of the Regulations). If there is a determination to revoke a certificate, any person aggrieved by such final decision may appeal to an appropriate U.S. district court within 30 days from the date on which the Department's final determination is published in the **Federal Register.**

Authority: sections 325.10(c)(4) and 325.11 of the Regulations.

Dated: November 20, 1991.

George Muller,

Director, Office of Export Trading Company Affairs.

[FR Doc. 91-28529 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DR-M

Minority Business Development Agency

Business Development Center Applications: Mayaguez Puerto Rico (Service Area)

AGENCY: Minority Business Development Agency, Commerce.

ACTION: Notice.

SUMMARY: In accordance with Executive Order 11625, the Minority Business Development Agency (MBDA) is soliciting competitive applications under its Minority Business Development Center (MBDC) program to operate an MBDC for approximately a 3-year period, subject to Agency priorities, recipient performance and the availability of funds. The cost of performance for the first Budget period (12 months) is estimated as $184,260 in Federal funds, and a minimum of $32,516 in non-Federal (cost sharing) contribution, from May 1, 1992 to April 30, 1993. Cost-sharing contributions, may be in the form of cash contributions, client fees, in-kind contributions or combinations thereof. The MBDC will operate in the Mayaguez, Puerto Rico SMSA geographic service area.

The funding instrument for the MBDC will be a cooperative agreement. Competition is open to individuals, non-profit and for-profit organizations, State and local governments, American Indian tribes and educational institutions.

The MBDC program is designed to provide business development services to the minority business community for the establishment and operation of viable minority businesses. To this end, MBDA funds organizations that can identify and coordinate public and private sector resources on behalf of minority individuals and firms; offer a full range of management and technical assistance; and serve as a conduit of information and assistance regarding minority business.

Applications will be evaluated initially by regional staff on the following criteria: The experience and capabilities of the firm and its staff in addressing the needs of the business community in general and, specifically, the special needs of minority businesses, individuals and organizations (50 points); the resources available to the firm in providing business development services (10 points); the firm's approach (techniques and methodologies) to performing the work requirements included in the application (20 points); and the firm's estimated cost for providing such assistance (20 points). An application must receive at least 70% of the points assigned to any one evaluation criteria category to be considered programmatically acceptable and responsive. The selection of an application for further processing by MBDA will be made by the Director based on a determination of the application most likely to further the purpose of the MBDC Program. The application will then be forwarded to the Department for final processing and approval, if appropriate. The Director will consider past performance of the applicant on previous Federal awards.

MBDCs shall be required to contribute at least 15% of the total project cost through non-Federal contributions. To assist them in this effort, MBDCs may charge client fees for management and technical assistance (M&TA) rendered. Based on a standard rate of $50 per hour, MBDCs will charge client fees at 20% of the total cost for firms with gross sales of $500,000 or less, and 35% of the total cost for firms with gross sales of over $500,000.

MBDCs performing satisfactorily may continue to operate after the initial competitive year for up to 2 additional budget periods. MBDCs with year-to-date "commendable" and "excellent" performance ratings may continue to be funded for up to 3 or 4 additional budget periods, respectively. Under no circumstances shall an MBDC be funded for more than 5 consecutive budget periods without competition. Periodic reviews culminating in year-to-date quantitative and qualitative evaluations will be conducted to determine if funding for the project should continue. Continued funding will be at the discretion of MBDA based on such factors as an MBDC's performance, the availability of funds and the Agency priorities.

Awards under this program shall be subject to all Federal and Departmental regulations, policies, and procedures applicable to Federal assistance awards.

In accordance with QMB Circular A-129, "Managing Federal Credit Programs," applicants who have an outstanding account receivable with the Federal Government may not be considered for funding until these debts have been paid or arrangements satisfactory to the Department of Commerce are made to pay the debt.

Applicants are subject to Governmentwide Debarment and Suspension (Nonprocurement) requirements as stated in 15 CFR part 26.

The departmental Grants Officer may terminate any grant/cooperative agreement in whole or in part at any time before the date of completion whenever it is determined that the MBDC has failed to comply with the conditions of the grant/cooperative agreement. Examples of some of the conditions which can cause termination are failure to meet cost-sharing requirements; unsatisfactory performance of MBDC work requirements; and reporting inaccurate or inflated claims of client assistance or client certification. Such inaccurate or inflated claims may be deemed illegal and punishable by law.

On November 18, 1988, Congress enacted the Drug-Free Workplace Act of 1988 (Pub. L. 100-690 title V subtitle D). The statute requires contractors and grantees of Federal agencies to certify that they will provide a drug-free workplace. Pursuant to these requirements, the applicable certification form must be completed by each applicant as a precondition for receiving Federal grant or cooperative agreement awards.

"Certification for Contracts Grants Loans, and Cooperative Agreements" and SF-LLL, the "Disclosure of Lobbying Activities" (if applicable) is required in accordance with Section 319 of Public Law 101-121, which generally prohibits

recipients of Federal contracts, grants, and loans from using legislative Branches of the Federal Government in connection with a specific contract, grant or loan.

CLOSING DATE: The closing date for application is December 30, 1991. Applications must be postmarked on or before December 30, 1991.

Proposals will be reviewed by the Washington Regional Office, mailing address for submission is:

ADDRESSES: Gina A. Sanchez, Regional Director, Washington Regional Office, Minority Business Development Agency, 14th & Constitution Ave. NW., room 6711, Washington DC 20230.

FOR FURTHER INFORMATION CONTACT: John F. Iglehart, Regional Director, New York Regional Office at (212) 264-3263.

SUPPLEMENTARY INFORMATION: Anticipated processing time of this award is 120 days. Executive Order 12372 "Intergovernmental Review of Federal Programs" is not applicable to this program. Questions concerning the preceding information, copies of application kits and applicable regulations can be obtained at the above New York address.

11.800 Minority Business Development

(Catalog of Federal Domestic Assistance)

Dated: November 19, 1991.

John F. Iglehart,

Regional Director, New York Regional Office.

[FR Doc. 91-28442 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-21-M

National Oceanic and Atmospheric Administration

Marine Mammals

AGENCY: National Marine Fisheries Service.

ACTION: Application for scientific research permit (P70E).

Notice is hereby given that William A. Watkins, Ph.D., Woods Hole Oceanographic Institution, Woods Hole, MA 02543, has applied in due form for a permit to take marine mammals as authorized by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973 (16 U.S.C. 1531-1544), and the regulations governing endangered fish and wildlife permits (50 CFR parts 217-222).

Species and Type of Take

The applicant requests a permit to harass up to 25 sperm whales (*Physeter catodon*) annually, over a five year period, in the course of tagging up to five animals each year with radio/satellite tags. Animals may be double tagged and, in some instances, individual whales may be repeatedly approached during maneuvering for tagging position or for re-tagging purposes. The objectives of the research are to: Provide unequivocal individual identification of whales in order to follow their distribution and movements, group association and movements, social activity, and acoustic activity; document individual dive profiles; and continue the development and testing of tagging systems.

Concurrent with the publication of this notice in the **Federal Register**, the Secretary of Commerce is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors.

Written data or views, or requests for a public hearing on this application should be submitted to the Assistant Administrator for Fisheries, National Marine Fisheries Service, U.S. Department of Commerce, 1335 East-West Hwy., room 7324, Silver Spring, Maryland 20910, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries.

All statements and opinions contained in this application are summaries of those of the Applicant and do not necessarily reflect the views of the National Marine Fisheries Service.

Documents submitted in connection with the above application are available for review by interested persons in the following offices:

By appointment: Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Hwy., suite 7324, Silver Spring, Maryland 20910 (301/427-2289);

Director, Southeast Region, National Marine Fisheries Service, 9450 Koger Blvd., St. Petersburg, Florida 33702 (813/893-3141);

Director, Northeast Region, National Marine Fisheries Service, One Blackburn Drive, Gloucester, Massachusetts, 01930 (508/281-9200).

Dated: November 21, 1991.

Nancy Foster,

Director, Office of Protected Resources.

[FR Doc. 91-28416 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-22-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcement of Import Restraint Limits and Guaranteed Access Levels for Certain Cotton, Wool, Man-Made Fiber and Other Vegetable Fiber Textiles and Textile Products from Jamaica

November 21, 1991.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing limits and guaranteed access levels for the new agreement year.

EFFECTIVE DATE: January 1, 1992.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 566-5810. For information on embargoes and quota re-openings, call (202) 377-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Bilateral Cotton, Wool, Man-Made Fiber and Other Vegetable Fiber Textile Agreement of August 27, 1986, as amended, between the Governments of the United States and Jamaica establishes limits and guaranteed access levels for the period beginning on January 1, 1992 and extending through December 31, 1992.

A copy of the agreement is available from the Textiles Division, Bureau of Economic and Business Affairs, U.S. Department of State, (202) 647-3889.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 55 FR 50756, published on December 10, 1990). Information regarding the 1992 CORRELATION will be published in the **Federal Register** at a later date.

Requirements for participation in the Special Access Program are available in **Federal Register** notices 51 FR 21208, published on June 11, 1986; 52 FR 6049, published on February 27, 1987; 52 FR 26057, published on July 10, 1987; and 54

FR 50425, published on December 6, 1989.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

November 21, 1991.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as further extended on July 31, 1991; pursuant to the Bilateral Cotton, Wool, Man-Made Fiber and Other Vegetable Fiber Textile Agreement of August 27, 1986, as amended, between the Governments of the United States and Jamaica; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on January 1, 1992, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton, wool, man-made fiber and other vegetable fiber textiles and textile products in the following categories, produced or manufactured in Jamaica and exported during the twelve-month period beginning on January 1, 1992 and extending through December 31, 1992, in excess of the following levels of restraint:

Category	Twelve-month restraint limit
331/631	350,000 dozen pairs.
336/636	118,000 dozen.
338/339/638/639	877,421 dozen.
340/640	410,305 dozen of which not more than 347,181 dozen shall be in shirts made from fabrics with two or more colors in the warp and/or the filling in Categories 340-Y/640-Y [1].
341/641	515,217 dozen.
342/642	175,000 dozen.
345/845	127,131 dozen.
347/348/647/648	947,066 dozen.
352/652	600,000 dozen.
445/446	49,397 dozen.
447	10,000 dozen.
632	100,000 dozen pairs.

[1] Category 340-Y: only HTS numbers 6205.20.2015, 6205.20.2020, 6205.20.2046, 6205.20.2050 and 6205.20.2060; Category 640-Y: only HTS numbers 6205.30.2010, 6205.30.2020, 6205.30.2050 and 6205.30.2060.

Imports charged to these category limits for the period January 1, 1991 through December 31, 1991 shall be charged against those levels of restraint to the extent of any unfilled balances. In the event the limits established for that period have been exhausted by previous entries, such goods shall be subject to the levels set forth in this directive.

The limits set forth above are subject to adjustment in the future according to the provisions of the current bilateral agreement between the Governments of the United States and Jamaica.

In accordance with the provisions of the Special Access Program, as set forth in 51 FR 21208 (June 11, 1986), 52 FR 26057 (July 10, 1987) and 54 FR 50425 (December 6, 1989), you are directed to establish guaranteed access levels for properly certified cotton, man-made fiber and other vegetable fiber textile products in the following categories which are assembled in Jamaica from fabric formed and cut in the United States and re-exported to the United States from Jamaica during the twelve-month period which begins on January 1, 1992 and extends through December 31, 1992.

Category	Guaranteed Access Level
331/631	1,320,000 dozen pairs.
336/636	125,000 dozen.
338/339/638/639	1,500,000 dozen.
340/640	300,000 dozen.
341/641	375,000 dozen.
342/642	200,000 dozen.
345/845	50,000 dozen.
347/348/647/648	2,000,000 dozen.
352/652	3,250,000 dozen.
447	30,000 dozen.
632	3,300,000 dozen pairs.

Any shipment for entry under the Special Access Program which is not accompanied by a valid and correct certification and Export Declaration in accordance with the provisions of the certification requirements established in the directive of February 19, 1987 shall be denied entry unless the Government of Jamaica authorizes the entry and any charges to the appropriate designated consultation levels or specific limits. Any shipment which is declared for entry under the Special Access Program but found not to qualify shall be denied entry into the United States.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 91-28518 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DR-F

Adjustment of Import Limits for Certain Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in Korea

November 21, 1991.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: November 27, 1991.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 343-6581. For information on embargoes and quota re-openings, call (202) 377-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limits for certain categories are being adjusted, variously, for swing and carryforward.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 55 FR 50756, published on December 10, 1990). Also see 55 FR 50860, published on December 11, 1990.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

November 21, 1991.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 5, 1990, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in

Korea and exported during the twelve-month period which began on January 1, 1991 and extends through December 31, 1991.

Effective on November 27, 1991, you are directed to amend the December 5, 1990 directive to adjust the limits for the following categories, as provided under the terms of the current bilateral textile agreement between the Governments of the United States and the Republic of Korea:

Category	Twelve-month limit [1]
Group I	
200, 201, 218-220, 222-229, 300-326, 360-363, 369-O [2], 400, 410, 414, 464-469, 600-607, 611-622, 624-629, 665-669 and 670-O [3], as a group.	389,154,480 square meters equivalent.
Sublevels in Group I	
200	410,367 kilograms.
201	1,488,240 kilograms.
410	3,840,525 square meters.
611	3,444,000 square meters.
613/614	5,586,250 square meters.
619/620	95,227,850 square meters.
625/626/627/628/629.	14,261,576 square meters.
Group II	
237, 239, 330-354, 359, 431-448, 459, 630-654 and 659, as a group.	562,682,380 square meters equivalent.
Sublevels in Group II	
338/339	1,107,000 dozen.
340	628,940 dozen of which not more than 326,566 dozen shall be in Category 340-D [4].
342/642	186,337 dozen.
347/348	483,740 dozen.
435	35,165 dozen.
442	50,770 dozen.
444	53,800 numbers.
448	35,717 dozen.
459-W [5]	96,617 kilograms.
632	1,450,964 dozen pairs.
633/634/635	1,373,601 dozen of which not more than 153,459 dozen shall be in Category 633 and not more than 575,262 dozen shall be in Category 635.
636	263,019 dozen.
Sublevel in Group III	
835	30,174 dozen.
Group VI	
369-L/670-L/870 [6], as a group.	54,414,168 square meters.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1990.

[2] Category 369-O: all HTS numbers except 4202.12.4000, 4202.12.8020, 4202.12.8060, 4202.92.1500, 4202.92.3015 and 4202.92.6000 (Category 369-L).

[3] Category 670-O: all HTS numbers except 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3030 and 4202.92.9020 (Category 670).

[4] Category 340-D: only HTS numbers 6205.20.2015, 6205.20.2020, 6205.20.2025 and 6205.20.2030.

[5] Category 459-W: only HTS number 6505.90.4090.

[6] Category 870; 369-L: only HTS numbers 4202.12.4000, 4202.12.8020, 4202.12.8060, 4202.92.1500, 4202.92.3015 and 4202.92.6000; Category 670-L: only HTS numbers 4202.12.8030, 4202.12.8070, 4202.92.3020, 4202.92.3030 and 4202.92.9020.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 91-28519 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DR-F

Adjustment and Amendment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Mexico

November 25, 1991.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting and amending limits.

EFFECTIVE DATE: November 25, 1991.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 535-9481. For information on embargoes and quota re-openings, call (202) 377-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Governments of the United States and the United Mexican States agreed to increase the current Normal Regime limits for certain categories. Also, the current limits for certain categories are being adjusted, variously, for carryforward, carryover, swing, special shift and special shift subtracted.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 55 FR 50756, published on December 10, 1990). Also see 55 FR 51755, published on December 17, 1990; and 56 FR 41830, published on August 23, 1991.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

November 25, 1991.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directives of December 11, 1990 and August 19, 1991, issued to you by the Chairman, Committee for the Implementation of Textile Agreements. Those directives concern imports of certain cotton, wool and man-made fiber textile products, produced or manufactured in the United Mexican States and exported during the period which began on January 1, 1991 and extends through December 31, 1991.

Effective on November 25, 1991, you are directed to adjust and amend the limits for the following categories, as provided under the terms of the current bilateral agreement between the Governments of the United States and the United Mexican States:

Category	Twelve-month restraint limit [1]
Sublevels in Group I	
313	21,500,000 square meters.
317	20,635,000 square meters.
611	2,350,185 square meters.
Levels not in a group	
347/348/647/648 (Special Regime).	4,500,000 dozen.
359-C/659-C [2] (Special Regime).	2,325,000 kilograms.
604-A [3]	2,298,505 kilograms.
604-O/607-O [4]	920,358 kilograms.
669-B [5]	800,629 kilograms.
Normal Regime Category	
347/348/647/648	925,000 dozen.
359-C/659-C (sublimit)	400,000 kilograms.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1990.

[2] Category 359-C: only HTS numbers 6103.42.2010, 6103.42.2025, 6103.49.3034, 6104.62.1010, 6104.62.1020, 6104.69.3010, 6114.20.0042, 6114.20.0048, 6114.20.0052, 6203.42.2005, 6203.42.2010, 6203.42.2090, 6204.62.2005, 6204.62.2010, 6211.32.0007, 6211.32.0010, 6211.32.0025, 6211.42.0007 and 6211.42.0010; Category 659-C: only HTS numbers 6103.23.0055, 6103.43.2015, 6103.43.2020, 6103.49.2000, 6103.49.3038, 6104.63.1010, 6104.63.1020, 6104.69.1000, 6104.69.3014, 6114.30.3044, 6114.30.3054, 6203.43.2005, 6203.43.2010, 6203.43.2090, 6203.49.1005, 6203.49.1010, 6203.49.1090, 6204.63.1505, 6204.63.1510, 6204.69.1005, 6204.69.1010, 6210.10.4015, 6211.33.0007, 6211.33.0010, 6211.33.0017, 6211.43.0007 and 6211.43.0010.

[3] Category 604-A: only HTS number 5509.32.0000.

[4] Category 604-O: all HTS numbers except 5509.32.0000 (Category 604-A); Category 607-O: all HTS numbers except 5509.53.0030 and 5509.53.0060 (Category 607-Y).

[5] Category 669-B: only HTS numbers 6305.31.0020 and 6305.39.0000.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 91-28590 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DR-F

Denial of Participation in the Special Access and Special Regime Programs

November 21, 1991.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs denying the right to participate in the Special Access and Special Regime Programs.

EFFECTIVE DATE: January 1, 1992.

FOR FURTHER INFORMATION CONTACT: Lori E. Goldberg, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-3400.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Committee for the Implementation of Textile Agreements (CITA) has determined that Apparel Service Works Corporation is in violation of the requirements set forth for participation in the Special Access and Special Regime Programs.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs, effective on January 1, 1992, to deny Apparel Service Works Corporation the right to participate in the Special Access and Special Regime Programs, for a period of one year, beginning January 1, 1992 and ending December 31, 1992.

Requirements for participation in the Special Access Program are available in **Federal Register** notices 51 FR 21208, published on June 11, 1986; 52 FR 26057, published on July 10, 1987; and 54 FR 50425, published on December 6, 1989.

Requirements for participation in the Special Regime Program are available in **Federal Register** notices 53 FR 15724, published on May 3, 1988; 53 FR 32421, published on August 25, 1988; 53 FR 49346, published on December 7, 1988; and FR 50425, published on December 6, 1989.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

November 21, 1991.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: The purpose of this directive is to notify you that the Committee for the Implementation of Textile Agreements has determined that Apparel Service Works Corporation is in violation of the requirements for participation in the Special Access and Special Regime Programs.

Effective on January 1, 1992, you are directed to prohibit Apparel Service Works Corporation from further participation in the Special Access and Special Regime Programs, for a period of one year, beginning January 1, 1992 and ending December 31, 1992. Goods accompanied by Form ITA-370P which are presented to U.S. Customs for entry under the Special Access and Special Regime Programs will no longer be accepted.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 91-28521 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DR-F

Denial of Participation in the Special Access and Special Regime Programs

November 21, 1991.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs denying the right to participate in the Special Access and Special Regime Programs.

EFFECTIVE DATE: January 1, 1992.

FOR FURTHER INFORMATION CONTACT: Lori E. Goldberg, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-3400.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Committee for the Implementation of Textile Agreements (CITA) has determined that I.F. Industries, Komodidad Distributors and Southwestern Sewing Sales and Service Company are in violation of the requirements set forth for participation in the Special Access and Special Regime Programs.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs, effective on January 1, 1992, to deny the aforementioned companies the right to participate in the Special Access and Special Regime Programs, for a period of three years, beginning January 1, 1992 and ending December 31, 1994.

Requirements for participation in the Special Access Program are available in **Federal Register** notices 51 FR 21208, published on June 11, 1986; 52 FR 26057, published on July 10, 1987; and 54 FR 50425, published on December 6, 1989.

Requirements for participation in the Special Regime Program are available in **Federal Register** notices 53 FR 15724, published on May 3, 1988; 53 FR 32421, published on August 25, 1988; 53 FR 49346, published on December 7, 1988; and FR 50425, published on December 6, 1989.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

November 21, 1991.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: The purpose of this directive is to notify you that the Committee for the Implementation of Textile Agreements has determined that I.F. Industries, Komodidad Distributors and Southwestern Sewing Sales and Service Company are in violation of the requirements for participation in the Special Access and Special Regime Programs.

Effective on January 1, 1992, you are directed to prohibit the aforementioned companies from further participation in the Special Access and Special Regime Programs, for a period of three years, beginning January 1, 1992 and ending December 31, 1994. Goods accompanied by Form ITA-370P which are presented to U.S. Customs for entry under the Special Access and Special Regime Programs will no longer be accepted.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 91-28520 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DR-F

Denial of Participation in the Special Access and Special Regime Programs

November 21, 1991.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs denying the right to participate in the Special Access and Special Regime Programs.

EFFECTIVE DATE: December 1, 1991.

FOR FURTHER INFORMATION CONTACT: Lori E. Goldberg, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-3400.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Committee for the Implementation of Textile Agreements (CITA) has determined that Block Industries is in violation of the requirements set forth for participation in the Special Access and Special Regime Programs.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs, effective on December 1, 1991, to deny Block Industries the right to participate in the Special Access and Special Regime Programs, for a period of nine months, beginning December 1, 1991 and ending August 31, 1992.

Requirements for participation in the Special Access Program are available in **Federal Register** notices 51 FR 21208, published on June 11, 1986; 52 FR 26057, published on July 10, 1987; and 54 FR 50425, published on December 6, 1989.

Requirements for participation in the Special Regime Program are available in **Federal Register** notices 53 FR 15724, published on May 3, 1988; 53 FR 32421, published on August 25, 1988; 53 FR 49346, published on December 7, 1988; and FR 50425, published on December 6, 1989.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

November 21, 1991.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: The purpose of this directive is to notify you that the Committee for the Implementation of Textile Agreements has determined that Block Industries is in violation of the requirements for participation in the Special Access and Special Regime Programs.

Effective on December 1, 1991, you are directed to prohibit Block Industries from further participation in the Special Access and Special Regime Programs, for a period of nine months, beginning December 1, 1991 and ending August 31, 1992. Goods accompanied by Form ITA-370P which are presented to U.S. Customs for entry under the Special Access and Special Regime Programs will no longer be accepted.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 91-28522 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DR-F

The Correlation: Textile and Apparel Categories With the Harmonized Tariff Schedule of the United States for 1992

November 21, 1991.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Notice.

FOR FURTHER INFORMATION CONTACT: Lori E. Goldberg, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-3400.

SUPPLEMENTARY INFORMATION:

The Committee for the Implementation of Textile Agreements (CITA) announces that the 1992 Correlation, based on the Harmonized Tariff Schedule of the United States, will be available on or after November 25, 1991.

Copies of the Correlation may be purchased from the U.S. Department of Commerce, Office of Textiles and Apparel, 14th and Constitution Avenue, NW., room H3100, Washington, DC 20230, ATTN: Correlation, at a cost of $30 per copy. Checks or money orders should be made payable to the U.S. Department of Commerce.

Auggie D. Tantillo,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 91-28523 Filed 11-26-91; 8:45 am]

BILLING CODE 3510-DR-F

DEPARTMENT OF DEFENSE

Department of the Army

Availability (NOA) of the Final Environmental Impact Statement (FEIS) for the Aerial Cable Test Capability (ACTC) Project To Be Located at White Sands Missile Range, NM

AGENCY: Department of the Army, DoD.

ACTION: Notice of availability.

SUMMARY: This announces the notice of availability of the final environmental impact statement (FEIS) on the potential impact of the development, integration, and operation of the proposed Aerial Cable Test Capability facility at White Sands Missile Range, New Mexico. The proposed ACTC facility will be used to test ground-to-air missiles against targets suspended from an aerial cable, and the aerial tramway will also be used for testing of other DoD materiel as an alternative to some of the testing requiring airborne target drones and manned aircraft. The FEIS examines the potential impacts of the development, integration, and operation of this ACTC facility at alternative sites within White Sands Missile Range and the "no-action" alternative. The "no-action" alternative is considered to be a continuation of present missile testing using airborne drone targets and manned aircraft delivery of DoD test materiel.

SUPPLEMENTARY INFORMATION: The Department of the Army published a Notice of Availability on August 21, 1991 (FR, No. 162, pp. 41530-41531) which provided notice that, pursuant to the National Environmental Policy Act and implementing regulations, it had prepared a Draft EIS for the Aerial Cable Test Capability project. Public hearings were held on 10 September 1991 at Socorro, New Mexico and on 11 September 1991 at Carrizozo, New Mexico to receive comments on this DEIS.

ADDITIONAL INFORMATION: The Environmental Protection Agency also will publish a Notice of Availability for the FEIS in the **Federal Register**. This FEIS will have a 30-day comment period from the date that the Environmental Protection Agency files a notice of availability in the **Federal Register**. Copies of this FEIS may be obtained by writing to the Commander, U.S. Army White Sands Missile Range, ATTN: STEWS-ID-DC (Mr. Henry B.

Stephenson, Jr.), White Sands Missile Range, New Mexico, 88002.

Lewis D. Walker,

Deputy Assistant Secretary of the Army, (Environment, Safety and Occupational Health), OASA (I, L&E).

[FR Doc. 91-28475 Filed 11-26-91; 8:45 am]

BILLING CODE 3710-08-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. JD91-07917T Oklahoma-9]

State of Oklahoma; Amended NGPA Notice of Determination by Jurisdictional Agency Designating Tight Formation

November 19, 1991.

Take notice that on October 31, 1991, the Oklahoma Corporation Commission for the State of Oklahoma (Oklahoma) amended its previously filed notice of determination that the Atoka Formation, located in portion of Latimer and LeFlore Counties, Oklahoma, qualifies as a tight formation under section 107(b) of the Natural Gas Policy Act of 1978 (NGPA). Oklahoma's original notice of determination for the Atoka Formation under FERC No. JD91-07917T was submitted to the Commission on July 15, 1991. Notice of receipt of that determination was issued by the Commission on July 17, 1991.

The amended notice of determination reduces both the stratigraphic interval and the geographical area being designated by Oklahoma. The revised stratigraphic interval consists of that portion of the Atoka Formation which is situated below a depth of 4,000 feet (as measured from the surface), down to but excluding the Basal Atoka Spiro sandstone. The revised geographical area consists of: all of T5N, R21E and T5N, R22E; sections 1-18 in T4N, R21E and T4N, R22E; and sections 4-9, 16-21, and 28-33 in T5N, R23E, all located in Latimer and LeFlore Counties, Oklahoma. The amended notice of determination also contains Oklahoma's findings that the referenced portion of the Atoka Formation meets the requirements of the Commission's regulations set forth in 18 CFR part 271.

The application for determination is available for inspection, except for material which is confidential under 18 CFR 275.206, at the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. Persons objecting to the determination may file a protest, in accordance with 18 CFR 275.203 and 275.204, within 20 days after the date this notice is issued by the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 91-28424 Filed 11-26-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. TQ92-1-20-001 & 002, TM92-3-20-001 and 002, TQ92-2-20-002 and 003, and RP90-22-016]

Algonquin Gas Transmission Co., Proposed Changes in FERC Gas Tariff

November 20, 1991.

Take notice that Algonguin Gas Transmission Company ("Algonquin") on November 15, 1991, tendered for filing proposed changes in its FERC Gas Tariff, Third Revised Volume No. 1, as set forth in the revised tariff sheets listed on Attachment A.

Algonquin states that these revised tariff sheets are being filed to comply with the Commission's Letter Order of October 31, 1991 in Docket Nos. TQ92-1-20-000 and TM92-3-20-000 ("October 31 Order"), which accepted the rate sheets filed in the above docket and directed Algonquin to refile within 15 days to track suppliers' rates in effect as of November 1, 1991.

Algonquin also states that this refiling causes the cumulative PGA in all subsequent filings to be changed in order to reflect the changes caused by the October 31 Order. These tariff sheets are also listed in Attachment A.

Algonquin further states that subsequent to Algonquin's filing of its regularly scheduled Quarterly PGA in Docket No. TQ92-2-20-000, CNG Transmission Corporation ("CNG") filed in Docket No. TQ92-3-22-000, et. al., primary and alternate versions of a tariff sheet that underlies Algonquin's sales schedules. In order to reflect this, Algonquin is filing primary and alternate sheets in Docket Nos. TQ92-2-20-001 and TM92-6-20-001 to track CNG's two versions.

If the Commission approves the primary rates filed in CNG's Docket No. TQ92-1-22-000, Algonquin proposes to place its primary tariff sheets into effect as of December 1, 1991. Otherwise, Algonquin proposes that the Commission place its alternate rate sheets into effect.

Algonquin also states that the Commission directed Algonquin to refile its 6 Rev Sheet No. 29 under Rate Schedule LFS to reflect the correct base rate and cumulative PGA adjustments. Therefore, Algonquin is filing a corrected tariff sheet for Rate Schedule LFS to be effective October 1, 1991 to reflect the revised base rate for the Cost or T & C by Others demand and commodity charges as approved for October 1, 1991 by the Commission in Docket Nos. RP90-22-000 and RP91-146-000, as well as revised tariff sheets for the following months.

Algonquin notes that copies of this filing were served upon each affected party and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before November 27, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-28425 Filed 11-26-91; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-4035-7]

Meeting on December 16, 1991: Industrialized Countries/OECD Working Group of the Trade and Environment Committee of the National Advisory Council for Environmental Policy and Technology (NACEPT)

Under Public Law 92463 (The Federal Advisory Committee Act), EPA gives notice of the meeting of the Industrialized Countries/OECD Working Group of the Trade and Environment Committee is a standing committee of the National Advisory Council for Environmental Policy and Technology (NACEPT), an advisory committee to the Administrator of the EPA. The meeting will convene December 16, 1991 from 10 a.m. to 4 p.m. at the offices of Wilmer Cutler and Pickering, 2445 M Street, NW., 9th Floor Boardroom, Washington, DC 20037-1420.

The Industrialized Countries/OECD Group will explore the linkages between trade and environment, and especially how they relate to the Organization of Economic Cooperation and Development. The working group will suggest practicable policy approaches to these linkages in order to draw out a general policy framework for the United

States. For further information, please call (202) 260-3198.

Dated: November 20, 1991.

Abby J. Pirnie,

NACEPT Designated Federal Official.

[FR Doc. 91-28482 Filed 11-26-91; 8:45 am]

BILLING CODE 6560-50-M

[FRL-4035-8]

Open Meeting on December 17, 1991: Industrial Pollution Prevention Project Focus Group of the Technology Innovation and Economics Committee, National Advisory Council for Environmental Policy and Technology (NACEPT)

Under Public Law 92463 (The Federal Advisory Committee Act), EPA gives notice of a meeting of the Industrial Pollution Prevention Project Focus Group of the Technology Innovation and Economics (TIE) Committee. The TIE Committee is a standing committee of the National Advisory Council for Environmental Policy and Technology (NACEPT), an advisory committee to the Administrator of the EPA. The meeting will convene December 17, 1991, from 8:30 a.m. to 5 p.m. at the Madison Hotel, 1177 15th Street, NW., Washington, DC 20005.

The Industrial Pollution Prevention Project Focus Group is examining methods by which pollution prevention can be encouraged, particularly through effluent guidelines. The TIE Committee believes that among the most important barriers to the implementation of pollution prevention concepts and programs are disincentives inadvertently built into the standard setting process, including the effluent guidelines. The Focus Group is a mechanism involving industry, academia, environmental groups, all levels of government, and other interested parties in the incorporation of pollution prevention into EPA's Office of Water effluent guidelines process and in EPA's effort to spread the pollution prevention ethic.

The Focus Group is an "Ongoing Forum" for the Industrial Pollution Prevention Project (IPPP). The meeting will discuss comments on IPPP draft products, including:

- Incentives Study
- 301(k) Variance Study
- Retrospective Study
- International Study
- Workplan for the consumer education task

Further items for discussion will include how to broaden the scope of the effluent guidelines in order to incorporate broader pollution prevention considerations and at the same time reduce the time and cost of developing an effluent guideline.

The December 17 meeting will be open to the public. Written comments will be received and reviewed by the Focus Group. Additional information may be obtained from David R. Berg or Morris Altschuler at 401 M Street, SW (A-101-F6), Washington, DC 20460, by calling 202-260-9153, or by written request sent by fax at 202-260-6882 or by mail at the above address.

Dated: November 20, 1991.

Abby J. Pirnie,

NACEPT Designated Federal Official.

[FR Doc. 91-28483 Filed 11-26-91; 8:45 am]

BILLING CODE 6560-50-M

[OPP-66153; FRL 3942-3]

Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations.

DATES: Unless a request is withdrawn all cancellations will be effective February 25, 1992.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Hollins, Office of Pesticide Programs (H7502C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location for commercial courier delivery and telephone number: Rm. 210, Crystal Mall # 2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 557-4461.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 6(f)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, provides that a pesticide registrant may, at any time, request that any of its pesticide registrations be cancelled. The Act further provides that EPA must publish a notice of receipt of any such request in the **Federal Register** before acting on the request.

II. Intent to Cancel

This Notice announces receipt by the Agency of requests to cancel some 20 pesticide products registered under section 3 or 24(c) of FIFRA. These registrations are listed in sequence by registration number (or company number and section 24(c) number) in the following Table 1:

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product Name	Chemical Name
958777 CA-87-0013	Roundup	Isopropylamine glyphosate (*N*-(phosphonomethyl)glycine)
000100-00623	Bicep 4.5I Herbicide	2-Chloro-4-(ethylamino)-6-(isopropylamino)-*s*-triazine 2-Chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-(2-methoxy-- 4-methylphenyl)acetamid
000400-00166	Rescue	Sodium *N*-1-naphthylphthalamate Sodium 4-(2,4-dichlorophenoxy)butyrate
000400-00345	NPA-3	Sodium *N*-1-naphthylphthalamate
000400-00418	Dwell 4L Nitrification Inhibitor	5-Ethoxy-3-(trichloromethyl)-1,2,4-thiadiazole
000400-00420	Dwell 4 Nitrification Inhibitor	5-Ethoxy-3-(trichloromethyl)-1,2,4-thiadiazole
000400-00421	Dwell 4E Nitrification Inhibitor	5-Ethoxy-3-(trichloromethyl)-1,2,4-thiadiazole
000524-00378	Convert-A-Clor One Inch Brominating Tablets	Potassium bromide Sodium dichloroisocyanurate dihydrate
000602-00071	Purina Poultry Dusting Power	1-Napthyl-*N*-methylcarbamate

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration No.	Product Name	Chemical Name
		Sulfur
000602-00122	Purina Starlicide	3-Chloro-*p*-toluidine hydrochloride
005481-00053	Alco Alcopon Grass Killer	Sodium dalapon (2,2-dichloropropionic acid)
005481-00115	Durham Durapon Grass Killer	Sodium dalapon (2,2-dichloropropionic acid)
005905-00499	2,4-D Acid	2,4-Dichlorophenoxyacetic acid
043410-00011	Citrus Keep	Triethanolamine 2,4-dichlorophenoxyacetate
050534-00013	Dacamine 4D Weed Killer	2,4-Dichlorophenoxyacetic acid *N*-Oleyl-1,3-propylenediamine 2,4-dichlorophenoxyacetate
050534-00014	Dacamine Herbicide	2,4-Dichlorophenoxyacetic acid *N*-Oleyl-1,3-propylenediamine 2,4-dichlorophenoxyacetate
050534-00102	Dacamine 360D	2,4-Dichlorophenoxyacetic acid *N*-Oleyl-1,3-propylenediamine 2,4-dichlorophenoxyacetate
051036-00095	Diazinon 5 Dust	*O,O*-Diethyl *O*-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate

Unless a request is withdrawn by the registrant within 90 days of publication of this notice, orders will be issued cancelling all of these registrations. Users of these pesticides or anyone else desiring the retention of a registration should contact the applicable registrant directly during this 90-day period. The following Table 2 includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA Company Number.

TABLE 2.—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company Name and Address
000100	Ciba-Geigy Corp., Box 18300, Greensboro, NC 27419.
000400	Uniroyal Chemical Co Inc., 74 Amity Rd, Bethany, CT 06524.
000524	Monsanto Co., 700 14th Street, N.W. Suite 1100, Washington, DC 20005.
000602	Purina Mills, Inc., Box 66812, St Louis, MO 63166.
005481	Amvac Chemical Corp., 4100 E. Washington Blvd., Los Angeles, CA 90023.
005905	Helena Chemical Co, 5100 Popular Ave., Suite 3200, Memphis, TN 38137.
043410	Agri-Chem, Inc., Box 607477, Orlando, FL 32860.
050534	ISK Biotech Corp., 5966 Heisley Rd. Box 8000, Mentor, OH 44061.
051036	Micro-Flo Co., Box 5948, Lakeland, FL 33807.
958777	California Fig Institute, Fresno, California, CA 90063.

III. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked before February 25, 1992. This written withdrawal of the request for cancellation will apply to the applicable section 6(f)(1) request listed in this notice. If the products have been subject to previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

IV. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generallly permit registrants to continue to sell and distribute existing stocks of the cancelled products for one year after the date of this notice. Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

Dated: October 28, 1991.

Susan H. Wayland,
Acting Director, Office of Pesticide Programs.

[FR Doc. 91-28484 Filed 11-26-91; 8:45 am]
BILLING CODE 6560-50-F

[OPP-180855; FRL 4003-7]

Emergency Exemption for the use of Maneb; Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted specific exemptions to the Florida Department of Agriculture and Consumer Services (hereafter referred to as the "Applicant") to use the fungicide maneb (CAS 12427-38-2) to treat 17,325 acres of peppers to control bacterial spot (*Xanthomonas campestris* pv. *vesicatoria*) and to treat 7,950 acres of lettuce (both head and leaf) to control downy mildew (*Bremia lactucae*). These exemptions authorized the use of maneb from October 29, 1991, to June 30, 1992. Both the incoming request and the Action Memorandum granting the request are available for public review at the address below for the Public Docket and Freedom of Information Section.

The specific exemptions are for the use of a chemical which is the subject of a Special Review. Normally, in accordance with 40 CFR 166.24, EPA would solicit public comment before making the decision whether or not to grant the exemption. However, in this instance the Agency inadvertently failed

to do so. Although, EPA has already authorized the use of maneb in Florida, due to the 8 -month duration of the exemption, the Agency is soliciting public comment on whether or not the use of maneb should be allowed to continue in Florida.

DATES: Comments must be received on or before December 12, 1991.

ADDRESSES: Three copies of written comments, bearing the identification notation "OPP-180855," should be submitted by mail to: Public Docket and Freedom of Information Section, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information." Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain Confidential Business Information must be provided by the submitter for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments filed pursuant to this notice will be available for public inspection in rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location and telephone number: Rm. 716, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-4359).

SUPPLEMENTARY INFORMATION: Pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), the Administrator may, at his discretion, exempt a State agency from any registration provision of FIFRA if he determines that emergency conditions exist which require such exemption.

The Applicant requested the Administrator to issue a specific exemption for the use of four registered maneb products on peppers to control bacterial spot and on lettuce to control downy mildew. Information in accordance with 40 CFR part 166 was submitted as part of this request.

On December 20, 1989, the EPA published in the **Federal Register** "Ethylene Bisdithiocarbamate; Notice of Preliminary Determination to Cancel Certain Registrations, Notice of Technical Support Document and Draft Notice of Intent to Cancel". EPA reviewed the registered EBDC fungicides (maneb, mancozeb, metiram, nabam, and zineb) and concluded that the risks from continued use of EBDCs outweighed the benefits. The EBDCs pose carcinogenic risks to consumers from dietary exposure and risks of carcinogenic, developmental and thyroid effects to mixers, loaders, and applicators of these pesticides. Prior to the notice, the four major registrants of the EBDC fungicides voluntarily withdrew 42 of the 55 food use registrations, including peppers and lettuce. As a result of the voluntary withdrawal, after January 1, 1990, growers were only able to purchase EBDC fungicides labeled for 13 crops: almonds, bananas, potatoes, sugar beets, sweet corn, asparagus, cranberries, figs, grapes, onions, peanuts, tomatoes, and wheat. Since December 31, 1989, growers have been using existing stocks of labeled materials purchased prior to December 1989 to obtain adequate control of bacterial spot on peppers and downy mildew on lettuce. These stocks have been depleted leaving growers with no means of controlling bacterial spot or downy mildew for the 1991-1992 season.

Since the voluntary action, both the registrants and the affected commodity groups have obtained and submitted additional information to the EPA. According to the Applicant, data generated through the Market Basket Survey by the EBDC/ETU Task Force and submitted to the EPA as part of the Special Review clearly indicates an acceptable level of carcinogenic dietary risk for these uses. It is the Applicant's opinion that when EPA completes the EBDC Special Review peppers and lettuce will be among the crops identified as appropriate crops to be put back onto the EBDC labels.

Growers who plan to plant a fall crop of peppers or lettuce do not have an effective means of preventing epidemic disease outbreaks of bacterial spot or downy mildew. The only way Florida growers can adequately manage this situation is to be allowed to use Maneb under an emergency exemption until a final decision is reached about future uses of EBDC fungicides.

Bacterial spot is the most serious pepper disease in Florida. It affects stems, leaves, and fruit. Yields may be indirectly affected as a result of defoliation or directly affected because of disease on the fruit itself. Because bacterial spot is so difficult to control, it is one of the major yield limiting pepper pests.

Downy mildew is a disease of lettuce found throughout the lettuce production areas in the United States. Up until the early eighties, downy mildew was controlled through the use of resistant varieties. In 1980, varieties that were previously tolerant began to exhibit symptoms of the disease. In 1983, metalaxyl was registered for use on head lettuce. Subsequently, strains of metalaxyl resistant downy mildew developed in California. Florida did not have a problem with metalaxyl resistant strains of downy mildew until 1989. The Florida resistant strain is identical to the California strain and is suspected to have come from California on infected plant material.

The Agency granted the specific exemptions for the use of maneb because an emergency situation appeared to exist in that the registered alternatives do not provide adequate control of the pest under the current conditions and that in the absence of EBDC's, Florida pepper and lettuce growers could be expected to incur yield losses that would lead to a significant economic loss. The voluntary withdrawal of the use of maneb on peppers and lettuce combined with the depletion of the existing stocks of labeled material purchased prior to December 1989, has left growers with no effective means of control. This lack of an effective means of control is expected to cause pepper and lettuce growers in Florida to suffer significant yield losses.

The carcinogenic risk estimates and margin of exposure for developmental toxicity and for thyroid effects for a single year's use under an emergency exemption indicate that the proposed use is not anticipated to pose an unreasonable risk to the public health. The proposed use is not expected to pose an unreasonable risk to the environment.

Maneb will be applied at the maximum rate of 1.6 lbs. active ingredient per acre with a maximum of 8 applications on 17,325 acres of peppers. This amounts to 221,760 pounds of active ingredient. A 7-day pre-harvest interval will be observed. On lettuce, maneb will be applied at the maximum rate of 1.6 lbs. active ingredient per acre with a maximum of 6 applications on 7,950 acres of lettuce. This amounts to 76,320 pounds of active ingredient. A 7-day pre-harvest interval will be observed. This is the first year that the Applicant has applied for specific

exemptions for the use of maneb on peppers and lettuce.

Although EPA has already authorized the use of maneb in Florida, due to the 8-month duration of the exemption the Agency is soliciting public comment on whether or not the use of maneb should be allowed to continue in Florida. Accordingly, interested persons may submit written views on this subject to the Field Operations Division at the address above.

Dated: November 8, 1991.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 91-28485 Filed 11-26-91; 8:45 am]

BILLING CODE 6560-50-F

[OPP-42067A; FRL-3939-7]

Shoshone-Bannock Tribes, Notice of Approval of Shoshone-Bannock Tribal Certification Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of approval of Tribal Plan.

SUMMARY: In the Federal Register of May 29, 1991, EPA announced its intent to approve the Shoshone-Bannock Tribes' Plan for Certification of Applicators of Pesticides Classified for Restricted Use. EPA hereby announces final approval of this Tribal Plan.

ADDRESSES: Copies of the Shoshone-Bannock Tribal Plan are available for review at the following locations during normal business hours.

1. Shoshone-Bannock Tribes Land Use Department, P. O. Box 306, Fort Hall, ID 83203, Telephone: (208) 238-3860.
2. Pesticides and Toxic Substances Branch, Air and Toxics Division, Region X, Environmental Protection Agency, 1200 Sixth Avenue, Seattle, WA 98101, Telephone: (206) 553-1980.
3. Field Operations Division (H7506C), Office of Pesticide Programs, Rm. 1128, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, Telephone: (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Allan Welch, Pesticides and Toxic Substances Branch (AT-083), Region X, Environmental Protection Agency, 1200 Sixth Avenue, Seattle, WA 98101, Telephone: (206) 553-1980.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 29, 1991 (56 FR 24188), EPA announced its intent to approve the Shoshone-Bannock Tribes' Plan for the Certification of Applicators of Pesticides Classified for Restricted Use. Interested persons were given 30 days to comment. No comments were received.

EPA therefore grants final approval of the Shoshone-Bannock Tribal Plan for Certification of Applicators of Pesticides Classified for Restricted Use.

Dated: October 4, 1991.

Dana A. Rasmussen,

Regional Administrator, Region X.

[FR Doc. 91-28486 Filed 11-26-91; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirements Submitted to Office of Management and Budget for Review

November 20, 1991.

The Federal Communications Commission has submitted the following information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of these submissions may be purchased from the Commission's copy contractor, Downtown Copy Center, 1114 21st Street, NW., Washington, DC 20036, (202) 452-1422. For further information on these submissions contact Judy Boley, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on these information collections should contact Jonas Neihardt, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503, (202) 395-4814.

OMB number: 3060-0349.

Title: Sections 76.73 and 76.75, Cable TV EEO Policy and Programs.

Action: Extension.

Respondents: Businesses or other for-profit (including small businesses).

Frequency of response: Recordkeeping requirement.

Estimated annual burden: 5,575 recordkeepers; 25.36 hours average burden per recordkeeper; 141,382 hours total annual burden.

Needs and uses: Section 76.73 provides that equal opportunity in employment shall be afforded by all cable entities to all qualified persons and no person shall be discriminated against in employment by such entities because of race, color, religion, national origin, age or sex. Sections 76.73 and 76.75 require that each cable employment unit shall establish, maintain and carry out a program to assure equal opportunity in every aspect of a cable entity's policy and practice. The data is used by cable entities in the preparation of the Cable Television Annual Employment Report (FCC Form 395-A). The data is also used by FCC staff, in field investigations involving equal employment opportunity. If this program was not maintained there could be no assurance that efforts are being made to afford equal opportunity in employment.

OMB number: 3060-0348.

Title: Section 76.79, Records available for public inspection.

Action: Extension.

Respondents: Businesses or other for-profit (including small businesses).

Frequency of response: Recordkeeping requirement.

Estimated annual burden: 2,144 recordkeepers, 2 hours average burden per recordkeeper; 4,288 hours total annual burden.

Needs and uses: Section 76.79 requires that every cable employment unit maintain, for public inspection, a file containing copies of all annual employment reports and related documents. The data is used by the general public to assess a cable unit's EEO program.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 91-28516 Filed 11-26-91; 8:45 am]

BILLING CODE 6712-01-M

[Report No. 1867]

Petitions for Reconsideration of Actions in Rule Making Proceedings

November 7, 1991.

Petitions for reconsideration have been filed in the Commission rule making proceedings listed in this Public Notice and published pursuant to 47 CFR 1.429(e). The full text of these documents are available for viewing and copying in room 239, 1919 M Street, NW., Washington, DC or may be purchased from the Commission's copy contractor Downtown Copy Center (202) 452-1422. Oppositions to these petitions must be filed December 13, 1991. See § 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

SUBJECT: Amendment of part 73 of the Commission Rules to Permit Short-Spaced FM Station Assignments by Using Directional Antennas. (MM Docket No. 87-121). *Number of Petitions Received:* 1.

SUBJECT: Resolution of Interface Between UHF Channels 14 and 69 Adjacent Channel Land Mobile Operations. (MM Docket No. 87-465) *Number of Petitions Received:* 3.

SUBJECT: Amendment of § 73.202(b), Table of Allotments, FM Broadcast Stations. (Culebra and Vieques, Puerto Rico, Christiansted, Virgin Virgin Islands) (MM Docket No. 89-495, RM Nos. 6940 & 7272). *Number of Petitions Received:* 1.

SUBJECT: Amendment of Part 90 of the Commission's Rules to Permit the Short-Spacing of Specialized Mobile Radio System Upon Concurrence from Co-Channel Licensees (MM Docket No. 90-34). *Number of Petitions Received:* 4.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 91-28517 Filed 11-26-91; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA-923-DR]

New Hampshire; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of New Hampshire (FEMA-923-DR), dated November 13, 1991, and related determinations.

DATED: November 13, 1991.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472 (202) 646-3606.

Notice

Notice is hereby given that, in a letter dated November 13, 1991, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*, Public Law 93-288, as amended by Public Law 100-707), as follows:

I have determined that the damage in certain areas of the State of New Hampshire resulting from a major coastal storm on October 30, 1991, through and including October 31, 1991, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the State of New Hampshire.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Public Assistance in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of Section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Mr. Richard H. Strome of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of New Hampshire to have been affected adversely by this declared major disaster:

Rockingham County for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Wallace E. Stickney,

Director, Federal Emergency Management Agency.

[FR Doc. 91-28464 Filed 11-26-91; 8:45 am]

BILLING CODE 6718-02-M

[FEMA-922-DR]

Washington; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Washington (FEMA-922-DR), dated November 13, 1991, and related determinations.

DATED: November 13, 1991.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472 (202) 646-3606.

Notice

Notice is hereby given that, in a letter dated November 13, 1991, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*, Public Law 93-288, as amended by Public Law 100-707), as follows:

I have determined that the damage in certain areas of the State of Washington, resulting from fire occurring October 16 through and including October 24, 1991, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the State of Washington. This major disaster declaration supersedes and rescinds fire suppression declaration FEMA-2079-FSA of October 18, 1991.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance and Public Assistance in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Mr. Richard A. Buck of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Washington to have been affected adversely by this declared major disaster:

The counties of Spokane, Stevens, Lincoln, and Pend Oreille for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83-516, Disaster Assistance.)

Wallace E. Stickney,

Director, Federal Emergency Management Agency.

[FR Doc. 91-28465 Filed 11-26-91; 8:45 am]

BILLING CODE 6718-02-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed; City of Long Beach, et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal

Maritime Commission, 1100 L Street, NW., room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224-002491-006

Title: Amended and Restated Preferential Assignment Agreement between City of Long Beach and International Transportation Service, Inc.

Parties:

City of Long Beach

International Transportation Service, Inc. (I.T.S.)

Synopsis: The Agreement, filed November 18, 1991, adds additional areas to be used by I.T.S. for the terminal premises, revises the rent payable for the use of the terminal, eliminates obsolete provisions and restates the Agreement.

Agreement No.: 224-200349-001

Title: Marine Terminal Lease Agreement between City of Salem Municipal Port Authority and Salem Marine Terminal Corporation.

Parties:

City of Salem Municipal Port Authority

Salem Marine Terminal Corporation ("SMTC")

Salem Stevedoring Corp. ("SSC")

Synopsis: The Agreement, filed November 18, 1991, provides for the assignment of all of the right, title and interest of SMTC to SSC.

Agreement No.: 224-200349-002

Title: Marine Terminal Lease Agreement between City of Salem Municipal Port Authority and Salem Marine Terminal Corporation.

Parties:

City of Salem Municipal Port Authority

Salem Marine Terminal Corporation ("SMTC")

Salem Stevedoring Corp. ("SSC")

Synopsis: The Agreement, filed November 18, 1991, is a primary "Collateral Agreement of Assignment" in which SSC grants SMTC a security interest in the Lease Agreement. This is to secure the performance by SSC and Salem Port Development Corp., under certain other agreements to which each is a party.

Agreement No.: 224-200349-003.

Title: Marine Terminal Lease Agreement between City of Salem Municipal Port Authority and Salem Marine Terminal Corporation.

Parties:

City of Salem Municipal Port Authority

Salem Marine Terminal Corporation ("SMTC")

Salem Stevedoring Corp. ("SSC")

Synopsis: The Agreement, filed November 18, 1991, is a secondary "Collateral Assignment" in which SMTC grants Monte Dei Paschi Di Siena a security interest in the Collateral Assignment to SMTC. This is to secure the performance by SMTC and the fifty/fifty partnership under certain other agreements to which each is a party.

Agreement No.: 212-009847-028.

Title: U.S. Atlantic Coast/Brazil Agreement.

Parties:

Companhia de Navegacao Lloyd Brasileiro

Companhia de Navegacao Maritime Netumar

Companhia de Maritima Nacional

American Transport Lines, Inc.

Synopsis: The proposed amendment would extend the current 98 percent carrying rate to June 30, 1992. It would divide calendar year 1992 into two six-month pool periods, and would provide for a 90-day notice period prior to a party's withdrawal from the Agreement.

Agreement No.: 212-009848-027.

Title: U.S. Gulf Ports/Brazil Agreement.

Parties:

Companhia de Navegacao Lloyd Brasileiro

Companhia de Maritima Nacional

American Transport Lines, Inc.

Synopsis: The proposed amendment would establish two six-month pool periods for calendar year 1992, and would establish a 95 percent carrying rate for the first 1992 pool period, as well as provide notice periods for withdrawal from the Agreement. The amendment would also extend the Agreement's alternate coast service and special forfeiture provisions through 1992.

Agreement No.: 212-010027-034.

Title: Brazil/U.S. Atlantic Coast Agreement.

Parties:

Companhia de Navegacao Lloyd Brasileiro

Companhia de Navegacao Maritima Netumar

Companhia de Maritima Nacional

American Transport Lines, Inc.

Empresa Lineas Maritimas Argentinas S/A

A. Bottacchi S.A. de Navegacion C.F.I.I. ("Bottacchi")

Synopsis: The proposed amendment would establish two six-month pool periods for calendar year 1992 and would decrease the special carrying rate of 100 percent to 98 percent for the first 1992 pool period. The amendment would also permit withdrawal from the Agreement on short notice during the first 1992 pool period and would delete Bottacchi as a party to the Agreement. The parties have requested a shortened review period.

Agreement No.: 212-011213-024.

Title: Spain-Italy/Puerto Rico Island Pool Agreement.

Parties:

Compania Transatlantica Espanola, S.A.

d'Amico Societa de Navigazione, S.p.A.

Nordana Line A/S

Sea-Land Service, Inc.

Synopsis: This modification revises the Agreement by adding a new pool period to cover the period of January 1, 1992 through June 30, 1992. Additionally, corresponding changes have been made to provide that no member may withdraw from the Agreement or any pool section until June 30, 1992.

Dated: November 21, 1991.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 91-28445 Filed 11-26-91; 8:45 am]

BILLING CODE 6730-01-M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Issuance of Certificate (Performance); Alaska Sightseeing Tours/Cruise West, Inc.

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3, Public Law 89-777 (46 U.S.C. 817(e)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Alaska Sightseeing Tours/Cruise West, Inc. and West Travel, Inc., Fourth and Battery Bldg., #700, Seattle, Washington 98121,

Vessel: Spirit of Discovery.

Dated: November 22, 1991.

Joseph C. Polking,

Secretary.

[FR Doc. 91-28461 Filed 11-26-91; 8:45 am]

BILLING CODE 6730-01-M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Issuance of Certificate (Performance); Danish Cruise Lines, Inc.

Notice is hereby given that the following have been issued a certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3, Public Law 89-777 (46 U.S.C. 817(e)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Danish Cruise Lines, Inc., Metro Office Park, Calle 1, Lot 11, Suite 4, Guaynabo, Puerto Rico 00968.

Vessel: Scandinavian Song.

Dated: November 22, 1991.

Joseph C. Polking,

Secretary.

[FR Doc. 91-28462 Filed 11-26-91; 8:45 am]

BILLING CODE 6730

FEDERAL RESERVE SYSTEM

Federal Open Market Committee; Domestic Policy Directive of October 1, 1991

In accordance with § 271.5 of its rules regarding availability of information, there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on October 1, 1991.[1] The Directive was issued to the Federal Reserve Bank of New York as follows:

The information reviewed at this meeting has been mixed, but it suggests on balance that economic activity has been expanding at a moderate pace. Total nonfarm payroll employment changed little over July and August, and the civilian unemployment rate was 6.8 percent in both months. Employment in manufacturing continued to advance in August, and industrial production posted a further rise after several months of sizable gains. Consumer spending increased considerably on balance in July and August. Recent data on orders and shipments of nondefense capital goods point to a small increase in real outlays for business equipment, but nonresidential construction has remained weak. Housing starts rose only slightly further in July and August after increasing appreciably on balance since January. The nominal U.S. merchandise trade deficit widened substantially in July and was considerably above its average rate in the second quarter. Increases in consumer prices have been small in recent months, owing to declines in food and energy prices.

Most interest rates have declined further since the Committee meeting on August 20. The Board of Governors approved a reduction in the discount rate from 5-1/2 to 5 percent on September 13. The trade-weighted value of the dollar in terms of the other G-10 currencies fell sharply over the intermeeting period; much of the drop retraced the previous run-up associated with the attempted coup in the Soviet Union that began shortly before the August Committee meeting.

After contracting in July, M2 was about unchanged in August and September. M3 declined further in July and August and is indicated to have changed little in September. For the year thus far, expansion of M2 and M3 has been at the lower end of the Committee's ranges.

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. In furtherance of these objectives, the Committee at its meeting in July reaffirmed the ranges it has established in February for growth of M2 and M3 of 2-1/2 to 6-1/2 percent and 1 to 5 percent, respectively, measured from the fourth quarter of 1990 to the fourth quarter of 1991. The monitoring range for growth of total domestic nonfinancial debt also was maintained at 4-1/2 to 8-1/2 percent for the year. For 1992, on a tentative basis, the Committee agreed in July to use the same ranges as in 1991 for growth in each of the monetary aggregates and debt, measured from the fourth quarter of 1991 to the fourth quarter of 1992. With regard to M3, the Committee anticipated that the ongoing restructuring of thrift depository institutions would continue to depress the growth of this aggregate relative to spending and total credit. The behavior of the monetary aggregates will continue to be evaluated in light of progress toward price level stability, movements in their velocities, and developments in the economy and financial markets.

In the implementation of policy for the immediate future, the Committee seeks to maintain the existing degree of pressure on reserve positions. Depending upon progress toward price stability, trends in economic activity, the behavior of the monetary aggregates, and developments in foreign exchange and domestic financial markets, slightly greater reserve restraint might or slightly lesser reserve restraint would be acceptable in the intermeeting period. The contemplated reserve conditions are expected to be consistent with growth of M2 and M3 over the period from September through December at annual rates of about 3 and 1-1/2 percent, respectively.

By order of the Federal Open Market Committee, November 21, 1991.

Normand Bernard,

Deputy Secretary, Federal Open Market Committee.

[FR Doc. 91-28443 Filed 11-26-91; 8:45 am]

BILLING CODE 6210-01-F

[1]Copies of the Record of policy actions of the Committee for the meeting of October 1, 1991, are available upon request to The Board of Governors of the Federal Reserve System, Washington, DC 20551.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Federal Allotments to States for Social Services Expenditures, Pursuant to Title XX, Block Grants to States for Social Services; Promulgation for Fiscal Year 1993

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notification of Allocation of State Title XX—Social Services Block Grant Allotments for Fiscal Year 1993.

SUMMARY: This issuance sets forth the individual allotments to States for Fiscal Year 1993, pursuant to Title XX of the Social Security Act, as amended (Act). The allotments to the States published herein are based upon the authorization set forth in section 2003 of the Act and are contingent upon Congressional appropriations for the fiscal year. If Congress enacts and the President approves an amount different from the authorization, the allotments will be adjusted proportionately.

FOR FURTHER INFORMATION CONTACT: L. Bryant Tudor, (202) 245-6275.

SUPPLEMENTARY INFORMATION: Section 2003 of the Act authorizes $2.8 billion for Fiscal Year 1993 and provides that it be allocated as follows:

(1) Puerto Rico, Guam, the Virgin Islands, and the Northern Mariana Islands each receives an amount which bears the same ratio to $2.8 billion as its allocation for Fiscal Year 1981 bore to $2.9 billion.

(2) American Samoa receives an amount which bears the same ratio to the amount allotted to the Northern Mariana Islands as the population of American Samoa bears to the population of the Northern Mariana Islands determined on the basis of the most recent data available at the time such allotment is determined.

(3) The remainder of the $2.8 billion is allotted to each State in the same proportion as that State's population is to the population of all States, based upon the most recent data available from the Department of Commerce.

For Fiscal Year 1993, the allotments are based upon the Bureau of Census population statistics contained in its report "Census Population—Housing" (CPH-L-4, Summer 1991) and "Census Bureau Press Releases" (CB 91-242 and CB 91-243, July 21, 1991), which is the most recent data available from the Department of Commerce at this time as to the population of each State.

EFFECTIVE DATE: The allotments shall be effective October 1, 1992.

Fiscal Year 1993 Federal Allotments to States for Social Services—Title XX Block Grants

Total	$2,800,000,000
Alabama	45,239,868
Alaska	6,157,369
American Samoa	104,188
Arizona	41,030,467
Arkansas	26,319,953
California	333,169,627
Colorado	36,877,042
Connecticut	36,798,675
Delaware	7,456,014
Dist. of Col.	6,795,496
Florida	144,843,705
Georgia	72,522,609
Guam	482,759
Hawaii	12,404,299
Idaho	11,273,583
Illinois	127,972,514
Indiana	62,066,278
Iowa	31,089,115
Kansas	27,741,745
Kentucky	41,254,371
Louisiana	47,243,812
Maine	13,747,725
Maryland	53,524,328
Massachusetts	67,350,420
Michigan	104,059,533
Minnesota	48,979,070
Mississippi	28,805,291
Missouri	57,285,920
Montana	8,944,978
Nebraska	17,666,051
Nevada	13,456,650
New Hampshire	12,415,495
New Jersey	86,539,020
New Mexico	16,960,752
New York	201,401,936
North Carolina	74,213,087
North Dakota	7,153,743
No. Mariana Islands	96,552
Ohio	121,434,508
Oklahoma	35,220,150
Oregon	31,816,804
Pennsylvania	133,021,557
Puerto Rico	14,482,759
Rhode Island	11,228,802
South Carolina	39,037,718
South Dakota	7,791,870
Tennessee	54,599,069
Texas	190,173,135
Utah	19,289,357
Vermont	6,302,907
Virgin Islands	482,759
Virginia	69,264,802
Washington	54,487,116
West Virginia	20,073,022
Wisconsin	54,766,997

Fiscal Year 1993 Federal Allotments to States for Social Services—Title XX Block Grants—Continued

Wyoming	5,082,628

Dated: November 13, 1991.

Eunice S. Thomas,

Director, Office of Community Services.

[FR Doc. 91-28437 Filed 11-26-91; 8:45 am]

BILLING CODE 4130-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA-060-00-4351-12]

Closure and Restrictions on Public Land

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of closure and restrictions on public land for the protection and rehabilitation of sensitive plant and wildlife resources.

SUMMARY: Pursuant to the regulations contained in 43 CFR 8364.1 the Bureau of Land Management is closing to motorized vehicle travel approximately 200 acres of public lands in and around Sheep Hole Oasis, located within the Orocopia Mountains Wilderness Study Area (WSA CDCA No. 344). This closure includes all dry canyon wash routes and other trails except for approximately 1/2 mile of the dry wash bed leading from Hidden Spring Canyon to within approximately 300 feet from Sheep Hole Oasis, which remains open from November 1 to June 1. The legal description of the closure is as follows:

T. 7S., R. 10E. SBBM., Riverside County, California;
Section 2: SW¼SW¼;
Section 3: SE¼SE¼, E½SW¼SE¼;
Section 10: E½NE¼NE¼, NW¼NE¼NE¼;
Section 11: NW¼NW¼, W½SW¼NW¼, NE¼SW¼NW¼.

A map of the area described above may be viewed in the Resource Area office. This closure is necessary to prevent further deterioration of the soil and vegetation resources in that area, and to permit rehabilitation of these resources.

Personnel that are exempt from the area closure include any Federal, State or local officer, or member of any organized rescue or fire-fighting force in the performance of an official duty, or any person authorized by the Bureau.

DATES: This closure is effective November 27, 1991, and shall remain in effect until rescinded by the authorized officer.

PENALTIES: Violators are subject to fines and/or imprisonment.

FOR FURTHER INFORMATION CONTACT: Russell L. Kaldenberg, Palm Springs-South Coast Resource Area Manager, 63-500 Garnet Avenue, P.O. Box 2000, North Palm Springs, CA 92258-2000. (619) 251-0812.

Dated: November 15, 1991.

Gerald E. Hillier,

District Manager.

[FR Doc. 91-28420 Filed 11-26-91; 8:45 am]

BILLING CODE 4310-40-M

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

Voluntary Foreign Aid Advisory Committee; Meeting

Pursuant to the Federal Advisory Committee Act, notice is hereby given of a meeting of the Advisory Committee on Voluntary Foreign Aid (ACVFA) Thursday, December 12, 1991, and Friday, December 13, 1991. Topic for discussion will be Effective Development Strategies for the '90's.

Date: December 12, 1991, 2-5:30 p.m. December 13, 1991, 9 a.m.-2:30 p.m.

Place: State Department.

The meeting is free and open to the public. However, notification by December 9, 1991, through the advisory committee headquarters is required.

Persons wishing to attend the meeting must call Theresa Graham or Susan Saragi (202) 663-2523, or facsimile (202) 663-2629. Persons attending must include their name, organization, birthdate and social security number for security purposes.

Dated: November 21, 1991.

Sally H. Montgomery,

Deputy Assistant Administrator, Private and Voluntary Cooperation, Food and Humanitarian Assistance.

[FR Doc. 91-28588 Filed 11-26-91; 8:45 am]

BILLING CODE 6116-01-M

INTERSTATE COMMERCE COMMISSION

[Ex Parte No. 394 (Sub-No. 9)]

Cost Ratio for Recyclables; 1992 Determination

AGENCY: Interstate Commerce Commission.

ACTION: Notice of rate caps and initiation of first annual compliance proceeding.

SUMMARY: The Commission has calculated proposed 1992 revenue-to-variable cost (R/VC) ratios as ceilings for rates on nonferrous recyclables under 49 U.S.C. 10731(e). The R/VC ratios were calculated in accordance with established procedures using the Uniform Railroad Costing System (URCS). Because URCS develops different variability percentages for different railroads the final rules adopted at 49 CFR part 1145, in Cost Ratios for Recyclables— Compliance Procedures, 8 I.C.C.2d 182 (1991), allow separate R/VC ratio ceilings for individual railroads to apply in the context of monitoring compliance. The proposed national average R/VC ratio is 141.0 percent. Individual and regional R/VC ratios are proposed. In addition, the Commission is initiating the first annual compliance proceeding in accordance with rules adopted in Ex Parte No. 394 (Sub-No. 3), *supra*, including the schedule for completing the proceeding.

EFFECTIVE DATE: December 17, 1991, unless, within that time, comments are received challenging the accuracy of the ratios, in which case a further decision will be issued.

FOR FURTHER INFORMATION CONTACT: William T. Bono (202) 275–7354 [TDD for hearing impaired (202) 275–1721].

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone (202) 289–4357/4359. Assistance for the hearing impaired is available through TDD services (202) 275–1721.

This decision will not significantly affect the quality of the human environment or the conservation of energy resources.

Authority: 49 U.S.C. 10321(a), 10731, 5 U.S.C. 553.

Decided: November 20, 1991.

By the Commission, Chairman Philbin, Vice Chairman Emmett, Commissioners Simmons, Phillips, and McDonald.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 91–28449 Filed 11–26–91; 8:45 am]

BILLING CODE 7035–01–M

[Finance Docket No. 31934]

South Central Tennessee Railroad Co.—Lease and Operation Exemption—CSX Transportation, Inc.

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission, under 49 U.S.C. 10505, exempts South Central Tennessee Railroad Company from the prior approval requirements of 49 U.S.C. 11343, *et seq.*, to lease and operate, as a Class III rail carrier, an approximately 0.72-mile rail line owned by CSX Transportation, Inc.

DATES: This exemption is effective on December 27, 1991. Petitions for stay must be filed by December 12, 1991 and petitions for reconsideration must be filed by December 23, 1991.

ADDRESSES: Send pleadings referring to Finance Docket No. 31934 to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

(2) Petitioners' representatives, Fritz R. Kah, Verner, Liipfert, Bernhard, McPherson and Hand, Suite 700, 901 15th Street, NW., Washington, DC 20005. Charles M. Rosenberger, CSX Transportation, Inc., 500 Water Street, J150, Jacksonville, FL 32202.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 275–7245.

(TDD for hearing impaired: (202) 275–1721).

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone (202) 289–4357/4359. Assistance for the hearing impaired is available through TDD services (202) 275–1721.

Decided: November 20, 1991.

By the Commission, Chairman Philbin, Vice Chairman Emmett, Commissioners Simmons, Phillips, and McDonald.

Sidney L. Strickland, Jr.

Secretary.

[FR Doc. 91–28448 Filed 11–26–91; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF LABOR

Bureau of Labor Statistics

State Research Advisory Committee on Occupational Safety and Health Statistics; Meeting

The State research Advisory Committee on Occupational Safety and Health Statistics, established to make recommendations to the Bureau of Labor Statistics on proposals for the redesign of the Bureau's safety and health statistics program, will meet on December 10, 1991. The Committee will meet at the Hotel Westcourt, 10220 N. Metro Parkway East, Phoenix, Arizona 85051. The meeting will be held from 8:30 a.m. until 5 p.m. in the hotel's Grande Ballroom.

The redesign of the Bureau's safety and health statistical program and plans for implementation will be discussed, including a review of pilot projects, computer hardware and software design and tests, and State participation.

The public is invited to attend. It is suggested that persons planning to attend as observers contact William Eisenberg, committee liaison, on (202) 501–6467. Official records of the meeting will be available for public inspection at the General Accounting Office Building, room 2870, 441 G Street, NW., Washington, DC 20212.

Due to scheduling difficulties, we are unable to provide the full 15 days of advance notice of this meeting.

Signed at Washington, DC, this 20th day of November 1991.

Janet L. Norwood,

Commissioner of Labor Statistics.

[FR Doc. 91–28481 Filed 11–26–91; 8:45 am]

BILLING CODE 4510–24–M

NATIONAL COMMUNICATIONS SYSTEM

Meeting; Industry Executive Subcommittee of the National Security Telecommunications Advisory Committee

A meeting of the Industry Executive Subcommittee of the National Security Telecommunications Advisory Committee will be held on Wednesday, December 11, 1991, from 9 a.m. to 1:15 p.m. The meeting will be held at the Mitre-Hayes Building, 7525 Colshire Dr., McLean, VA 27006. The agenda is as follows:

A. Administrative Remarks/NSTAC XIV Update
B. Network Security
C. Membership Issues (Energy, OWG/PWG, TSP Oversight)
D. Operations Working Group (OWG)
E. Plans Working Group (PWG)
F. National Level Program (NLP) Status Briefing
G. TSP Oversight Committee Report
H. National Coordinating Center (NCC) Status Update

Due to the requirement to discuss classified information, in conjunction with the issues listed above, the meeting will be closed to the public in the interest of National Defense. Any person desiring information about the meeting may telephone (703) 692-9274 or write the Manager, National Communications System, 701 S. Court House Rd., Arlington, VA 22202-2199.

Beverely Sampson,

Federal Register Liaison Officer.

Dennis I. Parsons,

Captain, USN, Assistant Manager, NCS Joint Secretariat.

[FR Doc. 91-28477 Filed 11-26-91; 8:45 am]

BILLING CODE 3610-05-M

NATIONAL SCIENCE FOUNDATION

Permit Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit issued under the Antarctic Conservation Act of 1978, Public Law 95-541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice of permits issued.

FOR FURTHER INFORMATION CONTACT: Charles E. Myers, Permit Office, Division of Polar Programs, National Science Foundation, Washington, DC 20550.

SUPPLEMENTARY INFORMATION: On October 17, 1991, the National Science Foundation published a notice in the **Federal Register** of permit applications received. A permit was issued to Natalie P. Goodall on November 20, 1991.

Charles E. Myers,

Permit Office Division of Polar Programs.

[FR Doc. 91-28450 Filed 11-26-91; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-267]

Environmental Assessment and Finding of No Significant Impact; Public Service Company of Colorado; Fort St. Vrain Nuclear Generating Station

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering issuance of an exemption from the requirements of 10 CFR 55.45(b), 10 CFR 55.33(a)(2), 10 CFR 55.59(a)(2), (c)(2), (c)(3), and (c)(4) to the Public Service Company of Colorado (PSC or the licensee) for possession of the Fort St. Vrain Nuclear Generating Station, Unit 1 (the facility) located in Weld County, Colorado.

Environmental Assessment

Identification of Proposed Action

The proposed action would grant an exemption from the requirements of 10 CFR 55.45(b), 55.33(a)(2), 55.59(a)(2), and 55.59(c)(3) to the extent that these regulations require the use of a simulation facility in implementing operating tests and on-the-job training. Additionally, the proposed action would grant an exemption from 10 CFR 55.59(a)(2), (c)(2), (c)(3), and (c)(4) to the extent that these regulations apply to requalification requirements specific to power operations of a nuclear facility. By letter dated November 9, 1990, PSC requested an exemption from the above specified requirements of 10 CFR part 55 related to the use of a simulation facility in implementing operating tests and on-the-job training. The U.S. Nuclear Regulatory Commission (NRC) is further proposing related action which includes an exemption from the regulations that apply to requalification requirements specific to power operations of a nuclear facility. The NRC has proposed this related action due to its practicality and close relation to the intent of the licensee's November 9, 1990 request.

The Need for the Proposed Action

The requirements of 10 CFR part 55 for a simulation facility are designed for operating power reactors. There are no plant-referenced simulator devices that reflect the current partially defueled and permanently shutdown condition of FSV. Likewise, the requalification requirements of 10 CFR 55.59 are designed for the complex operations associated with an operating plant from start-up through full-power operation. The licensee ceased power operation at FSV on August 18, 1989. In addition, the Commission issued a possession only license on May 21, 1991, preventing operation of the FSV reactor.

In the partially defueled and permanently shutdown condition, the principal operator activity will be to complete the defueling of the reactor and to monitor the spent fuel storage well to assure the continued safe storage of special nuclear material to that the public health and safety is not compromised. Additionally, the knowledge required of operators in a permanently shutdown status is far less than that required for an operating facility. The request for an exemption from the requirements of 10 CFR part 55, as mentioned above, is based on the above plant conditions and the licensee's intent not to resume power operations at FSV.

Environmental Impacts of the Proposed Action

The proposed exemption does not increase the risk of facility accidents because of the partially defueled and permanently shutdown condition of the plant. With the reactor vessel partially defueled and the licensee not licensed to resume power operation at FSV, design-basis accidents associated with an operating plant from start-up through full-power operation are no longer credible.

In the shutdown condition of the plant, the principal operator activity will be to complete defueling of the reactor and to monitor the spent fuel storage well to assure the continued safe storage of special nuclear material so that the public health and safety is not compromised. This exemption would enable the licensee to continue to train its operators for their principal activities without a simulation facility and without expending excessive resources and time training personnel for unrelated power activities. The remaining requalification training to be accomplished without a simulation facility ensures protection of the public health and safety and is appropriate to the partially defueled condition of the plant. Design-basis accidents for a nuclear facility in a defueled condition are all associated with a loss of fuel storage well cooling or with fuel handling. The remaining requalification training to be accomplished without a simulation facility ensures protection of the public health and safety and is appropriate to the partially defueled and permanently shutdown condition of the plant.

Any potential post-accident radiological releases will not differ from those determined previously, and the proposed exemption does not otherwise

affect facility radiological effluents or present any significant occupational exposures. The proposed exemption does not affect plant nonradiological effluents and thus has no adverse environmental impact. Therefore, the Commission concludes that there are no measurable radiological or nonradiological environmental impacts associated with the proposed exemption.

Since the Commission has concluded there are no measurable environmental impacts associated with the proposed exemption, any alternative will have either no environmental impact or a greater environmental impact. The principal alternative to the exemption would be to require a simulation facility and require requalification training geared to operating power reactors. Such action would not enhance the protection of the environment and would result in unnecessary expenditure of licensee and Commission resources.

Alternate Use of Resources

This action does not involve the use of resources not considered previously in the Final Environmental Statement for the Fort St. Vrain Nuclear Generating Station.

Agencies and Persons Consulted

The NRC staff reviewed the licensee's request and did not consult other agencies or persons.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC staff concludes that the proposed action will not have a significant effect on the quality of the human environment. Therefore, the Commission has determined not to prepare an environmental impact statement for the proposed exemption.

For further details with respect to this action, see the licensee's letter dated November 9, 1990, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the Greeley Public Library, City Complex Building, Greeley, Colorado 80631.

Dated at Rockville, Maryland this 20th day of November 1991.

For the Nuclear Regulatory Commission.

Richard F. Dudley, Jr.,

Acting Director Non-Power Reactors, Decommissioning and Environmental Project Directorate, Division of Advanced Reactors and Special Projects, Office of Nuclear Reactor Regulation.

[FR Doc. 91-28456 Filed 11-26-91; 8:45 am]

BILLING CODE 7590-01-M

Biweekly Notice Applications and Amendments to Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to Public Law (P.L.) 97-415, the Nuclear Regulatory Commission (the Commission) is publishing this regular biweekly notice. P.L. 97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from November 4, 1991 through November 15, 1991. The last biweekly notice was published on November 13, 1991 (56 FR 57687).

Notice Of Consideration Of Issuance Of Amendment To Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room P-223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland from 7:30 a.m. to 4:15 p.m. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555. The filing of requests for hearing and petitions for leave to intervene is discussed below.

By December 27, 1991, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room for the particular facility involved. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene.

Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington DC 20555, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 325-6000 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to **(Project Director)**: petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room for the particular facility involved.

Commonwealth Edison Company, Docket Nos. 50-237 and 50-249, Dresden Nuclear Power Station, Units 2 and 3, Grundy County, Illinois

Date of application for amendment request: October 14, 1991

Description of amendment request: The proposed amendments reflect the current turbine control valve fast acting solenoid valve design and the addition of pressure setpoints to activate the pressure switches. The current design utilizes a pressure switch to initiate the turbine generator load rejection scram (turbine control valve fast closure scram) function, instead of a limit switch as originally designed.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident.

The turbine generator load rejection scram (turbine control valve fast closure scram) is provided to mitigate the anticipated rapid increase in pressure and neutron flux resulting from the fast closure of the turbine control valves due to a load reject coupled with the subsequent failure of the bypass valves (UFSAR Sections 3.2.4.3.1 and 11.2.3.2). The turbine control valves are required to fast close as rapidly as possible to prevent overspeed of the turbine-generator rotor (and prevent any potential damage). The rapid closure of the control valves causes a sudden reduction of the steam flow which results in an increase to reactor pressure. The scram is provided to avoid exceeding the Minimum Critical Power Ratio (MCPR) safety limit.

The use of a pressure switch (in lieu of a limit switch) does not involve a significant increase in the probability of the transient. Upon actuation of the fast acting solenoid, the pressure switch will sense the decreasing electro-hydraulic control (EHC) fluid (which will cause control valve closure) and generate a reactor scram. The use of the pressure switch, therefore, provides the same function as the limit switch. In addition, the logic for the Reactor Protection System (RPS) trip remains the same. The pressure switches on fast acting solenoid valves for control valves nos. 1 and 2 input one of the two RPS channels (RPS channel 'B' for Unit 2 and RPS channel 'A' for Unit 3). Either pressure switch will cause the respective channel to trip. Similarly, the pressure switches on the fast acting solenoid valves for control valves nos. 3 and 4 input into the other RPS channel (RPS channel 'A' for Unit 2 and RPS channel 'B' for Unit 3). In order to achieve a full reactor

scram, RPS channels 'A' and 'B' must be tripped.

The MCPR safety limit and Operating Limit MCPR are not adversely affected by the implementation of the pressure switch; therefore, fuel cladding integrity is assured. Additionally, the proposed changes do not alter, degrade, or prevent the responses of systems assumed in any accident nor do they alter any assumptions previously made in evaluating the radiological consequences of any accident.

The consequences of the turbine generator load reject coupled with the subsequent failure of the bypass valves are not significantly increased by the use of the pressure switch. During the load reject event, the pressure switch provides a scram signal to RPS in the same time period as a position switch on the fast acting solenoid valve. The use of a pressure switch to input into the Reactor Protection System is widely used throughout the industry and has been shown to be reliable. The results of the transient analysis (the lowest MCPR achieved) are not significantly affected and compliance with 10 CFR 100 limits is ensured.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The use of the pressure switch design for the turbine generator load rejection scram eliminates the failure mode associated with the previously utilized limit switch design; however, the pressure switch inherently introduces its own failure mode. The failure of the tubing which connects the pressure switch to the solenoid valve would initiate a scram signal. The use of the pressure switch to input into the Reactor Protection System is widely used throughout the industry and has been shown to be reliable.

The logic for the RPS trip remains unchanged. In order to create a reactor scram, the logic is arranged such that actuation of the pressure switches for the fast acting solenoid valves on control valve nos. 1 or 2 and 3 or 4 will initiate a reactor scram. Therefore, in order for the scram function to fail, two pressure switches would have to fail within the same RPS channel.

The fast closure of the turbine control valves is considered to be an anticipatory reactor scram. The reactor pressure and neutron flux would increase significantly in the event of the turbine control valve fast closure without a scram; however, the high reactor pressure (1060 psig) or the high neutron flux scrams provide backup to the turbine generator load rejection scram, in the event that the pressure switches fail to actuate RPS.

The existence of the new failure mode, therefore, does not introduce the possibility of a new or different kind of accident than previously evaluated.

3. The proposed change does not involve a significant reduction in the margin of safety.

The limiting event associated with the turbine control valve fast closure is the load reject with failure of the bypass valves. A reactor scram is initiated when the turbine control valves fast close to mitigate the anticipated increase in reactor pressure and neutron flux. This function ensures that the MCPR safety limit is not exceeded. The use of the pressure switch does not affect the margin of safety associated with the MCPR safety limit since the pressure switch will initiate the reactor scram within the same time period as a position switch on the fast acting solenoid valve. The trip setpoint was calculated to ensure that pressure switch actuation will occur within 30 milliseconds after the start of turbine control valve fast closure. Dresden Station's Technical Specifications require actuation of the RPS trip contacts within 50 milliseconds of the actuation of the pressure switch. These times are consistent with the design values used in the Reload Licensing calculation to analyze the load reject without bypass valve transient. Additionally, recent response time testing has verified pressure switch actuation within the prescribed limits (30 milliseconds). Therefore, a significant reduction in the margin of safety is not involved.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendments involve no significant hazards consideration.

Local Public Document Room location: Morris Public Library, 604 Liberty Street, Morris, Illinois 60450.

Attorney for licensee: Michael I. Miller, Esquire; Sidley and Austin, One First National Plaza, Chicago, Illinois 60690.

NRC Project Director: Richard J. Barrett

Detroit Edison Company, Docket No. 50-341, Fermi-2, Monroe County, Michigan

Date of amendment request: September 24, 1991

Description of amendment request: The proposed change revises the Technical Specifications by changing the Rod Block Monitor (RBM) down scale trip set point.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change does not:

1) Involve a significant increase in the probability or consequences of an accident previously evaluated. The change makes setpoint modifications consistent with RBM system design changes such that the system will have greater sensitivity to RBM channel downscale conditions. Therefore, the RBM will terminate rod withdrawal sooner under these inappropriate conditions. The change does not affect the reliability of the RBM system. Therefore, the change does not involve a significant increase in the probability or consequences of any previously evaluated accident.

2) Create the possibility of a new or different kind of accident from any accident previously evaluated. The RBM downscale trip setpoint continues to function on abnormally low RBM channel signal output and acts to halt rod motion in the same manner. Therefore, no new accident scenarios are created.

3) Involve a significant reduction in a margin of safety. By providing greater sensitivity to RBM channel downscale condition safety margins are maintained.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Monroe County Library System, 3700 South Custer Road, Monroe, Michigan 48161.

Attorney for licensee: John Flynn, Esq., Detroit Edison Company, 2000 Second Avenue, Detroit, Michigan 48226.

NRC Project Director: L. B. Marsh.

Detroit Edison Company, Docket No. 50-341, Fermi-2, Monroe County, Michigan

Date of amendment request: September 25, 1991

Description of amendment request: The proposed amendment modifies the Reactor Protection System (RPS) Electrical Protective Assemblies (EPA) channel functional surveillance interval in Technical Specifications (TS) Surveillance Requirement 4.8.4.4.a. It changes the interval from at least once per six months to each time the plant is in cold shutdown for a period of more than 24 hours, unless the channel functional test has been performed in the previous six months. This eliminates the need to test the EPA during power operation and thereby reduces the possibility of inadvertent challenges to the protection systems. This surveillance requirement retains testing within a six-month interval when the unit is in cold shutdown for more than twenty-four hours. The proposed change is in accordance with the recommendations of Generic Letter 91-09.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

This amendment:

1. Does not involve a significant increase in the probability or consequences of an accident previously evaluated because this amendment does not alter the design, function, or operation of the EPAs. As stated in [Generic Letter 91-09], the benefit to safety by reducing the frequency of testing during power operation and the attendant possible

challenges to safety systems more than offsets any risk to safety from relaxing the surveillance requirement to test the EPAs during power operation.

2 Does not create the possibility of a new or different kind of accident from any accident previously evaluated. As stated above, this amendment does not alter the design, functions, or operation of the EPAs. The RPS relay trip logic remains protected from power supplies operating with out-to-tolerance voltage or frequency. Additionally, the redundancy of this protection is not changed. Therefore, no new or different accident scenarios are created.

3. Does not involve a significant reduction in a margin of safety because, as stated above, the benefit to safety by reducing the frequency of testing during power operation and the attendant possible challenges to safety systems more than offsets any risk to safety from relaxing the surveillance requirement to test the EPAs during power operation.

The NRC staff has reviewed the licensee's analysis and, based on this review, the staff has determined the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Monroe County Library System, 3700 South Custer Road, Monroe, Michigan 48161.

Attorney for licensee: John Flynn, Esq., Detroit Edison Company, 2000 Second Avenue, Detroit, Michigan 48226.

NRC Project Director: L. B. Marsh.

Entergy Operations, Inc., Docket Nos. 50-313 and 50-368, Arkansas Nuclear One, Unit Nos. 1 and 2 (ANO-1&2), Pope County, Arkansas

Date of amendment request: October 15, 1991

Description of amendment request: This amendment would revise ANO-1 Technical Specifications (TS) 3.16 and 4.16 and ANO-2 TS 3/4.7.8 by replacing the existing snubber visual inspection schedule in the respective surveillance requirements with the snubber visual inspection schedule recommended in NRC Generic Letter 90-09. The amendment would also revise the surveillance requirements for visual inspection acceptance criteria to conform with the recommendations of Generic Letter 90-09. Additionally, a change to the TS ACTIONS is being made to reformat the required actions and allow continued operation with an inoperable snubber, if an evaluation of the attached component shows that this alternative is acceptable.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Criterion 1 - Does not Involve a Significant Increase in the Probability or Consequences of an Accident Previously Evaluated.

Snubbers are installed to maintain the structural integrity of systems and components which either mitigate the consequences of an accident or failure of which may initiate a previously analyzed accident. No physical change to the facility or its operating parameters is being made. The proposed changes were developed by the NRC Staff and maintain the same confidence level as the existing visual snubber inspection schedule as specified within the Generic Letter 90-09. For these reasons, the response of the plant to previously evaluated accidents will remain unchanged. Therefore, this change does not involve an increase in the probability or consequences of an accident previously evaluated.

Criterion-2 - Does Not Create the Possibility of a New or Different Kind of Accident from any Previously Evaluated.

The proposed Technical Specification change does not change the number, type, design, function, or service life of snubbers in either Unit 1 or 2. The proposed change does not alter the configuration of the facility, plant operation, or accident analysis assumptions. Since no change is being made to degrade the design, operation, or maintenance of the plant, a new mode of failure is not created. The increase in the length of snubber visual inspection intervals and clarifications of existing visual inspection acceptance criteria have no effect on accidents. Changes to the visual inspection criteria which deviate from GL 89-09 are clarifications only and do not change the intended meaning of the criteria. The proposed TS change will maintain the snubber operability confidence level within acceptable limits. Therefore, a new or different kind of accident will not occur as a result of these changes.

Criterion 3 - Does Not Involve a Significant Reduction in the Margin of Safety.

The Surveillance Requirements set forth in Generic Letter 90-09 as alternate requirements for snubber visual inspection intervals were developed by the NRC Staff and, as addressed in Generic Letter 90-09 (including ANO's revisions), maintain the same confidence level as the present requirements. Therefore, incorporating the suggested Surveillance Requirements from Generic Letter 90-09 will not reduce any margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801

Attorney for licensee: Nicholas S. Reynolds, Esquire, Winston and Strawn, 1400 L Street, N.W., Washington, D.C. 20005-3502

NRC Project Director: John T. Larkins

Entergy Operations, Inc., Docket Nos. 50-313 and 50-368, Arkansas Nuclear One, Unit Nos. 1 and 2 (ANO-1&2), Pope County, Arkansas

Date of amendment request: October 15, 1991

Description of amendment request: The amendment would revise the Operating Licenses (OLs) and Technical Specifications (TSs) for Arkansas Nuclear One, Unit 1 and 2 (ANO-1 & 2). The proposed changes to the OLs are to add the NRC's standard OL condition for Fire Protection. The proposed changes to the TSs will relocate the Fire Protection requirements from the TSs to the respective Safety Analysis Reports (SARs) verbatim. These changes were prepared in accordance with Generic Letters 86-10 and 88-12.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes implement Generic Letter 86-10 and follow the guidelines given in Generic Letter 88-12. These changes are administrative, in that none of the technical requirements are being changed. The proposed changes remove the existing requirements from the TSs and place them verbatim in the SARs which are internally controlled documents. An amendment to the OLs is being added which prevents making changes to the program, which would adversely affect the ability to achieve and maintain safe shutdown without prior approval. Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident.

(2) Create the possibility of a new or different kind of accident from any previously evaluated.

The proposed changes to the Fire Protection requirements are adminstrative in nature since no design features are being modified. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

(3) Involve a significant reduction in the margin of safety.

The technical requirements for Fire Protection have been moved from the TSs to the SARs verbatim. Design features of ANO-1 & 2 are not being changed. Because the requirements have not changed, operating and testing procedures will, other than for minor changes to reference the SAR instead of the TSs, remain the same. Plant procedures will continue to provide specific instructions for implementing the Fire Protection

requirements. Therefore, the proposed changes do not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801

Attorney for licensee: Nicholas S. Reynolds, Esquire, Winston and Strawn, 1400 L Street, N.W., Washington, D.C. 20005-3502

NRC Project Director: John T. Larkins

Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-321 and 50-366 Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of amendment request: July 15, 1991

Description of amendment request: The proposed amendments would revise Hatch Unit 1 Bases Section 3.6.B. "Reactor Vessel Temperature and Pressure" and Hatch Unit 2 Technical Specification (TS) 3/4.4.6 "Pressure/Temperature Limits" and its associated Bases. The revision of Unit 2 TS is in response to Generic Letters (GL) 88-11 and 91-01. GL 88-11 requires Regulatory Guide (RG) 1.99, Revision 2, be used in calculating nil-ductility reference temperature of reactor vessel belting materials. The reference temperature relates to pressure-temperature (P/T) limits. The deletion of the schedule for removal of Unit 2 reactor pressure vessel (RPV) surveillance capsules from the TSs is in accordance with NRC GL 91-01. The revision to Unit 2 Bases Section 3/4.4.6 is to reflect the changes in TS 3/4.4.6 and to include a brief description of the use of revised TS curves during inservice hydrostatic/leakage testing. This brief description has also been added to Unit 1 Bases Section 3.6.B.

More specifically, proposed Change One is to modify Unit 2 TS P/T curves and associated Bases to reflect the results of surveillance specimen testing and incorporates NRC guidance provided in RG 1.99, Revision 2; and to include a minor clarification to Units 1 and 2 Bases Sections. Proposed Change Two is to delete from the TSs the schedule for removal of the RPV surveillance capsules and to relocate it in Unit 2 Final Safety Analysis Report; and to change the Bases section accordingly.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below for the two changes:

Proposed Change One

1. The proposed change does not increase the probability or consequences of an accident previously evaluated based on the specimen test results (i.e., flux wires, Charpy V-Notch impact test specimens, and uniaxial tensile test specimens) removed from the Unit 2 RPV in the Fall of 1989. The proposed limits are based on the analyses of the specimens using the methods described in 10 CFR 50, Appendix H, ASTM Standard E185, and Regulatory Guide 1.99, Revision 2, and meet the requirements of 10 CFR 50, Appendix G. No plant equipment or system, other than the RPV, is affected by the proposed changes.

2. The proposed change does not create the possibility of a new or different type of accident from any accident previously evaluated, because no new modes of operation are introduced. The proposed change places new limits on pressure and temperature, thus ensuring the RPV will not fail due to brittle fracture. The new limits were calculated using approved methods and meet the requirements of 10 CFR 50, Appendix G. Therefore, the possibility of vessel failure due to incorrect operating limits is not introduced.

3. The proposed change does not significantly reduce a margin of safety, since the margin of safety is maintained by imposing new limits on RPV pressure and temperature to account for the increase in reference temperature.

Proposed Change Two

1. The proposed change does not significantly increase the probability or consequences for an accident previously evaluated because the reactor vessel material surveillance program is not affected by the proposed change. Implementation of the proposed change will delete a license requirement that is redundant to the Code of Federal Regulations. Thus, this proposed Technical Specification is considered to be administrative in nature.

2. The proposed change will not create the possibility of a new or different kind of accident from any accident previously evaluated because implementation of this change will not alter plant configuration or mode of operation. Compliance with existing regulations will ensure continued confidence in reactor vessel material properties.

3. The proposed change will not involve a significant reduction in the margin of safety because the evaluation of reactor vessel material embrittlement is not altered by this change. Additionally, Surveillance Requirement 4.4.6.1.3 and Table 4.4.6.1.3-1 are not beneficial to the primary user of the Technical Specifications (i.e., the reactor operator). Thus, deletion of this material will actually enhance the usability of the Technical Specifications by plant operators.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Appling County Public Library, 301 City Hall Drive, Baxley, Georgia 31513

Attorney for licensee: Ernest L. Blake, Jr., Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: David B. Matthews

Maine Yankee Atomic Power Company, Docket No. 50-309, Maine Yankee Atomic Power Station, Lincoln County, Maine

Date of amendment request: November 15, 1991

Description of amendment request: The proposed amendment would change the Maine Yankee Security Plan to include the guidance of Regulatory Guide 5.66, Access Authorization Program for Nuclear Power Plants, dated June 1991, for cold shutdown. Specifically, Maine Yankee proposes to apply the cold shutdown provisions of Regulatory Guide 5.66 during their 1992 refueling outage, currently scheduled to begin on February 15, 1992. The proposed amendment would be restricted to the duration of the 1992 refueling outage, currently scheduled to last 8 weeks and employ approximately four hundred contracted workers.

Workers granted relaxed access authorization under the provisions of 10 CFR 73.56(i), Access Authorization Program for Nuclear Power Plants, would be issued unique key cards having a distinctive colored background and a restricted access level. These unique key cards will permit access through doors leading to the turbine hall, service building and circulating water pump house. Access through doors leading to other areas of the plant will be restricted to individuals having higher access levels. To further minimize the likelihood of inadvertent migration by these temporary workers beyond the affected area, security Watchpersons or Officers will be posted in the hallway leading to the primary auxiliary building, and to the alleyway between containment and the service building. (Current Maine Yankee Security Procedures require security Watchpersons or Officers at the containment equipment and personnel hatches when open, and at the stairway

leading to the spent fuel pool when refueling is in progress.)

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.92(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated. Maine Yankee's physical security controls will remain unchanged, but security personnel postings and tamper protection measures will be enhanced in the affected areas. The likelihood of an attempted sabotage or tampering incident is therefore believed to be minimal.

Also, because the relaxed access authorization controls are limited to operation at or below the cold shutdown operating condition—and much of the equipment and systems in the affected area will be out of service during this condition—the consequences of tampering or sabotage, should it occur, are therefore minimal. Additionally, for those systems that remain operating, the added tamper control measures, Maine Yankee security, supervisory presence on site dedicated to these temporary workers, and existing operating and abnormal operating procedures provide ample assurance that relaxed access authorization for Maine Yankee's 1992 refueling shutdown does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed amendment will not create the possibility of a new or different kind of accident from any accident previously evaluated. This change is in accordance with 10CFR 73.56(d), and does not create the possibility of a new or different accident from any previously evaluated.

3. The proposed amendment will not involve a significant reduction in a margin of safety. The relaxed access authorization rule was created, in part, because under cold shutdown conditions, it was recognized that the risk of sabotage is low when appropriate security for nuclear fuel is maintained. As described above, appropriate security controls are being maintained during Maine Yankee's 1992 refueling shutdown and this amendment therefore does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis, and based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Wiscasset Public Library, High Street, P.O. Box 367, Wiscasset, Maine 04578

Attorney for licensee: John A. Ritsher, Esquire, Ropes and Gray, One International Place, Boston, Massachusetts 02110-2624

NRC Project Director: Walter R. Butler

Northern States Power Company, Docket No. 50-263, Monticello Nuclear Generating Plant, Wright County, Minnesota

Date of amendment request: October 21, 1991

Description of amendment request: The proposed amendment would revise the Technical Specifications (TS) to include requirements to periodically verify the operability of the reactor feedwater pump trip per the commitments made by the licensee in its response to Generic Letter 89-19 regarding overfill protection. The amendment adds limiting conditions for operation and surveillance requirements for the reactor feedwater pump trip instrumentation to the TS. Specifically, the proposed amendment makes changes to Table 3.2.8 and 4.2.1, updates the associated Bases, and makes several clarifying editorial corrections.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) The proposed amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The overfill protection system is a commercial grade system that mitigates main feedwater overfeed events during reactor power operation. The reactor feedwater pump trip instrument limiting conditions for operation and surveillance requirements are being added to the Technical Specifications. These requirements are part of current plant practice. Other proposed changes correct or clarify existing wording.

Therefore, this amendment will not cause an increase in the probability or consequences of an accident previously evaluated for the Monticello plant.

(2) The proposed amendment will not create the possiblity of a new or different kind of accident from any accident previously analyzed.

This is an administrative change which simply adds an existing testing requirement to the Technical Specifications and makes a number of minor wording corrections. Therefore, the proposed amendment will not create the possibility of a new or different kind of accident.

(3) The proposed amendment will not involve a significant reduction in the margin of safety.

This is an administrative change which simply adds an existing testing requirement to the Technical Specifications and makes a number of minor wording changes. Therefore, this amendment will not reduce the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Minneapolis Public Library, Technology and Science Department, 300 Nicollet Mall, Minneapolis, Minnesota 55401.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037.

NRC Project Director: L. B. Marsh.

Northern States Power Company, Docket Nos. 50-282 and 50-306, Prairie Island Nuclear Generating Plant, Units Nos. 1 and 2, Goodhue County, Minnesota

Date of amendment request: October 4, 1991

Description of amendment request: The proposed amendments consist of two parts. The first part addresses the installation of a single-failure-proof crane and would revise Technical Specification Sections 3.8.B and its associated Bases to remove the restriction related to cask handling; add a new Section 4.19 and associated Bases which establish surveillance requirements for the Auxiliary Building crane lifting devices; and revise Section 5.6 to remove references to the spent fuel cask drop analysis and mitigation design features, and incorporate a new paragraph which states that spent fuel casks will be handled by a single-failure-proof handling system.

In the second part, the proposed amendments makes several changes of an administrative nature in Technical Specification Sections 3.8.B, 5.6, and in Table TS.4.1-2B in order to accommodate the Prairie Island Independent Spent Fuel Storage Installation (ISFSI) and to discuss the Bases for spent fuel boron requirements. Specifically, changes related to the ISFSI include requirements to maintain the boron concentration level, provide an action statement if boron concentration falls below required levels, and require a weekly verification of the boron concentration.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Part 1

(1) The proposed amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed amendment eliminates Technical Specification restrictions on cask handling that are designed to prevent or mitigate the consequences of a cask drop accident. However, in place of these existing restrictions on cask handling, the probability of a cask drop in the spent fuel pool is being significantly reduced by the upgrade of the auxiliary building crane to a single-failure-proof design in accordance with the requirements of NUREG-0612.

While the elimination of the Technical Specification restrictions on cask handling could have a significant effect on the consequences of a cask drop accident, the use of a single-failure- proof handling system will essentially eliminate the possibility of a cask drop event and thus the consequences of a cask drop event are of little concern. This conclusion is supported by the guidance in Section 5 of NUREG-0612 which specifically allows the use of a single-failure-proof handling system in place of the ability to withstand a load drop accident.

Therefore, the use of a single-failure-proof handling system for the handling of spent fuel casks and removal of the current Technical Specification restrictions on cask handling will not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) The proposed amendment will not create the possibility of a new or different kind of accident from any accident previously analyzed.

The proposed amendment eliminates Technical Specification restrictions on cask handling that are designed to prevent or mitigate the consequences of the previously analyzed cask drop accident. The upgrade of the auxiliary building crane to a single-failure-proof design and the handling of spent fuel casks with a single-failure-proof handling system will essentially eliminate the possibility of the previously analyzed cask drop accident.

There are no new failure modes or mechanisms associated with the proposed changes. The single-failure-proof handling system to be used in cask handling will be in compliance with all applicable regulatory requirements and will provide a significantly more reliable system for handling heavy loads than the current auxiliary building crane can provide.

Therefore, no different type of accident is created. No additional safety analyses are necessary. The accident analyses presented in the Updated Safety Analysis Report remain bounding.

(3) The proposed amendment will not involve a significant reduction in the margin of safety.

While the elimination of the Technical Specification restrictions on cask handling could have a significant effect on the consequences of a cask drop accident, the use of a single-failure- proof handling system will essentially eliminate the possibility of cask drop event. This significant reduction in the probability of a cask drop event will result in an increase in the plant's margin of safety.

The use of a single-failure-proof handling system which meets the requirements of NUREG-0612 ensures that the probability of a load drop is sufficiently small such that the activity release from a fuel handling accident assumed in the safety analyses will not be affected. The use of a single-failure-proof handling system for the handling of spent fuel casks and removal of the current Technical Specification restrictions on cask handling will not result in a reduction in any Technical Specification margin of safety. This conclusion is supported by the guidance in Section 5 of NUREG-0612 which specifically allows the use of a single-failure-proof handling system in place of the ability to withstand a load drop accident.

Therefore, the proposed changes will not result in any reduction in the plant's margin of safety.

Part 2

(1) The proposed amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The Technical Specification changes proposed by this portion of the License Amendment Request are required to accommodate the Prairie Island Independent Spent Fuel Installation and the storage of fuel in spent fuel storage casks.

Because the proposed changes are either administrative in nature or constitute additional restrictions not presently in the Technical Specifications, the proposed changes will not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) The proposed amendment will not create the possibility of a new or different kind of accident from any accident previously analyzed.

There are no new failure modes or mechanisms associated with the proposed changes. The proposed changes do not involve any modification in the operational limits or physical design of the involved systems. The change merely incorporates Technical Specification changes required to accommodate the Prairie Island Independent Spent Fuel Storage Installation and the storage of fuel in spent fuel storage casks.

The boron concentration limitations imposed by the proposed changes are consistent with the restrictions currently in the Technical Specifications to mitigate the consequences of a cask drop. Spent fuel pool boron concentration is normally maintained above the 1800 ppm limit. This new Technical Specification requirement will have no effect on plant operations.

As discussed above, the proposed changes do not result in any significant change in the configuration of the plant, equipment design or equipment use nor do they require any change in the accident analysis methodology. Therefore, no different type of accident is created. No safety analyses are affected. The accident analyses presented in the Updated Safety Analysis Report remain bounding.

(3) The proposed amendment will not involve a significant reduction in the margin of safety.

Because the proposed changes are either administrative in nature or constitute additional restrictions not presently in the Technical Specifications, the proposed changes do not involve a reduction in any Technical Specification margin of safety.

The additional restrictions imposed by the new spent fuel pool boron concentration requirements will ensure that k_{eff} for the spent fuel cask, including statistical uncertainties, will be less than or equal to 0.95 for all postulated arrangements of fuel within the cask.

Therefore, the proposed changes will not result in any reduction in the plant's margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts, and Trowbridge, 2300 N Street, NW, Washington, DC 20037.

NRC Project Director: L. B. Marsh.

Virginia Electric and Power Company, Docket Nos. 50-338 and 50-339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of amendment request: November 9, 1987, as supplemented March 31, 1988.

Description of amendment request: The proposed changes would revise the Technical Specifications (TS) for the North Anna Power Station, Units No. 1 and No. 2 (NA-1&2). The changes would reformat the operability and surveillance requirements for the intermediate range (IR) channels to be consistent with NUREG-0452, Revision 4, "Standard Technical Specifications (STS) for Westinghouse Pressurized Water Reactors" (Fall 1981), which are applicable to NA-1&2. Also, the proposed changes would revise the nominal IR high flux trip setpoint. The IR nuclear flux trips provide backup reactor core protection during reactor startup. The IR circuitry provides monitoring of the flux level over an eight decade range ($1x10^{-11}$ to $1x10^{-3}$ amperes). There is no operating condition under which the IR trip provides sole overpower protection. It is a backup trip only, and no credit is taken for the trip in the NA-1&2 Updated Final Safety Analysis Report (UFSAR). Operating experience at NA-1&2 has shown the IR channel response to be sensitive to core loading patterns, varying core burnups and control rod positions, and the variability in the channel response had made it difficult to maintain the channels in proper calibration. Therefore, the proposed change would elevate the nominal IR high flux trip

setpoint from a current equivalent to 25% of rated thermal power to a current equivalent to 35% of rated thermal power.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

[The proposed changes would not:]

1. involve a significant increase in the probability or consequences of an accident previously evaluated. There is no adverse impact on the safety analysis (since no credit is taken for the trips in the existing analyses), and no degradation of the protection system redundancy or reliability. This latter conclusion is based on sensitivity studies which show that the effectiveness of the flux trip system in protecting against the low power reactivity excursions examined in the FSAR is not sensitive to realistic variations in the actual flux trip setpoint.

2. create the probability of a new or different kind of accident from any accident previously identified, since the severity of the analyzed accidents is unchanged, and since only a change to a setpoint and the associated surveillance requirements for the reactor protection system is involved.

3. involve a significant reduction in a margin of safety, since none of the safety analysis input or assumptions are changed, nor are the probability [or] the consequences of any previously analyzed accidents increased.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: The Alderman Library, Special Collections Department, University of Virginia, Charlottesville, Virginia 22903-2498.

Attorney for licensee: Michael W. Maupin, Esq., Hunton and Williams, P.O. Box 1535, Richmond, Virginia 23212.

NRC Project Director: Herbert N. Berkow

Virginia Electric and Power Company, Docket Nos. 50-280 and 50-281, Surry Power Station, Unit Nos. 1 and 2, Surry County, Virginia

Date of amendment request: September 20, 1991

Description of amendment request: The proposed changes would delete the requirements for testing components prior to initiating maintenance on inoperable components in the safety injection, containment spray, recirculation spray, and auxiliary ventilation exhaust systems described in the Surry Power Station Technical Specifications (TS). With regard to the emergency diesel generators (EDGs), the redundant train testing requirement is not deleted. However, a limit is specified for the amount of time an EDG may rendered inoperable for such testing. In addition, typographical errors would be corrected on pages TS 3.3-6, TS 3.4-2, and TS 3.16-4. Also, the correct nomenclature, "system reserve transformer," would replace the obsolete term, "autotransformer," on page TS 3.16-4.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Operation of the facility in accordance with the proposed amendment[s] would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The design and performance criteria for the systems affected by this change are not being altered. The systems are designed to mitigate the consequences of accidents, therefore their availability has no bearing on the probability of an accident's occurrence. Also, since neither the systems themselves nor related test methods are being changed, there will be no effect on accident precursors. Therefore, this change does not increase the probability of occurrence of an accident previously evaluated.

In the cases of the Low Head Safety Injection System (T.S. 3.3), the Containment and Recirculation Spray Systems (T.S. 3.4), and the Auxiliary Ventilation Exhaust Filter Trains (T.S. 3.22), the current opposite train testing requirements have the potential for increasing consequences due to inability to perform a mitigating function since both trains have been declared inoperable (one due to failure and the other due to surveillance testing). Elimination of these requirements will serve to ensure that one train of safety equipment is always available to mitigate the consequences of a design basis accident (DBA) without increasing the rate of failure of the tested equipment. Despite a diminished likelihood of detecting a failure, should it occur during the surveillance interval when the opposite train failed, the probability of failure of the tested equipment would potentially be reduced due to a lower number of demands for performance. Furthermore, the equipment's ability to perform according to design is not adversely affected. Thus, in these cases, this change does not increase the probability or consequences of an accident previously evaluated.

In the case of the [EDGs] (T.S. 3.16), allowing two EDGs to be inoperable concurrently for a period of two hours impacts the reliability of the emergency power supply to, but not the actual, functional operability of safety systems in the event that a DBA was to occur during the period of inoperability. This relatively insignificant two-hour period of inoperability is used to determine whether or not a common mode failure of even greater significance is involved. Given that opposite train testing of an EDG would not be permitted without verifying that two offsite AC circuits are operable, this change does not involve a significant increase in the consequences of an accident previously evaluated.

(2) Use of the modified specification would not create the possibility of a new or different kind of accident from any accident previously evaluated.

As stated above, the proposed changes do not involve changes to the physical plant or operations. [These changes modify] equipment testing frequency requirements only and no new accident precursors are generated. Therefore, the proposed changes do not create the possibility of a new or different kind of accident.

(3) Use of the modified specification would not involve a significant reduction in a margin of safety.

The routine surveillance requirements which remain in the Technical Specifications, coupled with the EDG opposite train testing, provide adequate assurance of equipment operability. Since the reduction of testing may increase availability due to a lower number of challenges to the Low Head Safety Injection, the Containment and Recirculation Spray, and the Auxiliary Ventilation Exhause Filter Systems, margins of safety may be increased. In addition, because the performance of the equipment is not being changed nor is there any modification to the plant proposed by this Technical Specification change request, margins of safety associated with the equipment's ability to perform its design function will not be significantly reduced.

In addition, the changes to TS 3.3-6, TS 3.4-2 and TS 3.16-4 are administrative in nature and, therefore, do not involve a significant increase in the probability or consequences of an accident previously evaluated, would not create the possibility of a new or different kind of accident from any accident previously evaluated, and do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Swem Library, College of William and Mary, Williamsburg, Virginia 23185.

Attorney for licensee: Michael W. Maupin, Esq., Hunton and Williams, Post Office Box 1535, Richmond, Virginia 23213.

NRC Project Director: Herbert N. Berkow

Notice Of Issuance Of Amendment To Facility Operating License

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing in connection with these actions was published in the **Federal Register** as indicated. No request for a hearing or petition for leave to intervene was filed following this notice.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendments, (2) the amendments, and (3) the Commission's related letters, Safety Evaluations and/or Environmental Assessments as indicated. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, D.C., and at the local public document rooms for the particular facilities involved. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects.

Baltimore Gas and Electric Company, Docket Nos. 50-317 and 50-318, Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Calvert County, Maryland

Date of application for amendments: August 27, 1991, as superseded by letter dated August 30, 1991.

Brief description of amendments: The amendments revise the Technical Specification (TS) Table 4.3-2 and adds Note 2 for both Units 1 and 2 to allow the Safety Injection Actuation Signal (SIAS) logic that starts the Emergency Diesel Generators (EDGs) to be moved to a different subchannel of the SIAS. TS Table 4.3-2, Notes 3 through 6, wording is changed from "may be" to "are." These notes identify the logic circuits which are currently exempted from testing during power operation. The change also deletes TS 3/4.6.1.8 which provides limiting conditions for operation (LCO) and surveillance requirements for the containment vent isolation valves. These interim requirements are no longer needed since additional automatic isolation signals have been provided to assure closure of the containment isolation valves.

Date of issuance: October 31, 1991.

Effective date: October 31, 1991

Amendment Nos.: 164 and 144

Facility Operating License Nos. DPR-53 and DPR-69: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 18, 1991 (56 FR 47230) The Commission's related evaluation of these amendments is contained in a Safety Evaluation dated October 31, 1991.

No significant hazards consideration comments received: No

Local Public Document Room location: Calvert County Library, Prince Frederick, Maryland.

Connecticut Yankee Atomic Power Company, Docket No. 50-213, Haddam Neck Plant, Middlesex County, Connecticut

Date of application for amendment: August 13, 1991

Brief description of amendment: The amendment will allow temporary cooling of the operable emergency diesel generator in MODE 6 using alternate means while service water modifications to the emergency diesel generator heat exchangers are being performed during the upcoming refueling outage (Cycle 17).

Date of Issuance: November 7, 1991

Effective date: November 7, 1991

Amendment No.: 145

Facility Operating License No. DPR-61. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 4, 1991 (56 FR 43807) The Commission's related evaluation of this amendment is contained in a Safety Evaluation dated November 7, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room location: Russell Library, 123 Broad Street, Middletown, Connecticut 06457.

Duke Power Company, et al., Docket Nos. 50-413 and 50-414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina

Date of application for amendments: October 28, 1987, as supplemented June 18, 1991

Brief description of amendments: The amendments revise the Technical Specifications with four changes that are editorial in nature, corrections of typographical errors, and clarifications.

Date of issuance: November 4, 1991

Effective date: November 4, 1991

Amendment Nos.: 91, 85

Facility Operating License Nos. NPF-35 and NPF-52: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** November 15, 1989 (54 FR 47601) and August 21, 1991 (56 FR 41579) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 4, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room location: York County Library, 138 East Black Street, Rock Hill, South Carolina 29730

Duke Power Company, Docket Nos. 50-369 and 50-370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of application for amendments: April 18, 1991

Brief description of amendments: The amendments revise Technical Specification 5.3.1 to enable the use of two demonstration assemblies during McGuire Unit 1 Cycle 8, 9 and 10.

Date of issuance: October 31, 1991

Effective date: October 31, 1991

Amendment Nos.: 127, 109

Facility Operating License Nos. NPF-9 and NPF-17: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** June 12, 1991 (56 FR 27041) The Commission's related evaluation of the amendments is contained in an Environmental Assessment dated September 16, 1991, and in a Safety Evaluation dated October 31, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room location: Atkins Library, University of North Carolina, Charlotte (UNCC Station), North Carolina 28223

Entergy Operations, Inc., Docket No. 50-313, Arkansas Nuclear One, Unit No. 1, Pope County, Arkansas

Date of amendment request: June 27, 1991, as supplemented August 22, October 4, and October 16, 1991.

Brief description of amendment: The amendment revised the Technical Specifications for Arkansas Nuclear One, Unit 1, to allow a 17-ton shipping cask with two spent fuel rods to be handled for shipping by the auxiliary building crane during the period from October 15, 1991, through January 31, 1991.

Date of issuance: November 6, 1991

Effective date: November 6, 1991

Amendment No.: 153

Facility Operating License No. DPR-51. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 7, 1991 (56 FR 37581) The August 22, October 4, and October 16, 1991, letters provided clarifying information that did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 6, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801

Entergy Operations, Inc., Docket No. 50-282, Waterford Steam Electric Station, Unit 3, St. Charles Parish, Louisiana

Date of amendment request: September 25, 1991

Brief description of amendment: The amendment revised the Technical Specifications by adding a note to the emergency diesel generator test frequency table to not require the test failure on August 20, 1991, to count for adjustment of test frequency of the "A" diesel generator.

Date of issuance: November 1, 1991

Effective date: November 1, 1991

Amendment No.: 71

Facility Operating License No. NPF-38. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** October 1, 1991 (56 FR 49802) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 1, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room location: University of New Orleans Library, Louisiana Collection, Lakefront, New Orleans, Louisiana 70122.

Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-321 and 50-366, Edwin I. Hatch Nuclear Plant, Units 1 and 2, Appling County, Georgia

Date of application for amendments: April 12, 1991

Brief description of amendments: The amendments change the TSs for Units 1 and 2 to conform to the NRC staff position on Inservice Inspection (ISI) in Generic Letter (GL) 88-01, "NRC Position on IGSCC in BWR Austenitic Stainless Steel Piping," and NRC Safety Evaluation dated February 16, 1990.

Date of issuance: November 1, 1991

Effective date: 60 days from the date of issuance

Amendment Nos.: 176 & 117

Facility Operating License Nos. DPR-57 and NPF-5. Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** June 26, 1991 (56 FR 29275) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 1, 1991

No significant hazards consideration comments received: No.

Local Public Document Room location: Appling County Public Library, 301 City Hall Drive, Baxley, Georgia 31513

Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-424 and 50-425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of application for amendments: August 14, 1990

Brief description of amendments: The amendments change the Technical Specifications to delete the Negative Flux Rate Trip (NFRT) function from tables specifying Reactor Trip System instrumentation requirements.

Date of issuance: November 1, 1991

Effective date: Phase 1 effective beginning with Unit 1 Cycle 4; Phase 2 effective beginning with Unit 2 Cycle 3

Amendment Nos.: 48 and 27 (Phase 1); 49 and 28 (Phase 2)

Facility Operating License Nos. NPF-68 and NPF-81: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** May 1, 1991 (56 FR 20035) The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 1, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room location: Burke County Library, 412 Fourth Street, Waynesboro, Georgia 30830

Gulf States Utilities Company, Docket No. 50-458, River Bend Station, Unit 1 West Feliciana Parish, Louisiana

Date of amendment request: August 20, 1991, as supplemented by letters dated February 13, 1991, April 11, 1991, and August 9, 1991.

Brief description of amendment: The amendment revises Technical Specification 6.5.1, "Facility Review Committee," and 6.5.3, "Nuclear Review Board," by deleting the specific composition list for each and replacing it with general statements defining the number of members and the level of expertise for membership. Additional changes include qualification of alternate members, definition of a quorum, and deletion of a reference to the first year of plant operation that has been completed.

Date of issuance: November 6, 1991

Effective date: November 6, 1991, to be implemented 30 days from date of issuance.

Amendment No.: Amendment No. 61

Facility Operating License No. NPF-47. The amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** October 3, 1990 (55 FR 40466) The February 13, 1991, submittal requested partial withdrawal of the original amendment request. A Notice of Withdrawal of Application for Amendment was published on April 11, 1991 (56 FR 14718). The April 11, 1991, and August 9, 1991, submittals provided additional clarifying information and did not change the initial no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 6, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room location: Government Documents Department, Louisiana State University, Baton Rouge, Louisiana 70803

Houston Lighting & Power Company, City Public Service Board of San Antonio, Central Power and Light Company, City of Austin, Texas, Docket Nos. 50-498 and 50-499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: December 21, 1990, as supplemented by letter dated October 15, 1991.

Brief description of amendments: The amendments revised TS 3.4.9.3 to remove a conflict between it and TS 4.0.5. The change will permit full operability testing of an inoperable

pressurizer PORV following maintenance on the PORVs.

Date of issuance: November 8, 1991

Effective date: November 8, 1991

Amendment Nos.: 31 and 22

Facility Operating License Nos. NPF-76 and NPF-80. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** October 2, 1991 (56 FR 49918) The October 15, 1991, submittal provided additional clarifying information and did not change the initial no significant hazards consideration determination. The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 8, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room Location: Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, Texas 77488

Nebraska Public Power District, Docket No. 50-298, Cooper Nuclear Station, Nemaha County, Nebraska

Date of amendment request: April 23, 1991, as supplemented November 4, 1991

Brief description of amendment: The amendment changed the Technical Specifications to: 1) permit the use of certain NRC-approved neutron absorber materials in control rods, 2) require that Monthly Operating Reports be submitted in the manner specified in 10 CFR 50.4 and no later than the 15th day of the following month, and 3) make editorial changes that reflect the change of title of the "Safety Analysis Report" to the "Updated Safety Analysis Report."

Date of issuance: November 6, 1991

Effective date: November 6, 1991

Amendment No.: 149

Facility Operating License No. DPR-46. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** May 29, 1991 (56 FR 24212) The additional information contained in the supplemental letter dated November 4, 1991, was clarifying in nature and thus within the scope of the initial notice and did not affect the NRC staff's proposed no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 6, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room location: Auburn Public Library, 118 15th Street, Auburn, Nebraska 68305.

Public Service Electric & Gas Company, Docket No. 50-354, Hope Creek Generating Station, Salem County, New Jersey

Date of application for amendment: September 6, 1991

Brief description of amendment: This amendment changed the channel functional test surveillance intervals for the Reactor Protection System (RPS) Electrical Protective Assemblies (EPAs) and Power Range Neutron Monitoring System EPAs from "at least once per 6 months" to "each time the plant is in cold shutdown for a period of more than 24 hours, unless performed in the previous 6 months." This change to the surveillance intervals is in accordance with the guidance contained in Generic Letter 91-09.

Date of issuance: November 5, 1991

Effective date: As of the date of issuance and shall be implemented within sixty days of the date of issuance.

Amendment No. 44

Facility Operating License No. NPF-57. This amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** October 2, 1991 (56 FR 49925) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 5, 1991.

No significant hazards consideration comments received: No

Local Public Document Room location: Pennsville Public Library, 190 S. Broadway, Pennsville, New Jersey 08070

Tennessee Valley Authority, Docket Nos. 50-259, 50-260 and 50-296, Browns Ferry Nuclear Plant, Units 1, 2, and 3, Limestone County, Alabama

Date of application for amendment: September 13, 1991 (TS-299)

Brief description of amendment: Technical specifications surveillance frequency requirements for certain logic signal functional tests were extended from six months to 18 months.

Date of issuance: November 4, 1991

Effective date: November 4, 1991

Amendment No.: 186 - Unit 1; 199 - Unit 2; 158 - Unit 3

Facility Operating License Nos. DPR-33, DPR-52 and DPR-68: Amendments revise the technical specifications.

Date of initial notice in **Federal Register:** October 2, 1991 (56 FR 49927) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 4, 1991.

No significant hazards consideration comments received: None

Local Public Document Room location: Athens Public Library, South Street, Athens, Alabama 35611.

TU Electric Company, Docket No. 50-445, Comanche Peak Steam Electric Station, Unit 1, Somervell County, Texas

Date of amendment request: October 1, 1991

Brief description of amendment: The amendment revises Technical Specification Surveillance 4.5.2.h by lowering the minimum centrifugal charging pump and high head safety injection pump flow rate surveillance acceptance criteria. The purpose for the change is to avoid pump operation at flow rates exceeding runout limits for the pumps.

Date of Issuance: November 13, 1991

Effective date: November 13, 1991, to be implemented with 30 days of issuance

Amendment No.: Amendment No. 7

Facility Operating License No. NPF-87. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** October 9, 1991 (56 FR 50956) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 13, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room Location: University of Texas at Arlington Library, Government Publications/Maps, 701 South Cooper, P. O. Box 19497, Arlington, Texas 76019.

Wisconsin Public Service Corporation, Docket No. 50-305, Kewaunee Nuclear Power Plant, Kewaunee County, Wisconsin

Date of application for amendment: June 4, 1991, as supplemented September 4 and September 27, 1991.

Brief description of amendment: The amendment revised Technical Specification (TS) Section 4.13, "Radioactive Materials Sources," and TS Table 3.5-2, "Instrument Operation Conditions for Reactor Trip." The revisions added a new radiation calibrator and fission detectors to the list of sealed sources which are exempt from periodic leak testing, stated that fission detectors shall be leak tested prior to being subjected to core flux, and described the P-6 permissive set point in percent power consistent with the readout of the new fission detectors. Administrative changes are also included.

Date of issuance: November 12, 1991

Effective date: November 12, 1991

Amendment No.: 94

Facility Operating License No. DPR-43. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 7, 1991 (56 FR 37594) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 12, 1991. No significant hazards consideration comments received: No.

Local Public Document Room location: University of Wisconsin Library Learning Center, 2420 Nicolet Drive, Green Bay, Wisconsin 54301.

Wolf Creek Nuclear Operating Corporation, Docket No. 50-482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: June 21, 1991, as supplemented by letter dated September 11, 1991

Brief description of amendment: The amendment revises Technical Specification 4.6.2.3, "Containment Cooling System," and affected Technical Specification Bases to reduce the minimum required cooling water flow to the containment cooling units during accident conditions. The amendment also changes a monthly surveillance from a verification of flow to the coolers to a verification of valve alignment in order to ensure the coolers will perform their safety function.

Date of Issuance: November 4, 1991

Effective date: November 4, 1991

Amendment No.: Amendment No. 50

Facility Operating License No. NPF-42. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 7, 1991 (56 FR 37596) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 4, 1991. The September 11, 1991 letter provided clarifying information and an additional surveillance requirement to the proposed Technical Specification that did not change the initial proposed no significant hazards consideration determination.

No significant hazards consideration comments received: No.

Local Public Document Room Locations: Emporia State University, William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621

Wolf Creek Nuclear Operating Corporation, Docket No. 50-482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: March 5, 1991

Brief description of amendment: The amendment changes the Reactor Coolant System thermal design flow from the current Technical Specification value of 95,700 gpm/loop to a new value of 93,750 gpm/loop. Other Technical Specification changes related to the reduced thermal design flow include an increase in the setpoint of the pressurizer-pressure-low reactor trip system instrumentation, revision of Figure 2.1-1, reactor core safety limits, and various changes to the Bases to reflect the reduction in thermal design flow and utilization of a different critical heat flux correlation.

Date of Issuance: November 6, 1991

Effective date: November 6, 1991

Amendment No.: Amendment No. 51

Facility Operating License No. NPF-42. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** April 3, 1991 (56 FR 13673) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 6, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room Locations: Emporia State University, William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621

Wolf Creek Nuclear Operating Corporation, Docket No. 50-482, Wolf Creek Generating Station, Coffey County, Kansas

Date of amendment request: June 11, 1991 as supplemented by letters dated August 30, 1991, and September 20, 1991.

Brief description of amendment: The amendment revises Technical Specification Tables 2.2.1 and 4.3.1 and associated Bases to reflect the replacement of the existing resistance temperature detector (RTD) bypass system with an RTD thermowell system.

Date of Issuance: November 7, 1991

Effective date: November 7, 1991

Amendment No.: Amendment No. 52

Facility Operating License No. NPF-42. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** August 7, 1991 (56 FR 37395) The August 30, 1991, and September 20, 1991, submittals provided additional clarifying information and did not change the initial no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 7, 1991.

No significant hazards consideration comments received: No.

Local Public Document Room Locations: Emporia State University, William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621

Dated at Rockville, Maryland, this 20th day of November 1991.

For the Nuclear Regulatory Commission

Steven A. Varga,

Director, Division of Reactor Projects - I/II, Office of Nuclear Reactor Regulation

[Doc. 91-28367 Filed 11-26-91; 8:45 am]

BILLING CODE 7590-01-D

[Docket No. 50-54]

Cintichem, Inc., Research Reactor; Order Authorizing Dismantling of Facility and Disposition of Component Parts

By application dated October 19, 1990, as supplemented on January 11, 14, 28, February 19, March 8, April 24, May 21, June 25, July 17, August 6, and October 2, 1991, Cintichem, Incorporated (the licensee) requested authorization to dismantle the research reactor, Facility Operating License No. R-81, located in Tuxedo, New York and to dispose of the component parts, in accordance with the plan submitted as part of the application. A "Proposed Issuance of Orders Authorizing Disposition of Component Parts and Terminating Facility License" was published in the **Federal Register** on January 14, 1991 (56 FR 1422). A petition for leave to intervene was filed by the New York State Department of Environmental Conservation (NYSDEC) on February 14, 1991, but was withdrawn by NYSDEC on March 13, 1991, after a cooperation agreement was entered into between NYSDEC and the staff of the Commission covering NYSDEC's involvement in respect to the decommissioning activities.

The U.S. Nuclear Regulatory Commission (the Commission) has reviewed the application with respect to the provisions of the Commission's rules and regulations and has found that the dismantling and disposal of component parts as stated in the licensee's dismantling plan will be consistent with the regulations in 10 CFR chapter I, and will not be inimical to the common defense and security or to the health and safety of the public. The basis of these findings is set forth in the concurrently issued Safety Evaluation by the Office of Nuclear Reactor Regulation.

The Commission has prepared an Environmental Assessment and Finding of No Significant Impact for the proposed action. Based on that Assessment, the Commission has determined that the proposed action will not result in any significant environmental impact and that an environmental impact statement need not be prepared. (56 FR 58589 November 20, 1991)

Accordingly, it is ordered that the licensee is authorized to dismantle the reactor facility and dispose of the component parts as outlined in appendix A attached to this Order. The Technical and Environmental Specifications that are applicable during the decommissioning period are in appendix B attached to this Order.

After completion of the dismantling and disposal, the licensee will submit a report on the radiation survey it has performed to confirm that radiation and surface contamination levels in the facility area satisfy the values specified in the dismantling plan and in the Commission's guidance. Following an inspection by representatives of the Commission to verify the radiation and contamination levels in the facility, consideration will be given to issuance of a further order terminating Facility Operating License No. R-81.

For further details with respect to this action, see (1) the licensee's application for authorization to dismantle the facility and dispose of component parts, dated October 19, 1990, as supplemented on January 11, 14, 28, February 19, March 8, April 24, May 21, June 25, July 17, August 6, and October 2, 1991; (2) the Commission's related Safety Evaluation; and (3) the Environmental Assessment and Finding of No Significant Impact. These items are available for public inspection at the Commission's Public Document Room, 2120 L Street NW., Washington, DC. Copies of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Advanced Reactors and Special Projects.

Dated at Rockville, Maryland this 21st day of November 1991.

For the Nuclear Regulatory Commission.

Dennis M. Crutchfield, Director,

Division of Advanced Reactors and Special Projects, Office of Nuclear Reactor Regulation.

[FR Doc. 91-28457 Filed 11-26-91; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-483]

Union Electric Co.; Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF-30, issued to Union Electric Company (the licensee), for operation of the Callaway Plant, Unit No. 1 located in Callaway County, Missouri.

The amendment would correct the Callaway Technical Specification (TS) Surveillance Requirement 4.8.1.1.2.F.(2) by (deleting the reference to a value "greater than or equal to 1352 kW" as a criterion for an acceptable emergency diesel generator (EDG) load rejection test. That value was derived from sizing design calculations and is not representative of the largest single load on the diesel under design basis conditions. The revised requirement would reflect the criteria that have been used to demonstrate the capability of the EDGs to withstand the rejection of the largest load; namely, that voltage and frequency can be maintained within specified limits.

The proposed amendment is necessary in order to bring the current surveillance test into full, literal compliance with the TSs. The tests as conducted have been consistent with the licensing basis for the facility and have conformed with NRC Regulatory Guides 1.9 and 1.108.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee has provided an evaluation indicating that the proposed change does not involve a significant hazards consideration under the Commission's regulations in 10 CFR 50.92 as follows:

The proposed change does not involve a significant hazards consideration because operation of Callaway Plant in accordance with this change would not:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated.

The load rejection surveillance test in question is taken from Regulatory Guide 1.9, Revision 1, Position C.5 and Regulatory Guide 1.108, Revision 1, Position C.2.a.(4) which call for a test of the loss of the largest single load. This surveillance test is performed at Callaway by disconnecting an ESW pump motor with the ESW and AC power systems aligned in their emergency operation modes. Currently there is no direct way to assure that this rejected load equals the 1352 kW listed in the Technical Specifications. However, the actual kW load associated with the ESW pump motors is less than 1352 kW and can vary slightly depending on plant conditions and motor efficiency. This variance is insignificant as assured by the preventive maintenance program that monitors pump/driver performance. Therefore, there should be no listed value for this load in the Technical Specifications nor is one needed to satisfy the regulatory guide requirements. The intended requirement is to assure that the diesel meets the specified acceptance criteria given the rejection of the ESW pump motor load when the plant is in a lineup representative of emergency conditions at Callaway.

No new design requirements are being imposed on any plant systems or components. There is no change to the 12 second diesel start time assumed in the accident analyses and verified by Technical Specification 4.8.1.1.2.a.(4) nor is there is a change to the acceptance criteria for any of the diesel generator surveillance tests, including the startup, rated load, and load rejection tests. There will be no effect on the capability of the diesel generators to supply the loads assumed in the mitigation of the accidents analyzed in FSAR Chapter 15.

(2) Create the possibility of a new or different kind of accident from any previously evaluated.

The proposed change does not involve any design changes or hardware modifications nor will there be any changes to the intended manner of plant operation or in the method by which any safety-related plant system performs its safety function. No new accident initiators, transient precursors, failure

mechanisms, or limiting single failures are introduced as a result of this change.

(3) Involve a significant reduction in a margin of safety.

The requirement to test for the loss of the single largest load will continue to be satisfied given the approval of this amendment application. The proposed change does not alter the manner in which safety limits or limiting safety system settings are determined. The proposed change will have no effect on those plant systems necessary to assure the accomplishment of protection functions and meet the accident analysis acceptance criteria in FSAR Chapter 15. There will be no impact on DNBR limits, F_Q, F-delta-H, LOCA PCT, or any other defined safety margin.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied.

Accordingly, the Commission proposes to determine that this change does not involve a significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within fifteen (15) days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to room P-223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland, from 7:30 a.m. to 4:15 p.m. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC. The filing of requests for hearing and petitions for leave to intervene is discussed below.

By December 27, 1991, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for hearing and a petition for leave to intervene. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the Local Public Document Room located at the Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first pre-hearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene, which must include a list of the contentions that are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If the amendment is issued before the expiration of 30 days, the Commission will make a final determination on the issue of no significant hazards considerations. If a hearing is requested, the final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves a no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 15-day notice period. However, should circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 15-day notice period, provided that its final determination is that the amendment involves no significant hazards considerations. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1 (800) 325-6000 (in Missouri 1 (800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to John N. Hannon: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to Gerald Charnoff, Esq. and Thomas A. Baxter, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW., Washington, DC 20037, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated November 15, 1991, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the Local Public Document Room, located at the Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

Dated at Rockville, Maryland, this 20th day of November 1991.

For the Nuclear Regulatory Commission.

James R. Hall, Sr.,

Project Manager, Project Directorate III-3; Division of Reactor Projects III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 91-28458 Filed 11-26-91; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 30-03255, License No. 42-00084-06 EA 91-157]

In the Matter of Department of Veterans Affairs; Houston, TX; Confirmatory Order Modifying License (Effective Immediately)

I

The Department of Veterans Affairs (Licensee) is the holder of NRC License No. 42-00084-06 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR parts 30 & 35. The license authorizes the Licensee to possess and use a variety of radioisotopes in medical research, diagnosis and therapy at the Veterans Administration Medical Center (VAMC) in Houston, Texas. The license was most recently amended in its entirety on February 25, 1991, and was due to expire on August 31, 1991. The Licensee has submitted a timely application for the renewal of the license.

II

As indicated in the Notice of Violation and Proposed Imposition of Civil Penalty ($25,000) issued to the Licensee on this same date, a June 10–12 and June 18–20, 1991 inspection of this Licensee's NRC-licensed activities disclosed 22 violations of NRC radiation safety regulations and license commitments. In April 1990, NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty ($7,500) as a result of similar inspection findings. On May 10, 1990, the licensee paid this civil penalty. Inspection findings of this nature in successive inspections reduce NRC's confidence in the VAMC's ability to manage its NRC-license activities in a manner consistent with NRC's expectations of a holder of a broad-scope medical license.

At an enforcement conference conducted at the VAMC on August 9, 1991, the Licensee made a number of commitments to take action to resolve what the NRC perceived as fundamental weaknesses in the management of the Licensee's radiation safety program. Among the Licensee's planned corrective actions was a program of quarterly audits of its NRC-licensed programs to be conducted by representatives of the Department of Veterans Affairs (DVA) National Advisory Committee on Radiation Safety.

III

A. By letters dated August 13 and 28, 1991, the Licensee agreed that DVA's National Advisory Committee on Radiation Safety (Advisory Committee) will:

1. Direct audits of the Licensee's NRC-licensed activities;

2. Establish standards for the audit process and submit such standards, and the credentials of the auditors, to NRC Region IV for its approval;

3. Direct six audits at calendar quarterly intervals within 18 months of the date of this Order;

4. Provide written audit reports, including recommended corrective actions for findings identified during the audits, to the Licensee within two weeks of each audit;

5. Provide written audit reports to NRC Region IV within two weeks of each audit; and

6. Evaluate the Licensee's written responses to the audit findings (see paragraph B.1.).

B. By letter dated August 13, 1991, the Licensee agreed that: The Licensee will provide written responses to the Advisory Committee's audit findings, including corrective actions for deficiencies identified during each audit, and measures to prevent recurrence of similar deficiencies.

The NRC staff has reviewed the Licensee's submittal and agrees that conduct of the audits would contribute to providing additional assurance that licensed activities at the VAMC will be carried out in accordance with NRC regulations and license commitments.

I find that the Licensee's commitments as set forth in its letters of August 13 and 28, 1991, are acceptable and necessary and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that the public health, safety, and interest require that the Licensee's commitments in its August 13 and 28, 1991, letters be confirmed by this Order. The licensee has agreed to this action. Pursuant to 10 CFR 2.202, I have also determined that the public health, safety, and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161c, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR parts 30 and 35, *it is hereby ordered*, effective immediately, that license no. 42-00084-06 is modified as follows:

A. The Licensee shall have DVA's National Advisory Committee on Radiation Safety (Advisory Committee):

1. Direct audits of the Licensee's NRC-licensed activities;

2. Establish standards for the audit process and submit such standards, and

the credentials of the auditors, to NRC Region IV for its approval;

3. Direct six audits at calender quarterly intervals (three months) within 18 months of the date of this Order, the first audit shall be completed within three months of this Order;

4. Provide written audit reports, including recommended corrective actions for findings identified during the audits, to the Licensee within two weeks of the completion of the audit;

5. Provide written audit reports to NRC Region IV within two weeks of each audit; and

6. Evaluate the Licensee's written responses to the audit findings (see paragraph B.).

B. The Licensee shall provide written responses to the Advisory Committee's audit findings, including corrective actions for deficiencies identified during each audit, and measures to prevent recurrence of similar deficiencies.

The Regional Administrator, Region IV, may relax or rescind, in writing, any of the above conditions upon a showing by the Licensee of good cause.

V

Any person other than the Licensee adversely affected by this Confirmatory Order may request a hearing within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, suite 1000, Arlington, Texas 76011, and to the Licensee. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. An answer or a request for hearing shall not stay the immediate effectiveness of this order.

Dated at Rockville, Maryland this 15th day of November 1992.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support.

[FR Doc. 91-28459 Filed 11-26-91; 8:45 am]

BILLING CODE 7590-01-M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. 301-80]

Canadian Provincial Practices Affecting Canadian Imports of Beer

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of proposed determinations under section 304 of the Trade Act of 1974, as amended ("Trade Act"); and request for public comments.

SUMMARY: On June 29, 1990, the United States Trade Representative (USTR) initiated an investigation under section 302 of the Trade Act of certain practices of Canadian provincial liquor boards with respect to imported beer. The USTR proposes to determine that rights of the United States under the General Agreement on Tariffs and Trade are being denied as a result of these practices and, in the event that a mutually satisfactory resolution cannot be reached with Canada, to take appropriate action. Among the actions that the USTR would consider taking is the suspension of duty bindings and increase in duties on Canadian beer and other alcoholic beverages. The USTR invites public comments.

DATES: Comments from interested persons must be submitted in writing by 12 p.m. on December 23, 1991. The USTR expects to make final determinations under section 304 no later than December 29, 1991.

ADDRESSES: Comments should be addressed to the Chairman, Section 301 Committee, Office of the United States Trade Representative, room 223, 600 17th Street, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Rick Ruzicka, Director, Canadian Affairs, (202) 395-3412, Joseph Papovich, Senior Trade Advisor for Agricultural Affairs, (202) 395-5006, or Andrew Shoyer, Assistant General Counsel, (202) 395-7203.

SUPPLEMENTARY INFORMATION: In 1985, a panel was established by the Contracting Parties to the General Agreement on Tariffs and Trade (GATT) at the request of the European Community with regard to market access restrictions on imported alcoholic beverages, including beer, maintained by Canadian provincial marketing agencies or "liquor boards." In most of the ten Canadian provinces, these liquor boards not only regulate the marketing of domestic beer in the province, but serve as import monopolies and may also warehouse, distribute, and retail imported beer. The panel found in 1988 that certain practices were inconsistent with the GATT, including: (a) Restrictions on the number of locations at which imported beer may be sold ("points of sale"); (b) discriminatory practices concerning the authorization needed from the liquor board to begin to sell a brand of beer in the province or continue to have it sold ("listing" or "delisting" practices); and (c) discriminatory markups on the price of beer sold by the liquor boards. The GATT Contracting Parties requested that Canada take all reasonable measures available to address these practices.

Canada failed to eliminate the practices found in 1988 to be inconsistent with the GATT. In fact, some provinces have instituted practices since 1988 that have caused competitive conditions to worsen for U.S. brewers. On June 29, 1990, an investigation was initiated pursuant to section 302 of the Trade Act upon the petition of G. Heileman Brewing Company with respect to provincial liquor board practices concerning imported beer. On the same day, the United States requested consultations with Canada under Article XXIII:1 of the GATT, as required under section 303 of the Trade Act. Consultations were held with Canada in July 1990, but no mutually satisfactory resolution was reached at that time. On September 14, 1990, the Stroh Brewery Company submitted a section 301 petition concerning pricing and distribution practices in the province of Ontario. On October 19, 1990, the USTR determined to address these allegations in the existing investigation rather than to initiate a separate investigation.

At the December 1990 session of the Contracting Parties, the United States requested that the Panel that had issued the 1988 report in the case brought by the European Community be reconvened to consider the extent to which Canada was meeting its GATT obligations with respect to provincial liquor board practices concerning markups, points of sale and listing/delisting. In addition, the United States requested that the Panel consider certain practices that had not been addressed in the 1988 report, including: (1) Restrictions on

private delivery; (2) minimum purchase or sale price restrictions; (3) discriminatory imposition of cost-of-service charges; (4) discriminatory pricing methodologies; (5) discriminatory imposition of environmental taxes; and (6) failure to provide sufficient notice of new practices.

The Panel was established on February 6, 1991, and issued its report to the Contracting Parties on October 16, 1991. The Panel concluded, *inter alia*, that Canada had failed to make "serious, persistent and convincing efforts" to ensure observance by the provincial liquor boards of the provisions of the GATT as they relate to the restrictions on points of sale and discriminatory markups that had been found in 1988 to be inconsistent with the GATT, and that this failure constituted *prima facie* nullification and impairment of U.S. rights under the GATT. Moreover, the Panel found that the restrictions on the private delivery of imported beer maintained by 8 of the 10 Canadian provinces were inconsistent with Canada's national treatment obligation under the GATT, and that minimum price requirements set in relation to domestic prices were also inconsistent with the GATT. The Panel recommended that the Contracting Parties request Canada to take reasonable steps to ensure observance of the provisions of the GATT by the provincial liquor boards, and to report to the Contracting Parties on the measures taken with regard to access to points of sale and differential markups before the end of March 1992 and with regard to private delivery and other matters before the end of July 1992. A copy of the Panel report has been placed in the public file in this matter (Docket No. 301-80).

Consultations were commenced with the Government of Canada following receipt of the Panel report, but no mutually satisfactory resolution has been reached.

Proposed Determinations

On the basis of the investigation initiated under section 302 of the Trade Act, the consultations conducted pursuant to section 303 of the Trade Act, and the final report of the GATT dispute settlement panel, the USTR proposes to determine that the rights to which the United States is entitled under a trade agreement are being denied.

The USTR further proposes to continue consultations with the Government of Canada to reach a mutually satisfactory resolution in this matter. If such a resolution is not reached by December 29, 1991, or if one of the other conditions stated in section 301(a)(2) of the Trade Act has not been satisfied, then the USTR proposes to take action within the scope of section 301(c) of the Trade Act. Among the actions that the USTR would consider taking is the suspension of duty bindings and increase in duties on Canadian beer and other alcoholic beverages.

Public Comments

The public is invited to comment on: (1) Whether the Canadian provincial practices at issue are actionable under section 301, including comments on whether they deny benefits under a trade agreement; and if so, (2) the amount of the burden or restriction on U.S. commerce caused by the Canadian provincial practices; and (3) the appropriateness of each of the forms of action provided for in section 301(c). The comments submitted will be considered in determining actionability under section 301 and in recommending any action under section 301 to the USTR.

Comments should be submitted in writing, in 20 copies, by 12 p.m. on December 23, 1991. All written comments must be filed in accordance with 15 CFR 2006.8.

Comments will be placed in a file (Docket 301-80) open to public inspection pursuant to 15 CFR 2006.13, except confidential business information exempt from public inspection in accordance with 15 CFR 2006.15. (Confidential business information submitted in accordance with 15 CFR 2006.15 must be clearly marked "BUSINESS CONFIDENTIAL" in a contrasting color ink at the top of each page on each of 20 copies, and must be accompanied by a nonconfidential summary of the confidential information. The nonconfidential summary shall be placed in the public file.) The docket shall be available for public inspection at the USTR Reading Room, room 101, Office of the United States Trade Representative, 600 17th Street, NW, Washington, DC. An appointment to review the docket may be made by calling Brenda Webb, (202) 395-6186. The USTR Reading Room is open to the public from 10 a.m. to 12 p.m. and from 1 p.m. to 4 p.m., Monday to Friday (except holidays).

A. Jane Bradley,

Chairman, Section 301 Committee.

[FR Doc. 91-28468 Filed 11-26-91; 8:45 am]

BILLING CODE 3190-01-M

OVERSIGHT BOARD

National Advisory Board; Meeting

AGENCY: Oversight Board.

ACTION: Meeting notice.

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C.(A)), announcement is hereby published for a meeting of the National Advisory Board. The meeting is open to the public.

DATES: The meeting is scheduled for Monday, December 16, 9 a.m. to 12 noon.

ADDRESSES: The meeting will be held in the Office of Thrift Supervision, Amphitheater, Second Floor, 1700 G Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Jill Nevius, Committee Management Officer, Oversight Board for RTC, 1777 F Street, NW., Washington, DC 20232, 202/786-9675.

SUPPLEMENTARY INFORMATION: Section 501(a) of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (the ACT), Public Law No. 101-73, 103 Stat. 183, 382-383, directed the Oversight Board to establish one national advisory board and six regional advisory boards.

Purpose

The purpose of the National Advisory Board is to provide information and advice to the Oversight Board and the RTC on the disposition of real property assets.

Agenda

A detailed agenda will be available at the meeting. There will be briefings from the chairman of each of the six regional advisory boards on the regional meetings held throughout the country between November 13 and December 13, 1991. Discussion will focus on the key topics from the meetings: seller financing, SAMDA contracting, local real estate conditions, and auctions.

Statements

Interested persons may submit, in writing, data, information, or views on the issues pending before the National Advisory Board prior to or at the meeting. The meeting is open to the public. Seating is available on a first come first served basis.

Dated: November 22, 1991.

Jill Nevius,

Committee Management Officer, Oversight Board, Advisory Board Affairs.

[FR Doc. 91-28456 Filed 11-26-91; 8:45 am]

BILLING CODE 2222-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. IA-1292]

Intention To Cancel Registrations of Certain Investment Advisers

October 29, 1991.

Notice is given that the Securities and Exchange Commission (the "Commission") intends to issue an order, pursuant to section 203(h) of the Investment Advisers Act of 1940 (the "Act"), cancelling the registrations of those investment advisers whose names appear in the attached appendix.

Section 203(h) provides, in pertinent part, that if the Commission finds that any person registered under section 203, or who has pending an application for registration filed under that section, is no longer in existence, or is not engaged in business as an investment adviser, the Commission shall by order cancel the registration of such person.

Paragraph (b) of rule 204-1, requires an investment adviser to file promptly an amendment to its application for registration (Form ADV) when its address changes or when certain other information becomes inaccurate in a material manner.[1]

The Commission has been sending all registrants a booklet of registration materials annually since 1987. Each booklet contains copies of Forms ADV, ADV-S, ADV-E and ADV-W.[2] These forms, when properly filed, are used to update the Commission's records. Since the 1987 mailing, the Commission has had correspondence for each of the registrants listed in the Appendix returned as "undeliverable" (addressee unknown, forwarding order expired, or no longer at this address) by U.S. Postal Service. The Commission's records indicate that these registrants have not filed amendments to their registration, reflecting their current business and/or mailing addresses, as required by rule 204-1(b). The Commission's records also indicate that many of these registrants have not made annual filings of Form ADV-S, as required by rule 204-1(c). Accordingly, the Division of Investment Management believes that reasonable grounds exist for a finding that these registrants are no longer in existence or are no longer engaged in business as investment advisers.

Notice is also given that any interested person may, by December 20, 1991, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his interest, the reason for such request, and the issues, if any, of fact or law proposed to be controverted, and he may request that he be notified in the Commission should order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, DC 20549.

At any time after December 20, 1991, the Commission may issue an order cancelling any or all of the investment adviser registrations listed in the appendix, upon the basis of the information stated above, unless an order for hearing on the cancellation shall be issued upon request or upon the Commission's own motion. Persons who request a hearing, or to be advised as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For further information contact: Robert L. Lewis, Financial Analyst at (202) 272-3015 (Division of Investment Management, Office of Financial Analysis).

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

Appendix

Atlanta Regional Office
A&R Services (801-22981)
ALB & Associates, Inc. (801-30433)
Addison Advisory Services, Inc. (801-35558)
Advance Planning, Inc. (801-05551)
Anlo Financial, Inc. (801-17646)
Asset Planning, Inc. (801-30623)
Atlanta Securities & Investments, Inc. (801-30339)
Beasley, Donald Lawrence (801-34105)
Belida Evans Capital Management (801-31260)
Belmonte, Frank Howard /FL/ (801-33954)
Bernstein, Charles P. (801-19014)
Blackstock Capital Management Corp (801-16808)
Brown, Fritz Spitzer (801-29636)
Camilleri Financial Profiles, Inc. (801-31771)
Center for Estate & Financial Planning of St. Petersburg (801-27170)
Chase Southeast Corp (801-24761)
Collison, Slaney & Associates, Inc. (801-25645)
Corley, William Harold Jr. (801-32845)
Crabb, Maddox Investment Group (801-22883)
Darany, Michael Anthony (801-19717)
Darmstadter, Virginia Lagarde (801-33174)
Deemer Technical Research (801-15628)
Dewoody & Co (801-19777)
Diversified Capital Services (801-23122)
Dobbs Corp (801-17086)
Dorn, Linda Marie (801-26677)
Dunn, Henry Glenn (801-29017)
Estate Management Corp (801-29860)
F&M Capital Corp (801-29152)
FFC Advisors of Florida, Inc. (801-25234)
Fi Plan, Inc. (801-21777)
Financial Advisory Group, Inc. /FL/ (801-29526)
Financial Advisory Services of Tennessee (801-28000)
Financial Charting, Ltd. (801-18717)
Financial Concepts (801-19355)
Financial Independence Group, Inc. (801-29125)
Financial Planning Network Advisory (801-17847)
Financial Planning Solutions, Inc. /FL/ (801-31329)
First Financial Planning Corp (801-22700)
First North Carolina Corp (801-11314)
Fitzsimmons, Leonard Patrick (801-31727)
Flagler Investor Services, Inc. (801-27641)
Flagship Group, Inc. (801-30787)
Friend, William David (801-18293)
Gallo, Vincent J. & Associates, Inc. (801-28780)
Grieger, Edward Louis III (801-09965)
Gussio, John Florian Jr. (801-18795)
Hahn & Associates, Inc. (801-29770)
Hallum, Robert E. & Co. (801-17722)
Hamilton, Ralph Richard (801-23631)
Haskell, Samuel Delafield (801-26009)
Hill, Norman Bruce (801-17708)
Hollister, Robert Morris (801-13506)
Integrated Planning Group, Inc. (801-32016)
Integrated Planning Services, Inc. (801-29966)
International Investment Management Co. (801-31195)
Investors First, Inc. (801-30406)
JFB Planning Services, Inc. (801-34203)
Jackson, Philip Robert (801-23728)
Jenmar Waddell Securities, Inc. (801-24406)
Johnson, Sterling, Paul Securities, Inc. (801-32302)
Kaplan, Louise Goldman (801-15997)
Kennedy Financial Services, Inc. (801-34053)
King, Rigsbee & Co. (801-27678)
Kury Investment Advisory Corp (801-30321)
Landmark Advisory Corp (801-16832)
MacKenzie, Jason Securities Corp (801-25804)
MacLean, Gilbert Keith (801-26063)
Maragides & Associates (801-20317)
Matthews, Heron & Cutrer (801-33738)
McArver, James Hugh (801-27406)
McWilliams, Elbert Charles (801-35253)
Mitchell, Calvin Mace (801-28967)
Mull, Jack Howard Jr. (801-21858)
Net Worth Financial Advisors, Inc. (801-29330)
New Directions International, Inc. (801-16235)
Newman, Mitchell Keith (801-19789)
Northcutt, Owen & Co. (801-22251)
Pappas, Edward John (801-34230)
Perry, Christina (801-31500)
Perry, Nicholas Massenburg (801-25571)
Phillips, L.W., Inc. (801-30353)
Physicians Financial Group of America (801-24064)
Planners Equity Group, Ltd. (801-15278)
Porter, William Lansing (801-14275)

[1] Under section 204 of the Act and rule 204-1 thereunder, an investment adviser must also file an annual supplement (Form ADV-S) providing the Commission with certain information about its business activities.

[2] Form ADV-E is used by accountants for certification of client funds and securities in the possession of an adviser. Form ADV-W is used to voluntarily withdraw from registration as an investment adviser

Portfolio Planning Corp (801-22461)
Profile Investments Corp (801-33437)
RC Financial Planning, Inc. (801-31631)
Rabinsky, David (801-33905)
Raleigh Investment Management Co., Inc (801-33140)
Regional Investment Financial Corp (801-24998)
Resource Development Corp (801-18666)
SWM Financial Group, Inc. (801-26375)
Scogin, David Farrell (801-33450)
Shoemaker, J.H. Advisory Corp (801-17372)
Siberio & Co., PA (801-21670
Siggins, Joesph Patrick (801-27436)
Silverman, Robert Ivan (801-18997)
Southeastern Financial Group, Inc. (801-26512)
Stanley, William M., Inc. (801-31688)
Structured Shelters Financial Management (801-17799)
Tackyy Enterprises, Ltd. (801-32106)
Tarheel Investment Services, Inc. (801-30648)
Taylor, Thomas & Lord (801-19931)
Tench, Theodore Ryan (801-31374)
Tillinghast, Nelson & Warren, Inc. (801-09549)
Timing Consultants, Inc. (801-34207)
UP International Corp (801-28248)
Underwood, Richard Eugene (801-31423)
Vivian, Robert Carlton (801-29127)
Wagner, Cathy Ann (801-26100)
Walsh, John Marshall (801-25442)
Ward, James William (801-21886)
Warren Agency, Inc. (801-19335)
Wessinger, William Donald Sr. (801-31076)
Williams, Michael Wayne (801-30237)
Wolfson, Joel /FL/ (801-13532)
Woodbridge Financial Group (801-29863)
Ziegler, Stephen James (801-18695)

Boston Regional Office

Andersen, Thomas Walter (801-29634)
Beaumont Trust Associates (801-27434)
Bigus, Anatol Walter (801-25155)
Bishop, Robert Hudson III (801-13763)
Capital Planning Corp (801-27773)
Cook, Russell A., Inc. (801-13554)
Copley Financial Services Corp (801-13834)
Corporate Strategies, Inc. (801-23133)
Dedicated Financial Corp (801-30403)
Devonshire Trust Corp (801-28341)
Edds, Lyman Stanley (801-29747)
Essex Financial Management Goup, Ltd. (801-27707)
Feingold Insurance Planning Agency (801-20947)
Financial Planning Advisors, Inc. (801-19239)
Finklestein, Charles Irving (801-35750)
First American Financial Corp (801-29931)
Flagship Investment Counseling Service (801-27367)
Flynn, John C. (801-32451)
Freedom Financial Services, Inc. (801-17787)
Future Benefits, Inc. (801-32640)
Heckert, Ralph E. (801-27680)
Holt, T.J. & Co., Inc. (801-04261)
Howe, Jeffrey Lynn (801-30269)
Ivy Cash Management, Inc. (801-32553)
Kaestle, Paul Kruger (801-33339)
Karp, Stephen Michael (801-21825)
Lexington Financial Group, Inc. (801-28095)
Link, Stephen (801-33345)
Loomis, Lawrence Alfred Jr. (801-27429)
MAC Financial Services, Inc. (801-23919)
Maloy, James Rudolph (801-27998)
Mayflower Trust Corp (801-29205)
McDougall, Frederick Borrow (801-31840)
Mintz, David Jacob (801-30969)
Morgan, Jeffrey Hall (801-21613)
Morrison, Mike (801-31123)
New Cambridge Associates, Inc. (801-30228)
Noble Asset Management, Inc. (801-27416)
North Atlantic Planning Corp (801-28556)
O'Connor & Drew Financial Advisors, Inc. (801-31493)
Plante, Pierre Guy (801-24330)
Rahman, Habib (801-24886)
Rauseo Financial Group, Ltd. (801-31980)
Reinhalter Capital, Inc. (801-27749)
Rhodes Capital Management, Inc. (801-27597)
Rosson, Gloria (801-31954)
Sacarob, George Joseph (801-11887)
Slyuter, Robert Norman (801-28220)
Stevens, Ralph Lawson (801-28821)
Stockbridge, Charles William (801-22414)
Thompson, Kathleen Marie (801-33463)
United Fiduciary Services Corp (801-32594)
Weber, Arthur Morgan (801-07751)
Wheeler, Grant W. (801-18262)
Wilkens, Edward Henry (801-27154)
Zapata, Charles Albert (801-11200)

Chicago Regional Office

AGA Financial Services, Inc. (801-30611)
Allswang, Harry (801-22663)
American Service Press, Inc. (801-19246)
Ayling Capital Management, Inc. (801-22725)
Batt, Danny Lee (801-29740)
Bennis, John Lee (801-30239)
Berndt & Boone Associates, Inc. (801-28902)
Beta Investment Management, Inc. (801-29416)
Brandvein & Leppo, Inc. (801-28323)
Briely Financial Services, Inc. (801-24725)
Brown, Larry Dean (801-20573)
Busekrus, Mark H. & Co. (801-23889)
C&A Agency, Inc. (801-26090)
Campbell, W.Y. & Co. (801-32569)
Carnick, Bruce James (801-23565)
Carson Miller Planning Services, Inc. (801-29615)
Certified Financial Consultants, Ltd. (801-24306)
Christiansen & Associates, Inc. (801-24042)
Cipriano, Gene Louis (801-13521)
Coleman, S.M. & Co. (801-31595)
Cooper, Sharon Kay (801-23592)
Creative Planning Concepts, Inc. (801-28218)
Cummings, William Henry (801-28689)
Cyrwus, Kenneth John (801-28137)
DIA, Inc. (801-28115)
DIA Markets Advisory (801-34903)
Eissman, Mark Paul (801-30553)
Eldredge, Charles H. & Co., Inc. (801-09083)
Ellis Enterprises, Inc. (801-22639)
Ellward, Inc. (801-16386)
English, Wright, Collins & Co., Inc. (801-28800)
Equitrust, Inc. (801-29268)
Evergreen Financial Planning, Ltd. (801-24382)
Fasano & Associates, Inc. (801-19782)
Fedie, Donald Martin (801-20362)
Ferlis Financial Services, Inc. (801-31332)
Fifth Avenue Investments, Inc. /MI/ (801-35754)
Financial Planning Partners, Inc. (801-27711)
Financial Service Associates, Inc. (801-17471)
Financial Services Associates, Inc. (801-25488)
First Detroit Investment Planning, Inc. (801-22180)
First Financial Planning Services, Inc. (801-18410)
Foley, Irvine & Stafford Asset Management (801-30882)
Forrest, Terry L. (801-21794)
Frehse, Thomas Arthur (801-27229)
Garcia, Fernando Salcedo (801-30268)
Gardenier, Holly Jane (801-27963)
Garrison, Mark Michael (801-31813)
Cholston, Verna M. (801-28434)
Gilliam Trust Advisors, Inc. (801-27580)
Goldberg, Richard Harry (801-13949)
Gossman, Robert Carl (801-14294)
Great Lakes Capital Management Corp. (801-30244)
Greater Chicago Investment Advisors, Inc. (801-25561)
Greenblatt, Phillip J. Securities, Ltd. (801-28080)
Gross Financial Planning, Ltd. (801-20443)
Hagerty, Timothy Curtis (801-26691)
Hahn, H.E. Advisory & Consulting, Inc. (801-26170)
Hamilton, Rhodes Capital Management, Inc. (801-32110)
Hicks, Bruce Bennett (801-30026)
Hilbert, Anne Thompson (801-28630)
Huang, George Chen Ching (801-27355)
Investment Directions, Inc. (801-26152)
Investors Capital Management, Inc. (801-34364)
Investors Development Co. (801-22169)
JM Consultants, Inc. (801-21814)
JPW Investment Advisors, Inc. (801-26358)
Jaxon Corp. (801-32305)
Jenkins, Lawrence Allen (801-27278)
Johnson, Davis (801-21461)
Jones, Jay Arthur (801-23890)
Karr Financial Planning, Ltd. (801-26209)
Kenight, Sebastian J., Dr. (801-15152)
Ko, Moses Saibing (801-22022)
Kozelka, Steven Elden (801-27587)
Kurk & Kurk Financial Group, Inc. (801-25147)
Lang, David Frederick (801-26232)
Langley, Randal Scott /MI/ (801-34932)
Lawlor, P.M. & Co. (801-24375)
Laymon, Terry M. (801-26016)
Leventis Investment Co. (801-14430)
Lindow, Kenneth Allen (801-28190)
Lodden, Telford Alleman (801-26147)
MKS Investment Advisers, Inc. (801-30303)
Machala, Robert G. (801-20853)
Martin, Robert Scott (801-28057)
May, Kenneth Francis (801-17401)
McAtee, Carol Nemec (801-22560)
McClintic, Raymond Gerald Jr. (801-24392)
McCubbin, R. Shawn & Associates, Inc. (801-26954)
McMillin Investment Counsel, Inc. (801-27473)
McNary Financial Group, Inc. (801-24870)
Meridian Trading Co. (801-29887)
Merriman, L. Idris (801-22837)
Miller, Richard Francis II (801-22132)
Mills, B. Corp. (801-13976)
Mills, Vincent (801-34620)
Molvang, Eric A. (801-20559)
Moneybuilders, Inc. (801-30627)
Murray, Patrick Brain (801-27283)
Nabholz, Linda Lucille (801-33037)
Nickles To Net Profits, Inc. (801-30211)
Northeast Planning Associates, Inc. (801-33925)
Octagon Financial Corp /MN (801-29852)
Ojiaku, Uche Jim (801-31377)
Osborn & Associates, Inc. (801-18718)

PBS Investment Advisory Services, Inc. (801-20149)
PDS Securities International, Inc. (801-21125)
Penntax Advisory Group, Inc. (801-25051)
Personal Economics, Inc. (801-29881)
Pierson, Marshall Julius III (801-21411)
Rheingold Investment Group, Inc. (801-34486)
Ross, Craddock Associates, Inc. (801-24347)
Rowe & Associates, Inc. (801-23593)
Ryrie, Biermann & Ryrie Financial Services (801-26792)
SF Investment Management Services, Inc. (801-28146)
Scales, Scott Alan (801-29282)
Schoeck, John Fred (801-24006)
Schwartz, Paul Jerome (801-27591)
Searcy, L. Dwight (801-24953)
Shaw, Eric C. (801-19033)
Sidell, Richard John (801-21639)
Singer & Co. Planning Services, Inc. (801-31773)
Smith Financial Planning, Inc. (801-24463)
Spears, Joe Mack (801-28973)
Spectrum Consulting Corp (801-27969)
Strategic Financial Advisors, Inc. (801-21781)
Sullivan, Paul Joseph (801-33857)
Supena Nyman Investment Corp (801-25635)
Theiler, Richard Carl (801-27116)
Thompson, Leonard Arvin Jr. (801-14187)
Uniplan, Inc. (801-24133)
Vander Weele Investment Counsel, Inc. (801-32744)
Vroon, Kenneth James (801-31521)
Walsh, J.P. & Associates, Ltd. (801-27143)
Wealth Accumulation Concepts, Inc. (801-21067)
Weber Financial Services (801-21441)
Westport Financial Group, Inc. (801-24106)
Wilhelm, Donna Gayle (801-27437)
Winkelman, Stuart Herbert (801-30325)
Yield Growth Money Management Co. (801-19289)
654 Co. (801-15058)

Denver Regional Office

Advising Speculators Corp (801-26458)
American Asset Management Corp (801-17487)
Anderson, James William (801-25246)
Bonnell, Frederick Wayne (801-35090)
Broker Services, Inc. (801-12995)
Cleveland Management, Inc. (801-16181)
Cordovano & Co., Investment Advisors (801-32394)
Crosby Advisors, Inc. (801-29197)
Dadson Securities, Inc. (801-33818)
Davis, Ernest Guthrie (801-31642)
Doane, Elizabeth Lathan (801-20138)
Energy Investment Services, Inc. (801-26221)
Equidata, Inc. /CO/ (801-17002)
Equity Resource Planning, Inc. (801-24216)
Erisa Mortgage Co. (801-29695)
Financial Blueprints, Inc. /UT/ (801-28658)
Financial Planning Services, Inc. (801-18707)
Fleming, Marilyn Anne (801-22927)
Foreman, William Jr. (801-29425)
Four Corners Advisor (801-14139)
Geis, Don D. (801-15120)
Griffin, Douglas Devereaux (801-30657)
Hansen, Judith Ann (801-21195)
Harbor Financial Group, Inc. (801-32053)
Harris, Dixon Holman (801-26304)
Hilderbrand & Associates, P.C. (801-30137)
Hurley, Edward Francis (801-27293)
Innovative Asset Group, Inc. (801-33274)
Integrated Financial Securities, Inc. (801-28333)
Intermountain Capital Management, Inc. (801-28241)
Javer, Joel Barry (801-27021)
Lukton, Gerald Lloyd (801-22552)
MCO Financial Services, Inc. (801-28145)
Martin, Robert Fulton (801-31181)
Moffitt, Teran & Co. (801-28787)
Plesher, Peter Charles (801-34675)
Resource Group (801-31006)
Rose, Robert Daniel (801-29756)
Ruckel, Horace Anthony (801-28060)
Ruffell, William Murray (801-30813)
Stock Investors Services, Inc. (801-28592)
Stroms, Phillip Wayne (801-27728)
Sutton & Co. (801-26579)
Thornton, Jo Ellen Martin (801-18603)
Tintera & Co. (801-34025)
Ward, Thomas Arthur (801-23460)
Young, Robert Oldham (801-28361)

Fort Worth Regional Office

ANFS, Inc. (801-28539)
Access Investor Services, Inc. (801-29301)
Austin, Jerrold Dean (801-23049)
Avest, Inc. (801-31965)
Barenborg, Edward Paul (801-21837)
Birchtree Financial Advisors, Inc. (801-28525)
Brooks Group, Inc. (801-25568)
Brown, Rice E. (801-25489)
Cabrera, Florencia Fernandez (801-30561)
Columbia Financial Advisors, Inc. (801-27364)
Cornerstone Service Corp (801-23776)
Dfina, Inc. (801-26891)
Devlin, Brian Tuckey (801-28477)
Ehrman Investment Group, Inc. (801-21573)
Equity Mutual Corp (801-32141)
FSA Capital Management, Inc. (801-17282)
Fields, Spencer De (801-23819)
Financial Planning Assistance Corp (801-23516)
Fischer, Steven Neil (801-16186)
Golombeck, Richard Sidney (801-27196)
Grisbee Financial Advisers, Inc. (801-21402)
HLM Financial Advisory Services, Inc. (801-25423)
Hackney, Robert Eugene (801-31158)
Hallmark Financial, Inc. (801-30409)
Herman, Stanley Hubert (801-24791)
Holochuck, David William (801-27354)
ICP Integrated Capital Planning, Inc. (801-28008)
Innovative Money Advisory, Inc. (801-26347)
Institutional Asset Management, Inc. (801-32087)
King, David Stephen (801-27465)
Langdon Investment Advisors, Inc. (801-23760)
Lebair Financial Services, Inc. (801-29662)
Mitchell, Mark Michael (801-31420)
Pattison, Gregory Lynn (801-23830)
Peeke, James Barlow & Co., Inc. (801-15714)
Pilot Advisory Services, Inc. (801-22206)
Plaettner, Paul David (801-30240)
Practice Consultants, Inc. (801-28503)
Premier Financial Advisors, Inc. (801-30669)
Rainwater, Wayne Lindy (801-19586)
Roberts, Paul Best (801-32626)
Sage Investment Securities, Inc. (801-30933)
Santaularia, Joseph Earl Jr. (801-16846)
Sheffield Financial Management, Inc. /TX/ (801-17977)
Skaggs, Lynn Martin (801-30327)
Source Advisory, Inc. (801-25179)
State Directed Securities (801-27923)
Tannehill, Arthur Douglas (801-18339)
Vaughn George Frederick (801-29348)
Vranes & Co. (801-29121)
Whitfield, J. Charles (801-23375)
Wilde Advisory Services, Inc. (801-31466)
Yeater, Bradford Reid (801-30135)

Los Angeles Regional Office

Abrams, Nancy Lee (801-26931)
Advisors, Inc. (801-17581)
Advisory Network, Inc. (801-19489)
Aegis Asset Management, Inc. (801-16290)
Anttonen, Thomas Jackson (801-21100)
Arabia Financial Services, Inc. (801-29072)
Athletic Financial Planning, Inc. (801-15324)
Avila, Harold Celso (801-17613)
Baird, Anthony Sewell (801-32863)
Bayuk, Darryl Anthony (801-13536)
Beckett, Sheryl Anne (801-29787)
Berger, W. Craig Financial Service, Ltd. (801-27896)
Berlage, Frank Richard (801-31254)
Boardwalk Asset Management Corp (801-30659)
Bowers, Richard Jerome Jr. (801-27123)
Burnham, Perry Lorenzo (801-25593)
Burr, Don Charles (801-28422)
Burton Associates (801-30493)
CLM Financial Corp (801-11411)
CSI Capital Management (801-20379)
Cal State Associates, Inc. (801-21118)
Calculus (801-30911)
California Fund Timing Serivce (801-31040)
Candland, Kindschi & Associates (801-24162)
Canova, Terry Mac (801-28883)
Capital Action Planners, Inc. (801-23366)
Capital Appreciation Investments (801-19816)
Carroll, Cheryl Kapitan (801-30388)
Cazenave & C., Inc. (801-31533)
Centrecorp Investment Advisory Service (801-16666)
Childers, Swan & Co. (801-23690)
Choie, Edward Sungkyu (801-35608)
Clare, Richard T. (801-24994)
Claremont Economics Institute (801-14824)
Connolly, Michael Robert (801-27385)
Consolidated Financial Planning, Inc. (801-34754)
Coordinated Financial Design, Inc. (801-22168)
Cosentino, Vincent John (801-22487)
Crescent Investment Group, Inc. (801-18583)
Dacquisto, John Francis (801-21348)
Designed Retirement Plans, Inc. (801-24673)
Desktop Broker, Inc. (801-24739)
Dimirak Financial Corp, Inc. (801-32161)
Doherty, Robert H. (801-32399)
Double Eagle Financial Corp. (801-20588)
Dugan John Francis /CA/ (801-30024)
Duncan, Robert Case (801-29166)
Edwards, David Freeman (801-29827)
Financial Directions, Inc. (801-28974)
Financial Planning, Inc. (801-32435)
Financial Service Consultants, Inc. (801-23141)
Fischer, James Buckle (801-21909)
Forefront Financial Corp. (801-27346)
Fortner Financial Services Corp. (801-21312)
Fortune Capital Management (801-23814)
GCA Investment Corp. (801-09642)
Gallop Group, Inc. (801-18371)
Genès Capital Management Co. (801-28593)
Gershon Perlman Financial (801-25397)
Gettings Financial Group, Inc. (801-23633)
Gibney, William Arthur (801-33523)
Glass, Melvyn Stanley (801-14199)

Grant, Scott Wallace (801-20489)
Grattan Financial Strategies (801-28586)
Hanks, Arthur Ernest Jr. (801-34654)
Hanson Paul (801-18578)
Harrison, Allan Richard (801-27427)
Harvey, Junior Lee (801-27974)
Heath, Ronald G., & Associates, Inc. (801-25209)
Hedging Concepts, Inc. (801-30797)
Howard, Kevin John (801-27882)
Hubbard, Frank Langdon (801-34986)
Hunter, Robert Reichard (801-30904)
Hutchinson, William Harding (801-22354)
Hutchinson Securities (801-31812)
IPN Capital Management, Inc. (801-28917)
Ideco Financial Services Corp. (801-24185)
Institute For Financial Guidance (801-16817)
International Planning & Communication (801-22620)
Ishii, Roy Isamu (801-28420)
Iwata, Kay Kiyomi (801-31510)
JD Financial Planning Services, Inc. (801-27956)
James, Leon G., Inc. (801-28355)
Jannicelli, Dante Vincent (801-24100)
Jenny, Hans H. (801-31077)
Jewett, Grank Irving (801-21351)
Johnstown Investment Managers, Inc. (801-30066)
Joman Research, Inc. (801-22170)
Jones, Chris Leroy (801-27595)
Jordan, Pierretta Eva (801-25457)
Justine, A.J., Ltd. (801-18256)
Kalenda, Raymond Edward (801-17548)
Katersky Financial (801-18261)
Kenmar Investments (801-18174)
Lafayette Capital Corp., Inc (801-34832)
Lagomarsino Planning (801-24082)
Largent Capital International, Inc. (801-29507)
Lee, Joseph & Associates, Inc. (801-32729)
Mark, Bruno Francis (801-30385)
McCarthy, John Eugene (801-29941)
McEwen, Laurence Bishop Jr. (801-24752)
McKee, Stephen George (801-22482)
Melody, Robert Arlen (801-30432)
Merchant, Philip Everett (801-19770)
Miller, George Campbell (801-19654)
Moloney, Patrick Kevin (801-28178)
Monschein, Naomi Ruth (801-21528)
Moore, Philip Frederic (801-30619)
Morgan, Olmstead, Kennedy & Gardner Capital Corp (801-06189)
Murray, Carol Anne (801-32387)
Natapoff, Milton (801-25459)
Neely, John William (801-28924)
Nellis, Bryan Clifford (801-29260)
Nelson, Steven Charles (801-24399)
Newport Capital Management (801-10512)
Newport Investment Planning, Inc. (801-28880)
O'Hearn, William James (801-32052)
Orlich, Robert Douglas (801-28392)
Pacific Integrated Group, Inc. (801-31613)
Pacific Investment Counsel (801-23281)
Paramount Capital Corp. (801-33178)
Perry, Vernon Edward (801-31835)
Personal Financial Management, Inc. (801-13568)
Peterson, George Arthur (801-24722)
Petring, Terri Lynne (801-32706)
Phelps, George E. Co. (801-11326)
Pirtle, Paul Richard (801-29407)
Planvest Advisors, Inc. (801-25531)
Porter, Harold King III (801-30320)
Princeton, J.M. Co., Inc. (801-23467)
Protect America, Inc. (801-27636)
Provost, John Edward (801-30738)
Qualls, Patricia A. Associates, Inc. (801-22212)
Reeves Financial Advisors, Inc. (801-28618)
Regan, Michael John (801-21329)
Richard, Leo Jerry (801-29089)
Riggs, Thomas P. & Associates, Inc. (801-21321)
Rockey, Ruth Investments, Inc. (801-16453)
Rosenblum, Norman Mark (801-24684)
Rutemoeller, Robert August (801-32679)
Sakuma, Alan Advisors, Inc. (801-23823)
Sam Sin, Fernando Jamiel (801-24823)
Sandoval, Dennis Michael (801-16533)
Sanford, Carlisle Junior (801-30326)
Seel, Kenneth Lynn (801-24428)
Select Fund Advisors, Inc. (801-26825)
Seng, Richard Allen (801-32625)
Sheahan, Robert J. & Associates, Inc. (801-19419)
Sherman, L.F. & Company, Inc. (801-29517)
Shorr, Alan Lee (801-18486)
Smith, D.L., Inc. (801-22500)
Springhill Financial Services Corp. (801-29173)
Standing, Hugo J., Inc. (801-29149)
Steiner, Martin Henry (801-25255)
Strategic Defensive Investments, Inc. (801-33199)
Stronghold Capital Management, Inc. (801-24524)
Tax & Financial Programming, Inc. (801-14917)
Taxis, Ltd. (801-31432)
Torrey Pines Securities Corp. (801-25642)
Trademark Investment Services, Inc. (801-27603)
Transgroup Securities, Inc. (801-19073)
Triad American Securities, Inc. (801-17488)
U.S. Advisors, Inc. (801-31984)
U.S. Capital Investment Advisors Corp (801-32317)
Vest Corp of California (801-15494)
Vickery, Thomas Taylor (801-14396)
WCM Financial Corp. (801-30027)
Wall Street Pacific Financial Resources, Inc. (801-31111)
Warren, Theodore Arthur (801-04469)
Waul, Michael Anthony (801-24499)
Wesson, Vann Thomas (801-23222)
Westlake Securities, Inc. (801-18840)
Wetterschneider, Larry Kay (801-16765)
Wilcon Management (801-29535)
Wolcott, David (801-32615)
Wolfe, James Samuel (801-21920)

New York Regional Office)

Abrams, Harry (801-15042)
Academy Financial Management (801-16273)
Agrista, Stephen Joseph (801-19380)
American Precious Metals Advisors, Inc. (801-30442)
Amvest, Inc. (801-20240)
Asset Management Concepts, Inc. (801-31951)
Aston Lane, Inc. (801-25942)
Benefit Security Advisors, Inc. (801-30704)
Benner, H.D. & Co. (801-34970)
Bernstein, Michael & Associates, Inc. (801-12719)
Bettinger & Leech, Inc. (801-16502)
Birchwood, Inc. (801-22773)
Breidbart, Rank Mark (801-25104)
Brieff, Paul (801-25165)
Brignoli Advisers, Inc. (801-30913)
Brignoli Models, Inc. (801-15767)
Brignoli, Curley & Roberts Associates (801-22794)
Brown, E.M. Management Corp (801-30696)
Brown, Robert (801-23966)
Buck, Edwin Augustus (801-32669)
Burgess, Montague Stephen (801-02438)
Cadaret Brokerage Group, Inc. (801-28006)
Cadaret, Mac E. Associates, Inc. (801-21161)
Cadbury, Crosfield Christopher (801-32784)
Cambridge Financial Resources, Ltd. (801-26078)
Cambridge Venture Capital, Inc. (801-29182)
Cardell Advisory Services, Inc. (801-17750)
Casdin Associates, Inc. (801-28575)
Chase, Bart A. (801-32689)
Citizens Advisory Corp (801-29367)
Coastal Financial Group (801-33338)
Computime Institutional Services, Inc. (801-10777)
Continental Funding Group, Inc. (801-16940)
Copeland Securities, Inc. (801-27532)
Copeland, Wiley Securities, Inc. (801-31950)
Creative Capital Consultants, Ltd. (801-17453)
Cronin Enterprises, Inc. (801-29944)
D&B Financial Review, Inc. (801-26745)
Delvecchio, Jules Alexander (801-25537)
Desphande, Vijay Dattatraya (801-21736)
Diamant, David Neil (801-26859)
Doley, Govan Capital Management, Inc. (801-32402)
Donohue, Michael Robert (801-34017)
Dorman, L. Asset Management, Inc. (801-32867)
Dougherty, Pat & Associates, Inc. (801-23513)
Douglas Stewart, Inc. (801-18075)
Dowling, Oscar (801-27218)
Duane, James J. & Co., Inc. (801-20060)
Eastmont Securities Corp (801-29600)
Economics Directions, Inc. (801-32955)
Estner, Stephen Miles (801-34143)
Fels, Richard Merrill (801-23010)
Financial Management Corp (801-20897)
Financial Perspectives, Inc. (801-28045)
First Financial Consultants of New York (801-27342)
First New York Equity, Inc. (801-15688)
First Reserve Asset Management Corp (801-33533)
Fiscal Planning Concepts, Inc. (801-26748)
Frank, Conrad Bennett (801-18706)
GFA Timing Service, Inc. (801-19389)
Gallagher & Associates, Inc. (801-32763)
Gaul, James Carl (801-32244)
Geoffrey Advisory Corp (801-34636)
Goltermann, Richard Martin (801-26606)
Greeley Securities, Inc. (801-13622)
Greenwich Monitrend Corp (801-15629)
Guerin, B.R. Ltd., Inc. (801-28907)
Gutman, Peter (801-26171)
Hanover Capital Management, Inc. (801-27273)
Hartman, Nancy June (801-14619)
Haverlock, Kevin Daniel (801-21394)
Hummel, Ronald S. & Associates, Inc. (801-29477)
Hunzek, M., Inc. (801-22148)
IVM of New York, Inc. (801-27821)
Impac Group, Inc. (801-34094)
Incorvaia, Philip R. (801-24353)
Investment Research Associates /NY/ (801-13932)
Investment Research Associates, Inc. (801-22635)
Jenkins, Kenneth Thomas Jr. (801-30996)
Kaplan, David (801-25030)
Kaye, Stuart Curt (801-24552)
Kecalp, Inc. (801-17277)

Kenney, James Brennan (801-29571)
Kuhns Brothers & Laidlaw, Inc. (801-06609)
Labow, Ronald (801-28370)
Lapadula Financial Planners (801-22101)
Lasry, George (801-18720)
Levine, William Andy (801-24772)
Lewis, Mack (801-21654)
Lewis, Richard White (801-32403)
Long Perrin, Inc. (801-13559)
M 3 Money Management, Inc. (801-29474)
MHM Advisers, Inc. (801-27986)
MKT Associates, Inc. (801-28529)
Madison Park Investment Management, Inc. (801-18715)
Martin, Robert Leander Jr. (801-33454)
McMurray, John David (801-26470)
Medoff, Alan Jeffrey (801-21141)
Meehan, Eileen Marie (801-29995)
Merkle, E.A. & Associates, Inc. (801-13886)
Money Managers, Inc. (801-18614)
Muller & Co (801-16146)
Nuland, James Greenbury (801-27205)
O'Neil, T.S. & Co., Inc. (801-29427)
Oxford Capital Group (801-34109)
Paulson, Caroline (801-16678)
Payfer, Gustave Patrick (801-22107)
Pearce, Urstadt, Mayer & Greer Advisory Corp (801-17196)
Pearce, Urstadt, Mayer & Greer Advisory Corp (801-28427)
Rasmussen, Barry Irving & Associates, Inc. (801-32018)
Rosen, Robert Jay (801-24647)
Rosewood Investment Management, Inc. (801-31590)
Ruland, Ronald Edward (801-23230)
Schiff, Kenneth E. (801-23623)
Scrocca & Skinner Tax & Financial Planning (801-27449)
Selective Advisory Service, Inc. (801-28909)
Shelby Resources Planning Co. (801-18758)
Shove, John D. & Co. (801-02507)
Smilen Investment Research & Management (801-05114)
South Shore Securities, Inc. (801-30670)
Stochel, Daniel Edward (801-34440)
Stockato (801-26287)
Sullivan Financial Services, Inc. (801-28849)
Summit Capital Advisors, Inc. (801-32222)
Terenzi, Paul (801-20221)
Tower Asset Management, Inc. (801-19067)
Vareilles, Gail Lynn (801-24737)
Vespa, Edward J. (801-27668)
Vineyard Securities, Inc. (801-25682)
Vooys, James Donald (801-30822)
Wall Street Research Group, Ltd. (801-35049)
Windahall Investors, Inc. (801-34987)
Wooters, Edward Joseph (801-32245)
Zoullas, Nicholas Basil (801-31967)
Zucker, Stuart Craig (801-24280)

Philadelphia Regional Office

Alexander, Edward Lee (801-18570)
Alpha Investment Corp. (801-31606)
Apton Investment Adviser, Inc. (801-15389)
Argent Capital Management, Inc. (801-28409)
Bakin, Larry (801-26762)
Belinkie, Jon Stuart (801-21206)
Belle Day Enterprises, Inc. (801-17027)
Bentsen, Gary Merrill (801-16693)
Burke, Michael Leo (801-30265)
Carlin, Charles Creighton (801-33073)
Cash Management, Inc. (801-32560)
Cavill & Co. (801-22159)
Columbia Financial Advisors, Inc. (801-28808)
Commonwealth Financial Planning Services, Inc. (801-26596)
Conant & Associates, Inc. (801-27803)
Covert, Harold & Associates, Inc. (801-16409)
DMDEF Management, Inc. (801-32937)
Damar International Corp. (801-19810)
Davis Advisory Services, Inc. (801-22328)
Davis Financial Services, Inc. (801-25325)
Delong, James Lancaster IV (801-34002)
Dominion Financial Planning Services Co. (801-28737)
Duncan Consultants, Inc. (801-31808)
Equi Debt Financial Group, Inc. (801-24836)
Erenberg, Melvin Milford (801-20225)
Executive Financial Services, Inc. (801-19557)
Faux, William H. III & Associates, Ltd. (801-21997)
Financial Concepts & Plans, Inc. (801-18120)
Financial Counselors of Virginia Inc. (801-19623)
Financial & Investment Consultants, Ltd. (801-23674)
Fisher, Clark W., Jr. (801-32753)
Fixed Income Asset Management, Inc. (801-27565)
Fleet, John Louis Jr. (801-31403)
Gannon, John Richard (801-29421)
Grant Hill Associates (801-30509)
Guehn, Rodney Arnold (801-22580)
HFG, Ltd. (801-21556)
Hanover Asset Management Corp. (801-28189)
Hauf, Stephen Thomas (801-23908)
Hauf, Stephen Thomas (801-26786)
Hersey Capital Management (801-33657)
Investment Plus, Inc. (801-26795)
Investors Financial Services, Inc. (801-19909)
Isakson, Robert E., Inc. (801-26335)
Johnson, Kenneth Grant (801-31052)
Lerman, Arnold Jay (801-33926)
Lott Capital Management, Inc. (801-16200)
Lowry, Bittel, Perrot & Co., Fund Advisors (801-27070)
McConnell Financial, Inc. (801-33534)
McGlade, Matthew Nasal (801-17149)
Medford, Paul Nathaniel (801-32994)
Midatlantic Financial Management Corp. (801-33270)
Mitchell, Samuel Appleton (801-26377)
Money Planners, Inc. (801-19653)
Musso, Thomas Frank (801-29864)
Noble, Earl Myron (801-12195)
Olson, Wayne Leroy (801-28839)
Pankey, James Paul (801-31200)
Patel, Margaret Donaldson (801-32724)
Peterson, Harlan W., CPA, CFP, Ltd. (801-20920)
RF Advisors, Inc. (801-13660)
Roos, Norman Joseph Jr. (801-22782)
Sanna, Mark Anthony (801-22199)
Schaffer, Necker & Co. (801-30685)
Sigma Asset Management, Inc. (801-30923)
Strategic Investment Group, Ltd. (801-27870)
TSM Group, Inc. (801-30703)
Tedrick, James Lee (801-28290)
Yates, James William Jr. (801-17734)

Seattle Regional Office

Bell, Gordon Wolf (801-23578)
Chatterton & Chatterton, PC (801-33324)
Destiny Advisory Group, Inc. (801-31180)
Farsdahl, Mark Alvin (801-21956)
Galbraith, Scot Alan (801-24580)
IAM Corp. (801-15091)
Kinsela, James Michael (801-28665)
Ko Securities, Inc. (801-25313)
Lynott Investment Management Co., Inc. (801-18267)
Mehner, William Michel (801-32977)
Myatt, Michael Lewis (801-30270)
Paragon Financial Corp. (801-14312)
Ryder, David Owen (801-28230)
Smoot, Joan S. (801-23232)
Stephens, John Robert Chilton Jr. (801-23224)
TMA Financial Advisors, Inc. (801-26713)

Foreign Advisers

Scott, Walter International, Ltd. (801-23932)

[FR Doc. 91-28493 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-29969; File No. SR-Amex-91-29]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the American Stock Exchange, Inc., Relating to Percentage Orders

November 20, 1991.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on October 17, 1991, the American Stock Exchange, Inc. ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex is proposing to amend its Rules 131 and 154, on a permanent basis, to broaden a specialist's ability to represent percentage orders,[1] and to generally expand the types of percentage orders permissible. The Commission approved the proposed rule change on a one-year pilot basis, ending January 17, 1992.[2]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of

[1] Amex Rule 131(n) defines a percentage order as "a limited price order to buy (or sell) 50% of the volume of a specified stock after its entry."

[2] See Securities Exchange Act Release No. 28792 (January 17, 1991), 56 FR 2965 (order temporarily approving File No. SR-Amex-90-11 for a one-year pilot period).

and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

The Exchange is requesting permanent approval of changes to Exchange Rules 131 and 154, as they relate to percentage orders, which changes were approved previously by the Commission for a one-year pilot period ending January 17, 1992.[3] The Exchange believes that the changes made to these rules have contributed to the efficiency of the Exchange's market by providing specialists with the necessary flexibility to handle and service large-size orders.[4]

At the Commission's request, the Exchange is currently compiling information regarding its experience under the pilot. The Exchange expects to file its report with the Commission shortly.[5] The Exchange anticipates that the information contained therein will demonstrate that the new percentage order rules have enhanced the quality of the Exchange's auction market and ensured that the increased opportunities for converting percentage orders into limit orders do not come at the cost of unduly influencing the market.

2. Statutory Basis

As discussed in the Amex's earlier filing (File No. SR-Amex-90-11), the proposed rule change is consistent with section 6(b) of the Act in general and furthers the objective of section 6(b)(5) in particular in that it will promote the quality, depth and liquidity of the Exchange's stock market. By permitting the specialist to add depth and liquidity through his representation of percentage orders in situations where he may not have previously done so, this proposed rule change will have the effect of "facilitating transactions in securities" and will help to "perfect the mechanism of a free and open market" as called for in section 6(b)(5). By creating opportunities for participation of percentage orders in the Exchange's auctions where none previously existed, it will remove impediments to, and otherwise facilitate, a free and open market for stock transactions.

In addition, the proposed rule change will enable the Exchange to better handle large orders, thereby promoting intermarket competition for those orders. This will remove a burden on competition not necessary or appropriate in furtherance of the purposes of the Act as called for in section 6(b)(8), and will promote fair competition among brokers and dealers as called for in section 11A(a)(1)(C)(ii).

This proposed rule change also furthers the Congressional finding enunciated in section 11A(a)(1) in that better market conversions will help assure dissemination to brokers, dealers and investors of quotation information that better reflects the interest on the Floor.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change will impose no burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such other period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submission, all subsequent amendments all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR-Amex-91-29 and should be submitted by December 18, 1991.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-28494 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

[3] See note 2, *supra*.

[4] For a complete description of the proposed rule change, see File No. SR-Amex-90-11, note 2, *supra*.

[5] In this regard, the Commission notes that the report mentioned herein was filed with the Commission on October 21, 1991. See letter from Claudia Crowley, Special Counsel, Legal & Regulatory Policy Division, Amex, to Mary Revell, Branch Chief, Division of Market Regulation, dated October 18, 1991.

[6] 17 CFR 200.30-3(a)(12) (1990).

[Release No. 34-29959; File No. SR-CBOE-91-39]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Board Options Exchange, Inc., Relating to Offers of Settlement and Scheduling of Hearings

November 19, 1991.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on October 25, 1991, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to amend its rules relating to offers of settlements and the scheduling of hearings by modifying Exchange Rule 17.8. The proposed changes include limiting to 120 the number of days in which a respondent in a CBOE disciplinary proceeding may submit settlement offers after a statement of charges has been served

and limiting the number of settlement offers within that 120-day period to two. In addition, the proposal provides that a hearing will be scheduled following the end of the 120-day period, or earlier, if the Business Conduct Committee ("BCC") has rejected the respondent's second settlement offer. Finally, the proposal provides that respondents must request access to documents in writing within 60 days after being served a statement of charges. The text of the proposal is available at the Office of the Secretary, CBOE and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

Currently, the Exchange's disciplinary process allows a respondent to present an unlimited number of settlement offers up to the time the BCC renders a decision. The CBOE's rules do not provide specific time limits in which a disciplinary hearing must be held, nor do they limit the number of settlement offers a respondent may submit. As a result, as noted by the CBOE and by the Commission during an inspection of the Exchange last year, the Exchange's "disciplinary procedures have afforded respondents the opportunity to protract unreasonably the resolution of formal disciplinary matters through requests for dismissal of charges and unrealistic offers of settlement." In response to this problem, the Exchange proposes to limit to 120 days the time period for presenting settlement offers, as well as the number of settlement offers which may be submitted, to limit the time in which a respondent may request written access to documents, and to require the BCC to schedule a hearing at the end of the 120-day period, or earlier, if the BCC has rejected a respondent's second settlement offer.

Specifically, the CBOE proposes to amend Exchange Rule 17.8, "Offers of Settlement," to provide that a respondent will have 120 calendar days from the date of service of a statement of charges in which to present settlement offers. During that time, a respondent will be allowed to submit only two settlement offers, although the BCC, at its discretion, may permit a respondent to submit an additional settlement offer if the pertinent details of the respondent's offer are consistent with the parameters and criteria deemed acceptable by the BCC.

The CBOE's Office of Enforcement has concluded that unless respondents are under a time constraint such as the one proposed by the CBOE, respondents have no sense of urgency to settle matters. In fact, some respondents intentionally seek to delay the resolution of their matter. The CBOE notes that such delay causes evidence to become stale, witnesses to vanish, and justice to be circumscribed. Therefore, to augment and reinforce the proposed limitations on the number of settlement offers which may be submitted and the time constraints in which these offers may be presented, the CBOE also plans to require the BCC to schedule a hearing date at the end of the 120-day period, or earlier, if the BCC has rejected a respondent's second settlement offer. The CBOE believes that these amendments should allow the Exchange's disciplinary process to operate more efficiently and effectively.

Finally, the CBOE proposes to modify the respondent's right to have access to documents by providing that a respondent must make a written request for access to documents within 60 calendar days after being served a statement of charges. The Exchange believes that the 60-day time period should adequately protect a respondent's right to the documents and, at the same time, should prevent respondents from attempting to circumvent the 120-day period by requesting documents on the 119th day and then claiming that the Exchange unreasonably delayed the discovery process and thereby hindered settlement attempts. The Exchange notes that the 120-day period does not include the number of calendar days in excess of seven in which it takes the Exchange staff to provide access to documents after a request for documents is made by a respondent.

(2) Basis

The CBOE believes that the proposed rule change is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Section 6(b)(5), in particular, in that it protects investors and the public interest by promoting an efficient means of disciplining those who violate Exchange Rules and/or the Federal securities laws.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any inappropriate burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reason for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(a) By order approve such proposed rule change, or

(b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by December 18, 1991.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-28495 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

(Release No. 34-29977; File No. SR-DGOC-91-03

Self-Regulatory Organizations; Delta Government Options Corp.; Notice of Filing of Proposed Rule Change Relating to the Definition of Exercise Price

November 21, 1991.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on Novmeber 15, 1991, Delta Government Options Corp. ("DGOC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change (SR-DGOC-91-03) as described in Items I, II, and III below, which items have been prepared by DGOC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The purpose of the proposed rule change is to amend the definition of "Exercise Price" in DGOC's Procedures.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DGOC included statements concerning the purpose of and statutory basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. DGOC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule change

The purpose of the proposed rule change is to amend DGOC's Procedures so that "Exercise Price" is defined as the price stated in whole numbers and quarters for an option contract on a treasury bond or note with a remaining term to maturity of three years or more or the price stated in whole numbers and sixteenths for an option contract on a treasury bill or note with a remaining term to maturity of less than three years. Currently, Exercise Price is stated either in whole numbers and halves or in whole numbers and quarters, respectively. DGOC filed the proposal in order to respond to DGOC participants' requests for finer gradations in options prices especially with respect to options that are for shorter periods of time or are on underlying securities that have a shorter term to maturity. A more precise exercise price will afford DGOC participants greater flexibility and will enable such participants to engage in more trading especially during periods of low volatility where small incremental changes in options pricing become a more and more significant component of the decision to buy or sell an option.

The proposed rule change is consistent with the requirements of section 17A of the Act and the rules and regulations thereunder applicable to DGOC since it will permit more utilization of DGOC's Over-The-Counter Options Trading System by those participants who prefer to trade in options for hedging purposes or speculation. In particular, the tailoring of the option exercise price as proposed by DGOC will afford DGOC participants additional flexibility to choose an option exercise price that more precisely matches their overall treasury security portfolio. The proposal, moreover, will enable DGOC participants to submit for processing at DGOC over-the-counter treasury options trades that prior to this proposal could not be submitted because their stated exercise price was other than that previously available through DGOC.

DGOC's proposal, therefore, will allow for the automated clearance and settlement of securities that otherwise would have been cleared via a decentralized, inefficient, and labor-intensive process.

(B) Self-Regulatory Organization's Statement on Burden on Competition

DGOC does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purpose of the Act.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Not applicable.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to ninety days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which DGOC consents, the Commission shall:

(A) By order approve such proposed rule change or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any persons, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of DGOC. All submissions should refer to File No. SR-DGOC-91-03 and should be submitted by December 18, 1991.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-28497 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

(Release No. 34-29973; File No. SR-MBSCC-90-08)

November 20, 1991.

Self-Regulatory Organizations; MBS Clearing Corporation; Notice of Proposed Rule Change Relating to Revised Standards for Letter of Credit Issuers

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, ("Act") 15 U.S.C. 78s(b)(1), notice is hereby

given that on October 30, 1990, MBS Clearing Corporation ("MBSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. On August 19, 1991, MBSCC amended the proposed rule change, which MBSCC corrected on November 15, 1991.[1] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

MBSCC proposes to revise its eligibility standards for banks issuing letters of credit on behalf of MBSCC participants.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, MBSCC included statements concerning the purpose of, and basis for, the proposed rule change, and discussed any comments it received on the proposed rule change. The test of these statements may be examined at the places specified in Item II below. MBSCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to revise and strengthen MBSCC's criteria for issuers of letters of credit. Under its rule, deposits to the MBSCC Participants Fund, in excess o the basic deposit, may be made by delivery to MBSCC of an irrevocable letter of credit issued by an approved bank or trust company. MBSCC may approve as the issuer of the letter of credit any domestic or foreign bank or trust company meeting the requirements set forth in MBSCC's procedures. Under MBSCC's current procedures, both domestic and foreign issuers must demonstrate a Moody's Investor Service ("Moody's") long-term debt rating of at least A-3.[2]

MBSCC has conducted a comprehensive review of its risk management system with the goal of further minimizing related operational and financial risks. MBSCC's management has placed particular emphasis on letters of credit generally and letter of credit issuer eligibility standards in particular. MBSCC requires banks issuing letters of credit to honor drafts in accordance with MBSCC's instructions by 4:30 p.m. (Eastern Time) on the day of presentation, notwithstanding any contrary provision under commercial law.[3]

In the present rule filing, MBSCC is revising its standards for eligible issuers of letters of credit. Issuers will now be required to maintain prescribed Standard & Poor's, as well as Moody's, long term debt ratings. In the absence of available long term debt ratings, MBSCC will also consider as a substitute such issuer's Moody's or Standard & Poor's long term deposit ratings.

The proposed new standards for letter of credit issuers are summarized below:

1. Letter of credit issuers must have and maintain a Moody's long-term debt rating of at least A-3 and a Standard & Poor's long-term debt rating of at least A-.

2. In the event that a current or prospective letter of credit issuer does not have a Moody's or Standard & Poor's long-term debt rating, the long-term deposit rating must be at least A-3 in the case of Moody's and at least an A- in the case of Standard & Poor's.

3. In the event that a prospective letter of credit issuer has neither a Standard & Poor's nor a Moody's long-term debt rating, a determination of the eligibility of a prospective letter of credit issuer will be made by MBSCC's management and/or the Board of Directors, in consultation with the risk management committee. In no event will the aggregate value of the letters of credit issued by such banks exceed 0.5% or ½ of 1% of the total Participants' Fund deposit of all Participants.

The new standards retain the current Moody's A-3 requirement and further require an issuer to also maintain a prescribed Standard & Poor's rating. The standards also provide MBSCC management with the flexibility of reviewing and considering the independent ratings of two, rather than one rating agencies. The new standards would help ensure the continued liquidity and creditworthiness of MBSCC's Clearing Fund, and, thus, are consistent with the requirements of Section 17A of the Act and the rules and regulations thereunder.

B. Self-Regulatory Organization's Statement on Burden on Competition

MBSCC does not believe that the proposed rule will have an impact or impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change, Received From Members, Participants, or Others

MBSCC has advised all participants of the proposed rule change. No formal comments have been received, however, informal participant comment responses have been positive. The proposed rule change received the unanimous support of MBSCC's risk management committee.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

With 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if its finds such longer period to be appropriate and publishes its reason for so finding, or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed

[1] Amendment No. 1 initially clarified and corrected the original proposal to state that MBSCC management and/or the Board of Directors will have the authority to accept letters of credit issued by banks that do not meet the basic standards outlined in this Notice, provided the letters of credit issued by such banks should not exceed 5% of the total Participants' Fund deposits of all Participants. This figure was later changed, pursuant to MBSCC Board approval, to provide that such letters of credit do not exceed 0.5% or ½ of 1% of the total Participants' Fund deposits of all Participants. *See*, letter from Jeffrey E. Lewis, Associate Counsel and Assistant Secretary, MBSCC, to Ester Saverson, Branch Chief, Division of Market Regulation, Commission (November 15, 1991).

[2] A- and A-1, A-2, A-3 are credit ratings issued, respectively, by Standard and Poor's Corporation ("Standard & Poor's") and Moody's, to recommend the creditworthiness of various financial institutions with regard to certain financial obligations. These agencies may look at many factors, including profitability, capital, asset quality, liquidity, and management before assigning a rating to the obligations of a financial institution.

[3] See Securities Exchange Act Release No. 28800 (January 22, 1991), 56 FR 3129.

with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principle office of MBSCC. All submissions should refer to File No. SR-MBSCC-90-08 and should be submitted by December 18, 1991.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-28498 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

Self-Regulatory Organizations; Midwest Stock Exchange, Inc.; Application for Unlisted Trading Privileges in Over-the-Counter Issues and to Withdraw Unlisted Trading Privileges in Over-the-Counter Issues

November 21, 1991.

On November 13, 1991, the Midwest Stock Exchange, Inc. submitted an application for unlisted trading privileges ("UTP") pursuant to section 12(f)(1)(C) of the Securities Exchange Act of 1934 ("Act") in the following over-the-counter ("OTC") securities, *i.e.*, securities not registered under section 12(b) of the Act:

File No.	Symbol	Issuer
7-7529	CMCSA	Comcast Corp., Class A Common Stock, $1.00 par value.
7-7530	CSFN	Corestates Financial Corp., Common Stock, $1.00 par value.
7-7531	IMNX	Immunex Corporation, Common Stock, $.01 par value.
7-7532	SAFC	Safeco Corp., Common Stock, no par value.
7-7533	USBC	U.S. Bancorp, Common Stock, $5.00 par value.
7-7534	CTUS	Cetus Corporation, Common Stock, $.01 par value.
7-7535	QNTM	Quantum Corporation, Common Stock, $.01 par value.

The above-referenced issues are being applied for as an expansion of the exchange's program in which OTC securities are being traded pursuant to a grant of UTP.

The MSE also applied to withdraw UTP pursuant to section 12(f)(4) of the Act on the following issues:

The Exchange requests that Cetus Corporation be removed from the program due to its pending acquisition by Chiron Corporation. The Exchange also requests that Quantum Corporation be removed from the program due to its inactive trading.

Comments

Interested persons are invited to submit, on or before December 12, 1991, written comments, data, views and arguments concerning this application. Persons desiring to make written comments should file three copies with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

Commentators are asked to address whether they believe the requested grants of UTP would be consistent with section 12(f)(2), which requires that, in considering an application for extension of UTP in an OTC security, the Commission consider, among other matters, the public trading activity in such security, the character of such trading, the impact of such extension on the existing markets for such security and the desirability of removing impediments to and the progress that has been made toward the development of a national market system.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-28504 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-29974; File No. SR-NASD-91-57]

Self-Regulatory Organizations; Proposed Rule Change by National Association of Securities Dealers, Inc., Relating to Improvements in the NASD Code of Arbitration Procedure

November 20, 1991.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on November 4, 1991, the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NSAD proposes to amend part III, section 13(d) of the NASD Code of Arbitration Procedure (the "Code")[1] to improve the efficiency of its arbitration process. In general, the proposed rule change is intended to allow for a single arbitrator in simplified cases where a counterclaim exceeds $10,000.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Clarifying Panel Size in Simplified Cases: The proposed rule change to Section 13(d) would permit the appointment of a single arbitrator in simplified cases [2] where a counterclaim or third-party claim exceeds $10,000, unless the parties demand a panel of three arbitrators. This conforms to the provisions of section 19(a) of the Code, which provides that a single arbitrator may be appointed where the amount in controversy does not exceed $30,000. In the event that the amount in controversy exceeds $30,000, section 19(b) of the Code would require the appointment of a panel of three arbitrators. Additionally, minor punctuation changes have been made to conform section 13 to other sections of the Code.

[1] NADS Securities Dealers Manual, CCH ¶3713.

[2] Section 13 provides an arbitration procedure, characterized as Simplified Arbitration, for any dispute, claim or controversy which is subject to arbitration, arising between a public customer and an associated person or a member, involving a dollar amount not exceeding $10,000. Section 13(f) allows for a single arbitrator in Simplified cases, and upon request, Section 13(i) allows for the appointment of two additional arbitrators to decide the matter in controversy.

The NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act, in that the proposed rule change will facilitate the efficiency of the arbitration process, to the benefit of the public interest and the protection of investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believe that the proposed rule change imposes any burden on competition not necessary or appropriate in furtherance of the purpose of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so findings or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comment

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington DC 20549. Copies of the submission, all subsequent amendments, will written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted by December 18, 1991.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-28499 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-29976; File No. SR-NASD-91-49]

Self-Regulatory Organizations; Proposed Rule Change by National Association of Securities Dealers, Inc., Relating to Improvements in the NASD Code of Arbitration Procedure

November 21, 1991.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on September 24, 1991 the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASD proposes to amend Part III, sections 12, 13(h), 22, 29 and 41(h) of the NASD Code of Arbitration Procedure (the "Code") to improve the efficiency of its arbitration process.

In general, the proposed rule changes are intended to permit the referral of cases to the self-regulatory organization that supervises the market where the transaction occurred, provide pre-hearing procedures for simplified cases, provide a time period within which to raise a peremptory challenge to an arbitrator selected to determine pre-hearing matters, clarify the authority of arbitrators to proceed where a party fails to appear at any hearing session, and provide for the accrual of interest on awards.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The proposed rule change is intended to accomplish the following:

1. Referral of Cases to Other Self-Regulatory Organizations

Under the proposed rule change to section 12, the Arbitration Department would review each claim to determine whether all transactions are readily identifiable as arising out of another market. If so, the claimant would be contacted and asked to consent to having the case referred to the appropriate self-regulatory organization for that market. It is intended that the NASD would retain jurisdiction where the claim involved a mix of securities from different markets.

2. Pre-Hearing Procedures in Simplified Arbitrations

The proposed rule change to section 13(h) refers the parties to the general pre-hearing procedures of section 32 when a hearing is to be conducted, and sets shorter time frames for discovery where no hearing is to be conducted, in keeping with the policy of expediting small claims cases.

3. Peremptory Challenge to Selected Arbitrator

The proposed rule change to section 22 clarifies existing practice, wherein a peremptory challenge must be raised within five days of notification of the arbitrator named under either the general selection procedures of section 21 or the pre-hearing procedures of section 32 (d) or (e), whichever comes first in the course of the arbitration. Thus, a party that has not objected to an arbitrator selected to handle a pre-hearing conference or discovery dispute may not later raise a peremptory challenge to the same arbitrator when notification is made of the names of the entire panel.

4. Failure of a Party to Appear

The proposed rule change to section 29 clarifies the authority of the arbitrator(s) to proceed with and dispose of a case if a party fails to appear not only at the initial hearing, but at any continuation hearing session.

5. Interest Accrual on Awards

The proposed rule change to section 41 adds a new paragraph (h), providing that interest will accrue from the date of the award if the award is not paid within 30 days of receipt or if the award is the subject of a motion to vacate that is denied, unless otherwise specified by the arbitrators in the award. The rate of interest will be the legal rate (if any) prevailing in the state where the award was rendered, unless a different rate is set by the arbitrators.

The NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act, in that the proposed rule change will facilitate the arbitration process in the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Association does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Comments were neither solicited nor received

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted by December 18, 1991.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-28500 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-29979; File No. SR-NASD-91-60]

Self-Regulatory Organizations; Filing and Order Granting Accelerated Approval of Proposed Rule Change by the National Association of Securities Dealers, Inc., Relating to an Interim Extension of the OTC Bulletin Board Service through March 31, 1992

November 21, 1991.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on November 18, 1991, the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons, and to grant accelerated approval of the proposed rule change.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

On June 1, 1990, the NASD initiated operation of the OTC Bulletin Board Service ("Bulletin Board" or "Service") in accordance with the Commission's approval of File No. SR-NASD-88-19, as amended.[2] The Service provides a real-time quotation medium that NASD member firms can elect to use to enter, update, and retrieve quotation information (including unpriced indications of interest) for securities traded over-the-counter that are not included in the Nasdaq System nor listed on a registered national securities exchange (collectively referred to as "unlisted securities"). Essentially, the Bulletin Board is an electronic medium that supports NASD members' market making in unlisted securities through authorized Nasdaq Workstation units. Real-time access to quotation information captured in the Service is available to subscribers of Level 2/3 Nasdaq service as well as subscribers of vendors-sponsored services that now include Bulletin Board data. The Commission's approval of the Service was limited to a pilot term of one year, which expired on May 31, 1991. On May 28, 1991, the Commission granted an interim extension of the pilot through November 30, 1991.[3]

The NASD has filed this proposed rule change to obtain authorization for a further interim extension of the Service through March 31, 1992. During this four-month interval, there will be no changes in the Bulletin Board's operational features nor in the current fee structure.[4]

During the proposed extension, the NASD will also proceed to develop information for another 19b-4 filing that will address permanent status for the Service and the terms for continued inclusion of foreign securities/ADRs in the Service.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in Section (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of this filing is to ensure continuity in the operation of the

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[1] 15 U.S.C. 78s(b)(1) (1990).

[2] See Securities Exchange Act Release No. 27975 (May 1, 1990), 55 FR 19124.

[3] See Securities Exchange Act Release No. 29249 (May 28, 1991), 56 FR 26172.

[4] On August 27, 1991, the Commission approved a monthly charge of $5/security position on NASD member firms displaying quotations or trading interest in the Service and a $.50 increase in the monthly Level 1 subscriber charge for receipt of Bulletin Board information through vendor services. See Securities Exchange Act Release No. 29616 (August 27, 1991), 56 FR 43826.

Service while the NASD gathers information necessary to support another 19b-4 filing that will request permanent approval of the Service. As of October 31, 1991, the Bulletin Board carried broker-dealers' quotations/indications of interest on 4,117 unlisted securities. Moreover, there were 231 NASD member firms registered as market makers in these securities, with a total of 10,480 market making positions.

During the proposed extension, foreign securities/ADRs will remain subject to the twice-daily update limitation that traces back to the Commission's original approval of the Service's operation. As a result, all priced bids/offers for these securities that are displayed in the Service will remain indicative.

In conjunction with the operation of the Service, the NASD has established a filing requirement and review procedures to verify member firms' compliance with Rule 15c2-11 under the Act.[5] During the proposed extension, this review process will continue to be an integral component of the NASD's self-regulatory oversight of the Service. Additionally, the NASD expects to work closely with the Commission staff in developing enhancements to the Service mandated by passage of the Securities Enforcement Remedies and Penny Stock Reform Act of 1990.

The NASD relies on sections 11A(a)(1), 15A(b) (6) and (11), and section 17B of the Act as the statutory basis for the instant rule change proposal. Section 11A(a)(1) sets forth the Congressional findings and policy goals respecting operational enhancements to the securities markets. Basically, the Congress found that new data processing and communications techniques should be applied to improve the efficiency of market operations, broaden the distribution of market information, and foster competition among market participants. Section 15A(b)(6) requires, among other things, that the NASD's rules promote just and equitable principles of trade, facilitate securities transactions, and protect public investors. Additionally, subsection (11) authorizes the NASD to adopt rules governing the form and content of quotations for securities traded over-the-counter for the purposes of producing fair and informative quotations, preventing misleading quotations, and promoting orderly procedures for collecting and disseminating quotations. Finally, section 17B contains the Congressional findings and directives respecting the collection and distribution of quotation information on low-priced unlisted equity securities.

The NASD submits that extension of the Service through March 31, 1992, is consistent with the foregoing provisions of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believes that any burden will be placed on competition as a result of this filing.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The NASD requests that the Commission find good cause, pursuant to section 19(b)(2) of the Act, for approving the proposed rule change prior to the 30th day after its publication in the **Federal Register** to avoid interruption of the Service. The current authorization for the Service extends through November 30, 1991. Hence, it is imperative that the Commission approve the instant filing on or before that date. Otherwise, the NASD will be required to suspend operation of the Service pending Commission action on the proposed extension.

The NASD believes that accelerated approval is appropriate to ensure continuity in the Service's operation pending a later determination on permanent status for the Service. Continued operation of the Service will ensure the availability of an electronic quotation medium to support member firm's market making in approximately 4,000 unlisted equity securities. The Service's operation also expedites price discovery and facilitates the execution of customer orders at the best available price.

The Commission finds good cause for approving the interim extension prior to the 30th day after the date of publishing notice of this filing. The Commission agrees with the NASD that accelerated approval of the proposal is appropriate to ensure continuity in the Service's operation as an electronic quotation medium that supports NASD's member's market making in these securities and that facilitates price discovery and the execution of customers orders at the best available price. Additionally, continued operation of the Service will materially assist the NASD's surveillance of trading in unlisted securities that are quoted in the Service.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted by December 18, 1991.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the interim extension for the OTC Bulletin Board, be, and hereby is, approved for a four month period, ending on March 31, 1992.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-28501 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

[5] See section 4 of Schedule H to the NASD By-Laws.

[6] 17 CFR 200.30-3(a)(12)(1991).

[Release No. 34-29975; No. SR-NYSE-91-37]

Self-Regulatory Organizations; Proposed Rule Change by New York Stock Exchange, Inc., Relating to Amendments to its Arbitration Rules

November 21, 1991.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on October 24, 1991, the New York Stock Exchange, Inc. ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. On

November 13, 1991, the NYSE submitted to the Commission an amendment to clarify certain language in the proposal.[1] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NYSE proposes several amendments to its arbitration rules. The proposed adoption of rule 600(c) seeks to provide for a more efficient allocation of arbitration claims among the various self-regulatory organizations ("SROs"). The proposed amendment to rule 601(a) will codify the practice of the Exchange in applying simplified procedures to claims under $10,000 without the demand or written request of the customer. The proposed adoption of rule 601(h)(ii) codifies the applicability of the Exchange's current discovery procedures to simplified arbitrations when a public customer demands a hearing. The proposed adoption of rule 601(h)(iii) establishes a procedure by which an arbitrator may resolve discovery disputes over the production of documents in simplified arbitrations where no hearing has been demanded. The proposed amendment of rule 616 will clarify the rule regarding the failure of a party to appear at a hearing. The proposed amendment to rule 625 will require parties submitting amended pleadings to provide the Director of Arbitration with sufficient copies for distribution to the appointed arbitrators. It also will require those parties to serve directly all other parties with the amended pleadings. The proposed amendment also will require parties answering amended pleadings to directly serve all other parties and the Director of Arbitration with their responsive pleadings. The proposed amendment to rule 627(e) will require that the names of counsel representing the parties and the type of product or security involved in an arbitration appear in the award. The proposed amendment to rule 627(g), which also will consolidate rules 627 (g) and (h), requires that interest on awards will accrue from the date of the award only if the award is not paid within the required thirty day period or a motion to vacate has been unsuccessful. The rule will expressly permit the arbitrators to set a different date on which interest will begin to accrue.

[1] See letter from James E. Buck, Senior Vice President and Secretary, NYSE to Mary N. Revell, Branch Chief, Division of Market Regulation, Commission, data November 12, 1991.

II. Self-Regulatory Organization's Statement of the Propose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The proposed rule changes are based for the most part on proposals developed by the Securities Industry Conference on Arbitration. In general, the proposed rule changes are intended to address the allocation of securities claims among SROs, clarify the use of the Simplified Arbitration Procedure and the applicable discovery procedures, clarify the arbitrators' authority to proceed in any arbitration session at which any party has failed to appear, require parties filing amended pleadings to directly serve the pleadings on the other parties to the arbitration, include the name(s) of counsel and the security or product involved in an arbitration in an award, and clarify the accrual of interest on awards.

(a) The purposes of the proposed changes are to:

- Provide for a more efficient allocation of claims among the various SROs [rule 600(a)];
- Apply simplified arbitration procedures to all claims under $10,000 without demand or written request of the customer [rule 601(a)];
- Provide for discovery in simplified arbitrations [rule 601(h)];
- Specify when a party may exercise a peremptory challenge (rule 609);
- Clarify the authority of arbitrators to proceed with an arbitration when a party fails to appear at a hearing (rule 616);
- Conserve arbitral resources and shorten the time required by the pleadings stage by requiring the parties to serve amended pleadings [rule 625(a)];
- Include the name(s) of counsel and the type of security or product in controversy in the arbitration award form [rule 627(e)];
- Clarify when interest is payable on an award [rule 627(g)].

9(b) The proposed changes are consistent with section 7(b)(5) of the Act in that they promote just and equitable principles of trade by insuring that members and member organizations and the public have an impartial forum for the resolution of their disputes.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NYSE does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From members, Participants, or Others

The Exchange did not solicit comments on the proposed rule change. No letters were received from member organizations.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any persons, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC

20549. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to File No. SR-NYSE-91-37 and should be submitted by December 18, 1991.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-28502 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-29961 File No. SR-PSE-91-10]

Self-Regulatory Organizations; Pacific Stock Exchange Inc.; Order Approving Proposed Change Relating to the Disclosure of Member Financial Arrangements

November 19, 1991.

On May 7, 1991, the Pacific Stock Exchange, Inc. ("PSE" or "Exchange") submitted to the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and rule 19b-4 thereunder,[2] a proposed rule change to require PSE market makers, floor brokers, specialists or other PSE member organizations who enter into financial arrangements with any other PSE member to disclose to the Exchange the terms of such arrangements.[3]

The proposed rule change was published for comment in Securities Exchange Act Release No. 29248 (May 29, 1991), 56 FR 26176. No comments were received on the proposed rule change.

The PSE proposes to amend its rules relating to the disclosure of member financial arrangements by adding a new Exchange Rule 4.18 entitled "Disclosure of Financial Arrangements of Members." Specifically, new PSE Rule 4.18 would require each PSE market maker, floor broker, specialist or PSE member organization who enters into a financial arrangement with any other PSE member to disclosure to the PSE the name of such member and the terms of the arrangement.[4] The rule defines a financial arrangement to be: (1) The direct financing of a member's dealings upon the Exchange; (2) any direct equity investment or profit sharing arrangement; and (3) any consideration over the amount of $5,000.00 that constitutes a gift, loan, salary or bonus. In addition, the parties to a financial arrangement must provide a 10-day written notice period prior to the initiation or termination of such ar arrangement.

Existing PSE Rule 6.40 requires the disclosure of market maker financing arrangements to the Exchange.[5] This Rule mandates that market markers with financing arrangements between themselves disclose the arrangements to the Exchange in order to enhance the Exchange's ability to monitor the activity of market makers and their compliance with PSE rules. Because PSE Rule 6.40 only applies to options market makers, the Exchange currently does not have a rule governing the disclosure of financial arrangements between PSE members on its equity floor. Accordingly, the present proposal would expand the types of financial arrangements among PSE members that must be disclosed to the PSE to include all arrangements among PSE members. The Exchange believes that requiring disclosure of all financial arrangements among PSE members, not just options members, will serve to increase the PSE's ability to monitor existing financial arrangements in order to prevent potential collusive trading activity.

Proposed Rule 4.18 also provides the Exchange with the authority to restrict the trading activities of members with financial arrangements pursuant to PSE Rule 6.40. As discussed above, however, PSE Rule 6.40 applies solely to PSE options market makers, and the PSE does not intend to broaden the provisions of this rule to cover all PSE members.[6] Therefore, the language in proposed Rule 4.18 imposing trading restrictions on PSE members by cross-referencing the trading restrictions in rule 6.40 is limited solely to options market makers.[7]

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6 [8] and the rules and regulations thereunder. Specifically, the Commission finds that required full disclosure of financing arrangements among all Exchange members is a reasonable means to prevent fraudulent and manipulative acts and practices and promote just and equitable principles of trade. By requiring all PSE members who enter into a financial arrangement with any other PSE member to disclose the name of such member and the terms of the arrangement, the Commission believes the Exchange will be better able to identify and deter collusive or prearranged trading and other trading abuses among its membership. In addition, the Exchange's ability to monitor the financial condition of its members will be enhanced.

The Commission also finds that the requirement that members give the Exchange 10 days written notice prior to the initiation or termination of a financial arrangement with another PSE member is consistent with section 6(b)(5) and (8) of the Act.[9] In particular, the pre-effective disclosure requirement for the initiation and termination of member financial arrangements does not impose any limitation or restriction on the ability of Exchange members to enter into financial arrangements with other PSE members. Accordingly, this disclosure provision does not place PSE members at a competitive disadvantage and does not permit the Exchange to have any control over member business decisions that are appropriately left to the discretion of the members.[10] In fact.

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[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b-4 (1989).

[3] See, *infra* note 5 and accompanying text for a description of the Exchange's current rules with respect to the disclosure of financial arrangements among PSE members.

[4] The PSE amended its proposed Rule 4.18 by deleting language in the proposal which would have authorized the Exchange to restrict the trading activity of members with financial arrangements "in instances that it deems appropriate, as determined on a case-by-case basis." See letter from Esther M.W. Aw, Regulation Administrator, PSE, to Howard Kramer, Assistant Director, Division of Market Regulation, SEC, dated September 13, 1991.

[5] PSE Rule 6.40 was amended in June, 1990, in order to require PSE market makers to disclose to the Exchange those financial arrangements by which they extend credit or receive credit from other PSE market makers, and to implement trading rules for market makers having financial arrangements between themselves and market makers that are joint account participants. Specifically, an options market maker having an existing financial arrangement with another market maker is not permitted to concurrently bid, offer, purchase, sell, or enter orders in the same options series. See Commentary .01 to PSE Rule 6.40. In addition, a market maker may not bid, offer, purchase, sell, or enter orders in an option series in which a floor broker holds an order on behalf of a market maker with whom he has an existing financial arrangement. Finally, orders of market makers having an existing financial arrangement are also not permitted to be concurrently represented, by one or more floor brokers, in a particular options series. See Commentary .02, PSE Rule 6.40. See also Securities Exchange Act Release No. 28134 (June 19,1990), 55 FR 26320.

[6] See letter from Esther M.W. Aw, Regulation Administrator, PSE, to Jeffrey Burns, Attorney, Options Regulation, Division of Market Regulation, SEC, dated October 23, 1991.

[7] *Id.*

[8] 15 U.S.C. 78f (1982).

[9] 15 U.S.C. 78f(b)(5), (8) (1990).

[10] See also Securities Exchange Act Release No. 29797 (October 8, 1991), 56 FR 51945, in which the Commission found that a similar notice provision involving substantial business transactions of clearing members of the Chicago Board Options Exchange was consistent with the Act.

the Commission believes the disclosure requirement is wholly consistent with the PSE's stated purpose for its proposal, namely, the enhancement of Exchange surveillance and member firm monitoring capabilities.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[11] that the proposed rule change (SR-PSE-91-10) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-28530 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

[11] 15 U.S.C. 78s(b)(2) (1982).

[12] 17 CFR 200.30-3(a)(12) (1990).

[Release No. SIPA-157; File No. SIPC 91-1]

Securities Investor Protection Corporation; Order Approving Proposed Bylaw Change Relating to SIPC Fund Assessments on SIPC Members.

November 20, 1991.

On September 27, 1991, the Securities Investor Protection Corporation ("SIPC") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 3(e)(1) of the Securities Investor Protection Act of 1970 ("SIPA"), 15 U.S.C. 78ccc(e)(1), a proposed bylaw change.

I. Description of Proposed Bylaw Change

The proposed bylaw change would amend Section 1 of Article 6 of SIPC's bylaw regarding SIPC Fund assessments on SIPC's members.[1] The proposed bylaw provides that the amount of each member's assessment for the member's fiscal year beginning in 1991 and subsequent fiscal years shall be the product of the member's net operating revenues from the securities business for such fiscal year and the assessment rate established by SIPC for such fiscal year.[2] The assessment rate shall be that percent of each member's net operating revenue from the securities business required to bring the SIPC Fund [3] to a specified target balance on the next April 1.

The term "net operating revenues from the securities business" means gross revenues from the securities business less interest and dividend expenses. The total deduction of interest and dividend expenses will not be allowed to exceed the total of all interest and dividend income. As an alternative to the proposed net operating revenues assessment base, SIPC will continue its current practice of allowing members to deduct from their gross revenues from the securities business 40 percent of interest earned on customers' securities accounts.[4]

A formula will be used to arrive at the assessment rate. Pursuant to the formula, the projected SIPC Fund will be deducted from the SIPC Fund target balance as of the next April 1 to determine the needed assessment income. The projected SIPC Fund will be determined by taking the SIPC Fund balance as of September 30 with the following adjustments: (i) Deducting SIPC's assessment collections for the period from the prior April 1 to September 30, (ii) adding the amount of SIPC's estimated interest income from September 30 to the end of the next March, and (iii) deducting SIPC's estimated liquidation costs and operating expenses from September 30 to the end of the next March. The assessment rate will equal the amount of needed assessment income divided by the projected assessable revenues of New York Stock Exchange members.[5] However, if the assessment determined under the formula exceeds ½ of 1 percent of a member's gross revenues from the securities business, the assessment shall be ½ of 1 percent of that member's gross revenues from the securities business.[6]

The specified annual target balance for the SIPC Fund will be based on a net annual growth rate of 10 percent selected by the SIPC Board. This growth rate will enable the SIPC Fund to reach $1 billion by April 1, 1997.[7]

SIPC indicated that the SIPC Board's actions described above were based principally on the "Report and Recommendations of the SIPC Task Force on Assessments," and on the data gathered and analyzed by the task force. The task force was composed of representatives of SIPC members, self-regulatory organizations, securities industry associations, U.S. government agencies, and the SIPC staff. The task force's principal recommendations were that (1) the fund grow at an annual rate of 8 percent to reach the $1 billion level targeted by the SIPC Board and (2) the assessment basis be changed from gross revenues from the securities business to net operating revenue from the securities business while, in the alternative, allowing firms to continue deducting 40 percent of margin interest income if this amount were greater than the dividend and interest expense deduction.[8]

II. Request for Public Comment

Section 3(e)(1) of the SIPA provides that SIPC must file with the Commission a copy of proposed bylaw changes. That section further provides that bylaw changes shall take effect 30 days after filing, unless the Commission either (i) disapproves the change as contrary to the public interest or the purposes of SIPA, or (ii) finds that the change involves a matter of such significant public interest that public comment should be obtained, in which case, the Commission may, after notifying SIPC in writing of such finding, require that the proposed bylaw change be considered by the same procedures as a SIPC proposed rule change.

The SIPC Fund, which is built from assessments on its members and the interest earned on the Fund, is used for the protection of customers of members liquidated under SIPA to maintain investor confidence in the securities markets. In light of this fact and because the bylaw change provides for a new assessment basis to reach a targeted annual fund balance, the Commission found, pursuant to section 3(e)(1)(B) of SIPA, that the proposed bylaw change involved a matter of such significant

[1] All broker-dealers registered under section 15(b) of the Securities Exchange Act of 1934, with some minor exceptions, are SIPC members.

[2] The minimum assessment will continue to be $150 per annum.

[3] The SIPC Fund consists of cash and amounts invested in U.S. government or agency securities. As of September 30, 1991, the SIPC Fund totalled $662 million. In addition, SIPC has access to a $500 million line of credit established by SIPC with a consortium of banks. Further, the SIPA authorizes SIPC to borrow, through the Commission, up to $1 billion from the United States Treasury Department.

[4] As to the 40 percent deduction, SIPC indicated that its Board of Directors ("SIPC Board") will consider within the next year whether the alternative deduction should be eliminated. SIPC states that the SIPC Board did not believe that it had sufficient information as to the impact on its members had it chosen to eliminate the deduction. The SIPC Board directed the SIPC staff to gather additional information on this matter.

[5] Currently, each SIPC member is required to pay assessments at the rate of 3/16 of 1 percent of the member's gross revenues from the securities business with certain permitted deductions, with a minimum assessment of $150.

[6] The bylaw change also provides that if SIPC determines that the SIPC Fund totals or is reasonably likely to total less than $150 million, the amount of each member's assessment shall be the amount determined under the formula or ¼ of one percent per annum of such member's gross revenues from the securities business, whichever is greater. If the SIPC Fund totals or is reasonably likely to total less than $100 million, the amount of each member's assessment shall be ½ of 1 percent per annum of such member's gross revenues from the securities business.

[7] The SIPC Board also decided to pursue the possibility of an increase in the size of SIPC's current line of credit.

[8] The task force recommended that assessments continue to be based on revenues rather than any other basis.

public interest that public comment should be obtained, and that the procedures applicable to proposed SIPC rule changes in section 3(e)(2) of SIPA should be followed. As required by section 3(e)(1)(B) of the SIPA, the Commission notified SIPC of the Commission's finding in writing.

Notice of the Commission's action including its request for public comment on the proposed bylaw change and notice of the proposed bylaw change together with the terms of substance thereof were given by the issuance of a Commission release (Securities Investor Protection Act Release No. 156, October 11, 1991) and by publication in the **Federal Register** (56 FR 51952, October 16, 1991).

III. The Comment Letters and Commission Response

The comment period expired on November 6, 1991. Seventeen letters of comment were received strongly supporting SIPC's proposed actions with two caveats.

One commenter strongly supported the proposed bylaw change, but also supported the task force's recommendation that those firms affected by SIPC's 1990 interpretation that only interest expense on matched repurchase and securities lending transactions could be deducted in calculating assessments be given a credit towards future SIPC assessments in order to offset the amounts paid for fiscal year 1990. One other commenter also supported that same recommendation.

Because SIPC's Board rejected the recommendation regarding credit for amounts paid in 1990 based on SIPC's interpretation, the matter is not currently before the Commission.

One commenter noted that the current SIPC assessment allows SIPC members to deduct from revenues net dividends and interest from securities in trading accounts, as well as 40% of interest earned on customers' securities accounts. Under the proposed SIPC bylaw, which will allow for an assessment on net operating revenues, the greater of all interest and dividend expense (not to exceed interest and dividend income) or 40% of interest earned on customers' securities accounts will be the allowable deduction. Thus, well capitalized firms which use little or no debt to finance their inventory will no longer be able to take advantage of both deductions.

This issue was considered by the task force. Recognizing that some firms would be adversely affected by eliminating both the net interest and dividend deduction as well as the 40% deduction, the task force determined that the choice under the proposed bylaw, together with a reduced assessment rate if liquidations costs continue at the present rate, would be equitable to the brokerage community as a whole. The Commission agrees with that determination.

IV. Approval of Proposed Bylaw Changes

The Commission believes that SIPC's proposed actions provide substantial protection for customers of broker-dealers liquidated under SIPA. The Commission is of the view that the proposed bylaw change will not only result in an increase of the SIPC Fund, but also will promote investor confidence in the securities markets. The targeting of an annual balance for the SIPC Fund based on a net annual growth rate, ten percent, selected by the SIPC Board will increase the size of the SIPC Fund in stable planned, increments that will enable the SIPC Fund to reach the $1 billion level on a predetermined date in early 1997. The Commission also believes that it is appropriate to change the assessment base from gross revenues from the securities business to net operating revenues from the securities business in light of the increasing proportion of interest based transactions contributing to industry revenues.

Accordingly, the Commission finds that the proposed SIPC bylaw change is in the public interest and is consistent with the purposes of the SIPA.

It is therefore ordered, pursuant to Section 3(e)(2) of the SIPA, that the above-mentioned proposed bylaw change be, and hereby is, approved.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91-28492 Filed 11-26-91; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Advisory Commission on Conferences in Ocean Shipping; Open Meeting

AGENCY: Department of Transportation (DOT), Office of the Secretary.

ACTION: Notice of open meeting of the Advisory Commission on Conferences in Ocean Shipping.

SUMMARY: The Commission will be holding a meeting in Washington, DC on Monday and Tuesday, December 16-17, 1991; the meeting is open to the public. The Commission plans to examine key issues before the Commission, particularly service contracting and antitrust immunity.

DATES: *Meeting:* Monday and Tuesday, December 16-17, 1991; 9:30 a.m. to 5:30 p.m. e.s.t.

ADDRESSES: The address for the public meeting is Department of Transportation Headquarters Building, 400 Seventh Street, SW., Washington, DC, room 9230.

FOR FURTHER INFORMATION CONTACT: Florizelle B. Liser, Executive Director; telephone (202) 366-9781; FAX (202) 366-7870.

SUPPLEMENTARY INFORMATION: The Commission was created by the Shipping Act of 1984 to conduct an independent and comprehensive study of conferences in ocean shipping, particularly whether the Nation would be best served by prohibiting conferences, or by closed or open conferences. The Commission is to provide its report, including recommendations, to the President and the Congress by April 10, 1992. After holding five field hearings arond the country during the summer, the Commission began the deliberative stage of its work in October. At this meeting, the Commissioners will discuss preliminary background chapters and options for inclusion in the report. In particular, they will focus on service contracting on Monday, December 16, 1991 and on antitrust immunity on Tuesday, December 17, 1991.

Issued in Washington, DC on November 22, 1991.

Florizelle B. Liser,

Executive Director.

[FR Doc. 91-28476 Filed 11-26-91; 8:45 am]

BILLING CODE 4910-62-M

Coast Guard

[CGD 91-060]

Chemical Transportation Advisory Committee (CTAC) Meeting and CTAC Subcommittee on Tank Filling Limits Meeting

AGENCY: Coast Guard, DOT.

ACTION: Notice of meetings.

SUMMARY: A. The Chemical Transportation Advisory Committee (CTAC) will hold a meeting on Friday, February 28, 1992 in room 2415, U.S. Coast Guard Headquarters, 2100 2nd Street, SW., Washington, DC 20593. The meeting is scheduled to begin at 9:30 a.m. and end at 4 p.m.

The agenda for the meeting follows:

1. Opening remarks.
2. U.S. Coast Guard remarks.

3. General interest topics.
4. Issue briefs:
   Benzene regulations.
   Tankerman regulations.
   TSAC work—part 151.
5. Subcommittee reports:
   46 CFR part 151 update.
   Marine vapor recovery.
   Tank filing limits.
   Inert gas systems.
   Coal tar.
   Fire fighting media review/foam.
6. New tasks and initiatives.
7. International activities update.
8. Other business.
9. Closing.

B. The Subcommittee on Tank Filling Limits of the Chemical Transportation Advisory Committee (CTAC) will hold its meeting on Thursday, February 27, 1992 in room 1303, Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593. The meeting is scheduled to begin at 9:30 a.m. and end at 4 p.m. The Tank Filling Limits Subcommittee will continue its review of the proposal to change the filling limit requirements contained in the International Gas Code.

Attendance to both meetings is open to the public. Members of the public may present oral statements at the meetings. Persons wishing to present oral statements should notify the Executive Director of CTAC no later than the day before the meeting. Any member of the public may present a written statement to the Committee at any time.

FOR FURTHER INFORMATION CONTACT: Commander K.J. Eldridge or Mr. F.K. Thompson, U.S. Coast Guard Headquarter (G-MTH-1), 2100 Second Street SW., Washington, DC 20593, (202) 267-1217.

Dated: November 14, 1991.

[FR Doc. 91-28490 Filed 11-26-91; 8:45 am]

BILLING CODE 4910-14-M

[CGD 91-061]

Navigation Safety Advisory Council

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting.

As required by the Federal Advisory Committee Act, this notice announces a meeting of the Navigation Safety Advisory Council on Wednesday through Friday, December 11-13, 1991. The meeting will be held at the U.S. Coast Guard Reserve Training Center, Yorktown, VA. The Council will convene for a preliminary plenary session at 4 a.m. on Wednesday, December 11, 1991, in room 309, Hamilton Hall.

Committees will meet on Wednesday, December 11, from 8:30 to 11:30 a.m. and on Thursday, December 12 from 8 to 11 a.m. Committee discussions will include the following topics:

a. *Navigation Rules:*

1. Rule 23—Placement of masthead lights on vessels of 20 to 50 meters.

2. Rule 24—Proper lighting for barges being towed.

3. Rule 26—Lights and shapes displayed by vessels engaged in fishing.

4. Procedures for amending Inland/International Rules.

5. Consistency review of Navigation Rules.

b. *Routing Measures and Vessel Traffic Service (VTS) issues:*

1. National VTS regulations.

2. Review of Inland Rule 10 in relation to VTS, traffic separation schemes (TSS/'s) and International Rule 10.

3. Oil Pollution Act of 1990 mandated tanker movement study.

c. *Human Factors in Navigation Safety:*

1. Fatigue, work hours, and other human factors.

d, *Marine Information and Communications:*

1. Responsibility for maintaining approaches to commercial berths.

2. Metrication of charts.

e. *Ad hoc Committee:*

1. Evaluate the need to establish minimum under-the-keel clearance criteria.

The Council will convene in plenary session on Thursday, December 12 at 2:30 to 6:30 p.m. and reconvene on Friday, December 13 at 8 a.m. to hear Committee status reports and any matters properly brought before the Council.

The meeting is open to the public. Persons wishing to make oral statements should notify the Executive Director at the address below no later than Monday, December 9, 1991. Any person may present a written statement to the Council at any time without advance notice.

For additional information, contact Margie G. Hegy, Executive Director, Navigation Safety Advisory Council, U.S. Coast Guard (G-NSR-3), Washington, DC 20593-0001, Telephone (202) 267-0415.

Dated: November 20, 1991.

W. J. Ecker,

Rear Admiral, U.S. Coast Guard, Chief, Office of Navigation Safety and Waterway Services.

[FR Doc. 91-28941 Filed 11-26-91; 8:45 am]

BILLING CODE 4910-14-M

Office of Hearings

[Docket No. 47830]

Pan American World Airways, Inc.; Revised Prehearing Conference

Served November 21, 1991.

Notice is hereby given that the prehearing conference in this matter scheduled to be held on December 16, 1991, at 10 a.m. (local time), in room 5332, Nassif Building, 400 Seventh Street, SW., Washington, DC is postponed at the request of both parties. The time and location remain the same; but the new date for the prehearing conference is January 7, 1992. The parties's proposed schedule of preconference submissions is accepted.

Dated at Washington, DC, November 21, 1991.

Burton S. Kolko,

Administrative Law Judge.

[FR Doc. 91-28473 Filed 11-26-91; 8:45 am]

BILLING CODE 4910-62-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

November 21, 1991.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171, Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Departmental Offices

OMB number: 1505-0023.

Form number: Treasury International Capital Form CM.

Type of review: Extension.

Title: Dollar Deposit and Certificate of Deposit Claims on Banks Abroad.

Description: This report is required by law and is designed to gather timely and accurate information of international capital movements by collecting data on data deposit and certificate of deposit claims held on banks abroad by nonbanking enterprises in the United States.

Respondents: Business or other for-profit.

Estimated number of respondents: 175.

Estimated burden hours per response: 30 minutes.

Frequency of response: Monthly.

Estimated total reporting burden: 1,050 hours.

OMB number: 1505-0024.

Form number: International Capital Forms CQ-1 and CQ-2.

Type of review: Extension.

Title: Treasury International Capital Forms CQ-1 and CQ-2, Financial and Commercial Liabilities to, and Claims on, Unaffiliated Foreigners.

Description: These reports are required by law and are designed to collect timely and accurate information on international capital movements including data on financial and commercial liabilities to, and claims on, unaffiliated foreigners held by U.S. nonbanking business enterprises.

Respondents: Businesses or other for-profit.

Estimated number of respondents: 500.

Estimated burden hours per response: 4 hours.

Frequency of response: Quarterly.

Estimated total reporting burden: 8,000 hours.

OMB number: 1505-0088.

Form number: International Capital BL-3.

Type of review: Extension.

Title: Treasury International Capital BL-3, Intermediary's Notification of Foreign Borrowing Denominated in Dollars.

Description: This form is designed for use by a bank or other institution to notify a nonbanking customer of its obligation to report on TIC Form CQ-1 borrowings from foreigners that will not be reported by the bank or other intermediary as a custody liability on TIC Form BL-2.

Respondents: Businesses or other for-profit.

Estimated number of respondents: 50.

Estimated burden hours per response: 30 minutes.

Frequency of response: On occasion.

Estimated total reporting burden: 300 hours.

Clearance Officer: Lois K. Holland (202) 566-6579, Departmental Offices, Room 3171, Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

OMB Reviewer: Milo Sunderhauf (202) 395-6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 91-28471 Filed 11-26-91; 8:45 am]

BILLING CODE 4810-25-M

Public Information Collection Requirements Submitted to OMB for Review

November 21, 1991.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB number: 1545-1224.

Regulation ID number: INTL-112-88 Final Regulations.

Type of Review: Extension.

Title: Allocation and Apportionment of Deduction for State Income Taxes.

Description: The reporting requirements affect those taxpayers claiming foreign tax credits that elect to use an alternative method of allocating and apportioning deductions for state income taxes. This information will be used by the IRS to estimate resources to be required in auditing income tax returns, and should facilitate the completion of audits.

Respondents: Business of other for-profit.

Estimated number of respondents: 1,000.

Estimated burden hours per respondent: 1 hour.

Estimated total reporting burden: 1,000 hours.

Clearance Officer: Garrick Shear (202) 535-4297, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Milo Sunderhauf (202) 395-6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 91-28472 Filed 11-26-91; 8:45 am]

BILLING CODE 4830-01-M

Internal Revenue Service

[Delegation Order No. 155 (Rev. 3)]

Delegation of Authority

AGENCY: Internal Revenue Service, Treasury.

ACTION: Delegation of authority.

SUMMARY: This delegation order extends to all Associate Chief Counsels the authority, the matters under their respective jurisdictions, to sign recommendation letters to the Department of Justice concerning Settlement Offers for years or parties not in suit, but related to pending refund suits for other years or parties. In exercising this authority, the advice of the National Director of Appeals must be considered. The Associate Chief Counsels may redelegate this authority to their Deputies. The previous delegation order limited this authority to the Associate Chief Counsel (Litigation). That position was eliminated, effective October 1, 1991, as part of the reorganization of the Chief Counsel's Office, and the new positions of Associate Chief Counsels (Domestic), (Employee Benefits and Exempt Organizations), and (Enforcement Litigation) were created. The previous delegation order also required consideration of the advice of the Director, Tax Litigation Division (now the Assistant Chief Counsel (Tax Litigation). That requirement has been eliminated.

EFFECTIVE DATE: October 1, 1991.

FOR FURTHER INFORMATION CONTACT: Jody J. Brewster, Special Assistant to the Associate Chief Counsel (Domestic), 1111 Constitution Avenue, NW., room 3508, Washington, DC 20224, Tel. No. (202) 566-5850, (not a toll-free number).

Recommendations Concerning Settlement Offers in Refund Suits

[Order No. 155 (Rev. 3]

Effective date: 10-1-91.

1. Pursuant to the authority vested in the Commissioner of Internal Revenue by 26 CFR 301.7122-1 and 26 CFR 301.7701-9, the Chief Counsel and the Associate Chief Counsels are delegated the authority for matters under their respective jurisdictions to sign recommendation letters to the Department of Justice concerning Settlement Offers for years or parties not in suit, but related to pending refund suits for other years or parties. In exercising this authority, the advice of the National Director of Appeals shall be considered.

2. The authority delegated herein may not be redelegated, except that the Chief Counsel and the Associate Chief Counsels may redelegate the authority herein to their Deputy Associate Chief Counsels.

3. To the extent that the authority previously exercised consistent with this order may require ratification, it is hereby approved and ratified.

4. Delegation Order No. 155 (Rev. 2), issued June 17, 1982, is superseded.

Dated: October 15, 1991.

Michael J. Murphy,

Deputy Commissioner.

[FR Doc. 91-28509 Filed 11-26-91; 8:45 am]

BILLING CODE 4830-01-M

[Delegation Order No. 220 (Rev. 2)]

Delegation of Authority

AGENCY: Internal Revenue Service, DOT.

ACTION: Delegation of authority.

SUMMARY: This delegation order extends to the Assistant Chief Counsel (Disclosure Litigation) the authority to claim executive privilege with respect to Internal Revenue Service records and information in matters before the United States Claims Court, the United States Tax Court, and other Federal Courts. In the absence of or at the request of the Assistant Chief Counsel (Disclosure Litigation), the Deputy Assistant Chief Counsel (Disclosure Litigation) may exercise this authority in the name of the Assistant Chief Counsel (Disclosure Litigation). The previous delegation order extended this authority to the Director, Disclosure Litigation Division. The Director, Disclosure Litigation Division, has been renamed the Assistant Chief Counsel (Disclosure Litigation).

EFFECTIVE DATE: October 1, 1991.

FOR FURTHER INFORMATION CONTACT: Jody J. Brewster, Special Assistant to the Associate Chief Counsel (Domestic), 1111 Constitution Avenue, NW., room 3508, Washington, DC 20224, Tel. No. (202) 566-5850, (not a toll-free number).

Authority To Claim Executive Privilege in Matters Before the Claims Court, the Tax Court and Other Federal Courts

[Order No. 220 (Rev. 2)]

Effective Date: 10-1-91.

1. The authority vested in the Commissioner of Internal Revenue by Treasury Department Order 150-10 to claim executive privilege with respect to Internal Revenue Service records and information in matters before the United States Claims Court, the United States Tax Court, and other Federal Courts is hereby delegated, through the Chief Counsel and the Associate Chief Counsel (Enforcement Litigation), to the Assistant Chief Counsel, (Disclosure Litigation). In the absence of or at the request of the Assistant Chief Counsel (Disclosure Litigation), the Deputy Assistant Chief Counsel, (Disclosure Litigation), may exercise this authority in his/her name for the Assistant Chief Counsel (Disclosure Litigation). This authority may not be redelegated.

2. The Claims Court and certain other federal courts only recognize agency claims of executive privilege as the sole basis for protecting internal or inter-agency records that reflect recommendations, advisory opinions, and deliberations, comprising the process by which governmental decisions and policies are formulated. Executive privilege does not encompass those records whose disclosure would harm our national security or the conduct of international relations. These records fall within the government's states secrets privilege which is not delegated herein. With respect to these records, the Commissioner of Internal Revenue will claim the states secrets privilege.

3. Executive privilege may only be claimed for those Internal Revenue Service records and information that are predecisional and deliberative, the disclosure of which would significantly impede or nullify Internal Revenue Service actions in carrying out a responsibility or function, or would constitute an unwarranted invasion of personal privacy. Prior to asserting the claim of executive privilege with respect to the records described herein, coordination with the interested function(s) (including but not limited to the office of the Commissioner of Internal Revenue) shall be affected.

4. To the extent that the authority previously exercised consistent with this Order may require ratification, it is hereby approved and ratified.

5. Delegation Order No. 220 (Rev. 1), effective December 20, 1987, is superseded.

Dated: October 15, 1991.

Fred T. Goldberg, Jr.,

Commissioner.

[FR Doc. 91-28508 Filed 11-26-91; 8:45 am]

BILLING CODE 4830-01-M

[Delegation Order No. 97 (Rev. 30)]

Delegation of Authority

AGENCY: Internal Revenue Service, Treasury.

ACTION: Delegation of authority.

SUMMARY: This delegation order extends to all Associate Chief Counsels the authority, for matters under their respective jurisdictions, to enter into and approve a written agreement with any person relating to the Internal Revenue tax liability of that person for a taxable period ended prior to the date of agreement and related specific items affecting other taxable periods. The previous delegation order limited this authority to the Associate Chief Counsels (Technical) and (International). The position of Associate Chief Counsel (Technical) was eliminated, effective October 1, 1991, as part of the reorganization of the Chief Counsel's Office, and the new positions of Associate Chief Counsels (Domestic), (Employee Benefits and Exempt Organizations), and (Enforcement Litigation) were created. The revised delegation order also permits the Chief Counsel to redelegate any authority delegated to him under the delegation order to the Associate Chief Counsels and their Deputies and Assistant Chief Counsels for cases under their respective jurisdictions that do not involve precedent issues.

EFFECTIVE DATE: October 1, 1991.

FOR FURTHER INFORMATION CONTACT: Jody J. Brewster, Special Assistant to the Associate Chief Counsel (Domestic) 1111 Constitution Avenue, NW., room 3508, Washington, DC 20224, Tel. No. (202) 566-5850, (not a toll-free number).

DATES: Effective date: November 1, 1991.

Subject: Closing agreements concerning Internal Revenue Tax Liability.

[Amended and Supplemented by Delegation Order No. 225]

Pursuant to authority granted to the Commissioner of Internal Revenue by 26 CFR 301.7121-1(a); Treasury Order No. 150-07; Treasury Order No. 150-09; and Treasury Order No. 150-17, subject to the transfer of authority covered in Treasury Order No. 120-01, as modified by Treasury Order No. 150-27, as revised, this authority is hereinafter delegated.

1. The Chief Counsel is hereby authorized in cases under his/her jurisdiction to enter into and approve a written agreement with any person relating to the Internal Revenue tax liability of such person (or of the person or estate for whom he/she acts) in respect to any prospective transactions or completed transactions if the request to the Chief Counsel for determination or ruling was made before any affected returns have been filed.

2. The Associate Chief Counsels and the Assistant Commissioners (Examination) and (International) are hereby authorized for matters under their respective jurisdictions to enter into and approve a written agreement with any person relating to the Internal Revenue tax liability with any person relating to the Internal Revenue tax liability of such person (or of the person or estate whom he/she acts) for a

taxable period or periods ended prior to the date of agreement and related specific items affecting other taxable periods. The Assistant Commissioner (International) is also authorized to enter into and approve a written agreement with any person relating to the Internal Revenue tax liability of such person (or of the person or estate for whom he/she acts) with respect to the performance of his/her functions as the competent authority under the tax conventions of the United States.

3. The Assistant Commissioner (Employee Plans and Exempt Organizations) is hereby authorized to enter into and approve a written agreement with any person relating to the Internal Revenue tax liability of such person (or of the person or estate for whom he/she acts) in cases under his/her jurisdiction, that is, in respect of any transaction concerning employee plans or exempt organizations.

4. The Assistant Commissioner (International); Regional Commissioners; Regional Counsel; Assistant Regional Commissioners (Examination); Service Center Directors; Director, Austin Compliance Center; District Directors; Chiefs and Associate Chiefs of Appeals Offices and Appeals Team Chiefs with respect to his/her team cases, are hereby authorized in cases under their jurisdiction (but excluding cases docketed before the United States Tax Court) to enter into and approve a written agreement with any person relating to the Internal Revenue tax liability of such person (or of the person or estate for whom he/she acts) for a taxable period or periods ended prior to the date of agreement and related specific items affecting other taxable periods.

5. The Associate Chief Counsels; the Assistant Commissioners (Employee Plans and Exempt Organizations) and (International); Regional Commissioners; Regional Counsel; Chiefs and Associates Chiefs of Appeals Offices; and Appeals Team Chiefs with respect to his/her teams cases, are hereby authorized in cases under their jurisdiction docketed in the United States Tax Court and in other Tax Court cases upon the request of Chief Counsel or his/her delegate to enter into and approve a written agreement with any person relating to the Internal Revenue tax liability of such person (or of the person or estate for whom he/she acts) but only in respect to related specific items affecting other taxable periods.

6. The Assistant Commissioner (International) is hereby authorized to enter into and approve a written agreement with any person relating to the Internal Revenue tax liability of such person (or of the person or estate for whom he/she acts) in cases under his/her jurisdiction, and to provide for the mitigation of economic double taxation under section 3 of Revenue Procedure 64-54, C.B. 1964-2, under Revenue Procedure 72-22, C.B. 1972-1, 747, and under Revenue Procedure 69-13, C.B. 1969-1, 402, and to enter into and approve a written agreement providing the treatment available under Revenue Procedure 65-17, C.B. 1965-1, 833.

7. The authority delegated herein does not include the authority to set aside any closing agreement.

8. Authority delegated in this Order may not be redelegated, except that the Chief Counsel may redelegate the authority contained in paragraph 1 to the Associate Chief Counsels, the Deputy Associate Chief Counsels, and the Assistant Chief Counsels, for cases under their respective jurisdictions that do not involve precedent issues; the Assistant Commissioners (Examination) and (International) may redelegate the authority contained in paragraph 2 of this Order to the Deputy Assistant Commissioners (Examination) and (International); the Deputies Chief Counsel may redelegate the authority in paragraph 2 of this Order but not lower than the Deputy Associate Chief Counsels; and the Assistant Commissioner (Employee Plans and Exempt Organizations) may redelegate the authority contained in paragraph 3 of this Order to the Deputy Assistant Commissioner (Employee Plans and Exempt Organizations) and to the Technical Advisors on the Staff of the Assistant Commissioner (Employee Plans and Exempt Organizations) for cases that do not involve precedent issues; Service Center Directors and Director, Austin Compliance Center may redelegate the authority contained in paragraph 4 of this Order but not below the Chief, Examination Support Unit with respect to agreements concerning the administrative disposition of certain tax shelter cases; and not below the Chief; Windfall Profit Tax Staff, Austin Service Center or Austin Compliance Center with respect to entering into and approving a written agreement with the Tax Matters Partner/Person (TMP) and one or more partners or shareholders with respect to whether the partnership or S corporation, acting through its TMP, is duly authorized to act on behalf of the partners or shareholders in the determination of partnership or S corporation items for purposes of the tax imposed by chapter 45, and for purposes of assessment and collection of the windfall profit tax for such partnership or S corporation taxable year. The Assistant Commissioner (International) and District Directors may redelegate the authority contained in paragraph 4 of this Order but not below the Chief, Quality Review Staff/Section with respect to all matters, and not below the Chief, Examination Support Staff/Section, or Chief, Planning and Special Programs Branch/Section, with respect to agreements concerning the administrative disposition of certain tax shelter cases, or Chief, Special Procedures function, with respect to the waiver of right to claim refunds for those responsible officers who pay the corporate liability in lieu of a 100-percent penalty assessment under IRC 6672.

9. To the extent that the authority previously exercised consistent with this Order may require ratification, it is hereby affirmed and ratified.

10. Delegation Order No. 97 (Rev. 29) effective October 4, 1990, is hereby superseded.

Approved: October 15, 1991.

Michael J. Murphy,

Deputy Commissioner.

[FR Doc. 91-28510 Filed 11-26-91; 8:45 am]

BILLING CODE 4830-01-M

[Delegation Order No. 96 (Rev. 11)]

Delegation of Authority

AGENCY: Internal Revenue Service, Treasury.

ACTION: Delegation of authority.

SUMMARY: This delegation order extends to all Associate Chief Counsels and their Deputies the authority, for matters under their respective jurisdictions, to describe the extent, if any, to which any ruling issued by or pursuant to authorization from the Chief Counsel relating to the internal revenue laws is applied without retroactive effect. The previous delegation order limited this authority to the Associate Chief Counsels (Technical) and (International) and the Deputy Associate Chief Counsel (Technical). The positions of Associate Chief Counsel (Technical) and Deputy Associate Chief Counsel (Technical) were eliminated, effective October 1, 1991, as part of the reorganization of the Chief Counsel's Office, and the new positions of Associate Chief Counsels (Domestic), (Employee Benefits and Exempt Organizations), and (Enforcement Litigation) and their Deputies were created.

EFFECTIVE DATE: October 1, 1991.

FOR FURTHER INFORMATION CONTACT: Jody J. Brewster, Special Assistant to the Associate Chief Counsel (Domestic), 1111 Constitution Avenue, NW., room

3508, Washington, DC 20224, Tel. No. (202) 566-5850, (not a toll-free number).

Effective Date: November 1, 1991.

Application of Rulings Without Retroactive Effect

1. Pursuant to authority granted to the Commissioner of Internal Revenue by 26 CFR 301.7805-1(b):

a. The Associate Chief Counsels and the Deputy Associate Chief Counsels are hereby authorized for matters under their respective jurisdictions to prescribe the extent, if any, to which any ruling issued by or pursuant to authorization from the Chief Counsel relating to the internal revenue laws shall be applied without retroactive effect.

b. The Assistant Commissioner (Employee Plans and Exempt Organizations) and the Deputy Assistant Commissioner (Employee Plans and Exempt Organizations) are hereby authorized to prescribe the extent, if any, to which any ruling issued by or pursuant to authorization from the Assistant Commissioner relating to the internal revenue laws shall be applied without retroactive effect.

2. a. Pursuant to authority granted to the Commissioner of Internal Revenue by 26 CFR 301.7805-1(b), there is hereby delegated to the Director, Employee Plans Technical and Actuarial Division of the National Office, and to the Director of each EP/EO Key District, the authority to limit the retroactive effect of the revocation of any determination letter or opinion letter issued with respect to employee plans if the conditions set forth in the Notice 86-3 are met;

b. Partial relief will be granted through section 7805(b) such as described in Notice 86-3.

3. The section 7805(b) authority described in sections 2a and 2b will be exercised except in rare and unusual circumstances. Where rare and unusual circumstances exist, denial of section 7805(b) relief will be applied only if approved by the National Office.

4. The authority delegated in section 1 may not be redelegated.

5. The authority to grant 7805(b) relief in certain employee plan matters herein delegated to the Director, Employee Plans Technical and Actuarial Division and to the Director of Qualifications Branch and Chief, EP/EO Division, respectively.

6. This delegation order expires with respect to the Director of each EP/EO Key District on December 31, 1989.

7. To the extent that the authority previously exercised consistent with this order may require ratification, it is hereby approved and ratified.

8. Delegation Order No. 96 (Rev. 10) effective February 23, 1988, is superseded.

Dated: October 15, 1991.

Michael J. Murphy,

Deputy Commissioner.

[FR Doc. 91-28511 Filed 11-26-91; 8:45 am]

BILLING CODE 4830-01-M

[Delegation Order No. 42 (Rev. 25)]

Delegation of Authority

AGENCY: Internal Revenue Service, Treasury.

ACTION: Delegation of authority.

SUMMARY: This delegation order extends to all Associate Chief Counsels the authority, for matters under their respective jurisdictions, to sign all consents fixing the period of limitations on assessment or collection. In the previous delegation order, the only Associate Chief Counsels delegated this authority were the Associate Chief Counsels (Technical) and (International). The position of Associate Chief Counsel (Technical) was eliminated, effective October 1, 1991, as part of the reorganization of the Chief Counsel's Office, and the new positions of Associate Chief Counsels (Domestic), (Employee Benefits and Exempt Organizations), and (Enforcement Litigation) were created.

EFFECTIVE DATE: October 1, 1991.

FOR FURTHER INFORMATION CONTACT: Jody J. Brewster, Special Assistant to the Associate Chief Counsel (Domestic), 1111 Constitution Avenue, NW., room 3508, Washington, DC 20224, Tel. No. (202) 566-5850, (not a toll-free number).

DATES: Effective Date: October 1, 1991.

Authority To Execute Consents Fixing the Period of Limitations on Assessment or Collection Under Provisions of the 1939, 1954, and 1986 Internal Revenue Codes

1. Pursuant to authority vested in the Commissioner of Internal Revenue by Treasury Order 150-10; 26 U.S.C. 6229; 26 CFR 301.6501(c)-1; 26 CFR 301.6502-1; 26 CFR 301.6901-1(d); and 26 CFR 301.7701-9; the authority to sign all consents fixing the period of limitations on assessment or collection is delegated to the following officials:

a. Associate Chief Counsels (for matters under their respective jurisdictions);

b. Assistant Commissioner (International);

c. Assistant Commissioner (Employee Plans and Exempt Organizations) but limited to Form 872-C, Consent Fixing Period of Limitation Upon the Assessment of Tax Under section 4940 of the Internal Revenue Code;

d. Regional Counsel;

e. Regional Directors of Appeals:

f. Service Center Directors;

g. Director, Austin Compliance Center; and

h. District Directors.

2. This authority may be redelegated but not below the following levels for each activity:

a. Service Centers—Chief, Accounting Branch; Chief, Quality Assurance; Chief, Adjustment/Correspondence; Revenue Officers and Collection Branch managers Grade GS-9 or higher; Chief, Classification function; and personnel assigned to the Examination Support Unit, Grade GS-11 or higher;

b. Austin Compliance Center-Underreporter Division-Branch Chiefs; Collection Division-all Branch Chiefs and Chief, Quality Analysis Staff; Examination Division-Chiefs, Examination Branches, Chief, Quality Assurance Staff, Chief, Classification Branch; and personnel assigned to the Windfall Profits Staff, GS-11;

c. Collection-Revenue Officers; Collection Support function managers Grade GS-9 or higher; Automatic Collection Branch managers, Grade GS-9 or higher;

d. Examination-Reviewers, Grade GS-11 or higher; Group managers (including large case managers); Chiefs, Planning and Special Programs and personnel assigned thereto Grade GS-11 or higher; Returns Classification Specialists and Returns Classification Officers Grade GS-11;

e. Criminal Investigation-Chiefs, Criminal Investigation Divisions, except in those districts where the Criminal Investigation Group managers report directly to the District Directors, the authority is limited to the District Director.

f. Appeals—Appeals Officers;

g. Assistant Commissioner (International)—Representatives at foreign posts; Revenue Agents, Tax Auditors, and Special Agents on foreign assignments; and levels indicated in c, d, and e, above;

h. EP/EO—For Form 872-2, Exempt Organizations Technical Division Group Managers Conferee/Reviewers and

i. District Employee Plans and Exempt Organizations—Reviewers, Grade GS-11 or higher; and Group Managers.

3. No authority is delegated under this Order to the District Counsel.

4. To the extent that the authority previously exercised consistent with this order may require ratification, it is hereby approved and ratified.

5. Delegation Order No. 42 (Rev. 24), effective February 8, 1991, is superseded

Dated: October 15, 1991.

Michael J. Murphy,

Deputy Commissioner.

[FR Doc. 91-28512 Filed 11-26-91; 8:45 am]

BILLING CODE 4830-01-M

[Delegation Order No. 11 (Rev. 21)]

Delegation of Authority

AGENCY: Internal Revenue Service, Treasury.

ACTION: Delegation of authority.

SUMMARY: This delegation order extends to all Associate Chief Counsels the authority, for matters under their respective jurisdictions, to accept offers in compromise and to reject offers in compromise, regardless of the amount of the liability sought to be compromised. In the previous delegation order, the only Associate Chief Counsels delegated this authority were the Associate Chief Counsels (Technical) and (International). The position of Associate Chief Counsel (Technical) was eliminated, effective October 1, 1991, as part of the reorganization of the Chief Counsel's Office, and the new positions of Associate Chief Counsels (Domestic), (Employee Benefits and Exempt Organizations), and (Enforcement Litigation) were created.

EFFECTIVE DATE: October 1, 1991.

FOR FURTHER INFORMATION CONTACT: Jody J. Brewster, Special Assistant to the Associate Chief Counsel (Domestic) 1111 Constitution Avenue NW., room 3508, Washington, DC 20224 Tel. No. (202) 566-5850, (not a toll-free number).

Authority to Accept or Reject Offers in Compromise

The authority vested in the Commissioner of Internal Revenue by Treasury Order Nos. 150-04 and 150-09, 26 CFR 301.7122-1, and 26 CFR 301.7701-9 and Treasury Order No. 150-13 is hereby delegated as follows:

1. The Deputy Assistant Commissioner (International), Associate Chief Counsels, Assistant District Directors, Regional Counsel, Chiefs and Associate Chiefs, Appeals Offices, are delegated authority, under section 7122 of the Internal Revenue Code, to accept offers in compromise and to reject offers in compromise for matters under their respective jurisdictions regardless of the amount of the liability sought to be compromised. This authority does not pertain to offers in compromise of liabilities arising under laws relating to alcohol, tobacco, and firearms taxes. The authority delegated to District Directors may not be redelegated lower than Division Chief; except that the authority with respect to the withdrawal of an offer in compromise based upon doubt as to collectibility may be redelegated to Chief, Special Procedures. The authority delegated to Regional Counsel may not be redelegated, except that the authority to reject offers in compromise may be redelegated, but not lower than to District Counsel. Regional Director of Appeals, Chiefs and Associate Chiefs, Appeals Offices, may not redelegate this authority.

2. Assistant Service Center Directors and Assistant Director, Austin Compliance Center are delegated authority, under section 7122 of the Internal Revenue Code, to accept offers in compromise, limited to penalties based solely on doubt as to liability, and to reject offers in compromise, limited to penalties, regardless of the amount of the liability sought to be compromised, and to summarily rejected without further investigation, offers based solely on doubt as to liability regardless of the amount of the liability sought to be compromised, limited to obvious offers that are frivolous, groundless or dilatory, or where the liability has been finally determined by the Tax Court or other courts, or by a Commissioner's final closing agreement, or where the offer is based upon an agreed liability in which administrative appeal rights have been exercised or waived. This authority does not pertain to offers in compromise of liabilities arising under laws relating to alcohol, tobacco, and firearms taxes. This authority may be redelegated only to the Chief, Compliance Division (Service Centers) and Chief, Collection Division (Austin Compliance Center).

3. To the extent that the authority previously exercised consistent with this Order may require ratification, it is hereby approved and ratified.

4. Delegation Order No. 11 (Rev. 20), effective October 4, 1990, is superseded.

Dated: October 15, 1991.

Michael J. Murphy,

Deputy Commissioner.

[FR Doc. 91-28513 Filed 11-26-91; 8:45 am]

BILLING CODE 4830-01-M

Office of Thrift Supervision

[AC-56; OTS No. 0809]

Amity Federal Bank for Savings, Tinley Park, IL: Final Action; Approval of Conversion Application

Notice is hereby given that on November 12, 1991, the Office of the Chief Counsel, Office of Thrift Supervision, acting pursuant to delegated authority, approved the application of Amity Federal Bank for Savings, Tinley Park, Illinois for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and the Central Regional Office, Office of Thrift Supervision, 111 East Wacker Drive, suite 800, Chicago, Illinois 60601-4360.

Dated: November 21, 1991.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 91-28426 Filed 11-26-91; 8:45 am]

BILLING CODE 6720-01-M

[AC-59; OTS No. 0067]

Bell Federal Savings and Loan Association, Chicago, IL Final Action; Approval of Conversion Application

Notice is hereby given that on November 12, 1991, the Office of the Chief Counsel, Office of Thrift Supervision, acting pursuant to delegated authority, approved the application of Bell Federal Savings and Loan Association, Chicago, Illinois for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and Central Regional Office, Office of Thrift Supervision, 111 East Wacker Drive, Chicago, Illinois 60601.

Dated: November 21, 1991.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 91-28427 Filed 11-26-91; 8:45 am]

BILLING CODE 6720-01-M

[AC-58; OTS No. 3935]

Brookings Federal Bank, a Federal Savings Bank, Brookings, SD: Final Action; Approval of Conversion Application

Notice is hereby given that on November 12, 1991, the Office of the Chief Counsel, Office of Thrift Supervision, acting pursuant to delegated authority, approved the application of Brookings Federal Bank, a federal savings bank, Brookings, South Dakota for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and the Des Moines Area Office, Office of Thrift Supervision, Regency West 2, 1401 50th Street, suite 300, West Des Moines, Iowa 50265-5924.

Dated: November 21, 1991.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 91-28428 Filed 11-26-91; 8:45 am]

BILLING CODE 6720-01-M

[AC-53: OTS No. 4770]

Citizens Federal Savings and Loan Association of Rutherfordton, Rutherfordton, NC; Final Action; Approval of Conversion Application

Notice is hereby given that on November 12, 1991, the Office of the Chief Counsel, Office of the Thrift Supervision, acting pursuant to delegated authority, approved the application of Citizens Federal Savings and Loan Association of Rutherfordton, Rutherfordton, North Carolina for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and District Director, Office of Thrift Supervision of Atlanta, 1475 Peachtree Street, NE., Atlanta, Georgia 30309.

Dated: November 21, 1991.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 91-28429 Filed 11-26-91; 8:45 am]

BILLING CODE 6720-01-M

[AC-52; OTS No. 2943]

Citizens Federal Bank, Federal Savings Bank, Dayton, OH: Final Action; Approval of Conversion Application

Notice is hereby given that on November 8, 1991, the Office of the Chief Counsel, Office of Thrift Supervision, acting pursuant to delegated authority, approved the application of Citizens Federal Bank, Federal Savings Bank, Dayton, Ohio for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and the Cincinnati Area Office, Office of Thrift Supervision, 525 Vine Street, suite 700, Cincinnati, Ohio 45202.

Dated: November 21, 1991.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 91-28430 Filed 11-26-91; 8:45 am]

BILLING CODE 6720-01-M

[AC-57; OTS No. 1631]

First Federal Savings and Loan Association of Lake Wales, Lake Wales, Florida: Notice of Final Action; Approval of Conversion Application

Notice is hereby given that on November 12, 1991, the Office of the Chief Counsel, Office of Thrift Supervision, acting pursuant to delegated authority, approved the application of First Federal Savings and Loan Association of Lake Wales, Lake Wales, Florida for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and the Southeast Regional Office, Office of Thrift Supervision, 1475 Peachtree Street, NE., Atlanta, Georgia 30309.

Dated: November 21, 1991.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 91-28431 Filed 11-26-91; 8:45 am]

BILLING CODE 6720-01-M

[AC-60: OTS No. 0709]

Guardian Savings Bank, F.S.B., Cincinnati, OH Final Action; Approval of Conversion Application

Notice is hereby given that on November 12, 1991, the Office of the Chief Counsel, Office of the Thrift Supervision, acting pursuant to delegated authority, approved the application of Guardian Savings Bank, F.S.B., Cincinnati, Ohio for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and Cincinnati Area Office, Office of Thrift Supervision, 525 Vine Street, 7th Floor, Cincinnati, Ohio 45201.

Dated: November 21, 1991.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 91-28432 Filed 11-26-91; 8:45 am]

BILLING CODE 6720-01-M

[AC-51; OTS No. 1207]

Liberty Federal Savings Bank, Chicago, IL: Final Action; Approval of Conversion Application

Notice is hereby given that on November 8, 1991, the Office of the Chief Counsel, Office of Thrift Supervision, acting pursuant to delegated authority, approved the application of Liberty Federal Savings Bank, Chicago, Illinois for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and the Central Regional Office, Office of Thrift Supervision, 111 East Wacker Drive, suite 800, Chicago, Illinois 60601-4360.

Dated: November 21, 1991.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 91-28433 Filed 11-26-91; 8:45 am]

BILLING CODE 6720-01-M

[AC-50; OTS No. 4105]

State Home Savings Bank, F.S.B., Bowling Green, OH: Final Action; Approval of Conversion Application

Notice is hereby given that on October 20, 1991, the Office of Thrift Supervision approved the application of State Home Savings Bank, F.S.B., Bowling Green, Ohio for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW.,

Washington, DC 20552, and the Central Regional Office, Office of Thrift Supervision, 111 East Wacker Drive, Chicago, Illinois, 60601.

Dated: November 20, 1991.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 91-28434 Filed 11-26-91; 8:45 am]

BILLING CODE 6720-01-M

[AC-55: OTS No. 1897]

Tri-County Federal Savings Bank, Covington, TN; Final Action; Approval of Conversion Application

Notice is hereby given that on November 12, 1991, the Office of the Chief Counsel, Office of the Thrift Supervision, acting pursuant to delegated authority, approved the application of Tri-County Federal Savings Bank, Covington, Tennessee for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and Area Director, Office of Thrift Supervision of Cincinnati, 525 Vine Street 7th Floor, Cincinnati, Ohio 45202.

Dated: November 21, 1991.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 91-28435 Filed 11-26-91; 8:45 am]

BILLING CODE 6720-01-M

[AC-54: OTS No. 0084]

Union Federal Savings, Lansing, MI; Final Action; Approval of Conversion Application

Notice is hereby given that on November 12, 1991, the Office of the Chief Counsel, Office of the Thrift Supervision, acting pursuant to delegated authority, approved the application of Union Federal Savings, Lansing, Michigan for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and Indianapolis Area Office, Office of Thrift Supervision, 8250 Woodfield Crossing Blvd., suite 305, Indianapolis, Indiana 46240.

Dated: November 21, 1991.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 91-28436 Filed 11-26-91; 8:45 am]

BILLING CODE 6720-01-M

Sunshine Act Meetings

Federal Register
Vol. 56, No. 229
Wednesday, November 27, 1991

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

NATIONAL WOMEN'S BUSINESS COUNCIL

ACTION: Notice of Hearing.

SUMMARY: In accordance with the Women's Business Ownership Act, Public Law 100–533 as amended, the National Women's Business Council announces a forthcoming hearing. The focus of the hearing will be to hear testimony and gather information regarding women's contributions in high technology. Testimony will be received from public and private sector decisionmakers and entrepreneurs, professional experts, corporate leaders and representatives of key interest groups and organizations.

DATE: December 6, 1991, 9:00 am to 5:00 pm.

ADDRESS: University of Texas at Arlington, Room 100, Engineering Building II, 416 Yates Street.

STATUS: Open to the public.

CONTACT: For further information or to submit written testimony only, contact Wilma Goldstein, Executive Director or Diane Cullo, Legislative Analyst, National Women's Business Council, 2100 Pennsylvania Avenue, NW, # 690, Washington, DC 20037, (202) 254–3850. Deadline date for submission of written testimony is December 9, 1991.

Wilma Goldstein,

Executive Director, National Women's Business Council.

[FR Doc. 91–28700 Filed 11–25–91; 2:29 pm]

BILLING CODE 6820-AB-M

NATIONAL WOMEN'S BUSINESS COUNCIL

AGENCY: National Women's Business Council.

SUMMARY: In accordance with the Women's Business Ownership Act, Public Law 100–533 as amended, the National Women's Business Council announces a forthcoming meeting and roundtable discussion. The roundtable discussion will center on examination of barriers to women in high technology as well as offer recommendations that could overcome these barriers. Meeting issues to be discused are the annual report and various Council office administrative issues.

DATE:

December 7, 1991, 9:00 am–12:00 noon. (Roundtable).

December 7, 1991, 1:00 pm–4:00 pm. (Meeting)

PLACE:

University of Texas at Arlington, Rady Room (6th floor), Engineering II Building, 416 Yates Street. (Roundtable only)

Radisson Suite Hotel-Arlington, 700 Avenue H East, Arlington, TX 76011. (Meeting location only)

STATUS: Both meeting and roundtable are open to the public.

CONTACT: Wilma Goldstein, Executive Director or Diane Cullo, Legislative Analyst, National Women's Business Council 2100 Pennsylvania Avenue, NW, #690, Washington DC, 20037, (202) 254–3850.

Wilma Goldstein,

Executive Director, National Women's Business Council.

[FR Doc. 91–28701 Filed 11–25–91; 2:29 pm]

BILLING CODE 6820-AB-M

federal register

Wednesday
November 27, 1991

Part II

Department of Agriculture

Food Safety and Inspection Service

9 CFR Parts 317, 320, and 381

Nutrition Labeling of Meat and Poultry Products; Proposed Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 320, and 381

[Docket No. 91-006P]

RIN 0583-AB34

Nutrition Labeling of Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat and poultry products inspection regulations by permitting voluntary nutrition labeling on single-ingredient, raw meat and poultry products, and by establishing mandatory nutrition labeling for all other meat and poultry products, with the exception of products used for further processing. Under the mandatory nutrition labeling program, processors of products in small packages and products packaged in other than consumer-size packages shall have the option of providing nutrition labeling information either on the package or by alternate means. Food and Drug Administration (FDA) is undertaking various regulatory proceedings to comply with the Nutrition Labeling and Education Act of 1990, which requires mandatory nutrition labeling of most foods under FDA's jurisdiction. FSIS is committed to providing consumers with the most informative labeling system possible. FSIS is proposing nutrition labeling regulations for meat and poultry products which will parallel, to the extent possible, as authorized by the FMIA and the PPIA, FDA's nutrition labeling initiatives. However, FSIS is also seeking comments on alternatives to mandatory nutrition labeling and the extent to which FSIS requirements must duplicate or complement new FDA requirements to maximize informative labeling in a cost effective manner.

DATES: Comments must be received on or before February 25, 1992.

ADDRESSES: Written comments to: Policy Office, ATTN: Linda Carey, FSIS Hearing Clerk, Room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments as provided by the Poultry Products Inspection Act should be directed to Mr. Charles Edwards at (202) 205-0080. (See also "Comments" under "**SUPPLEMENTARY INFORMATION.**")

FOR FURTHER INFORMATION CONTACT: Mr. Charles Edwards, Director, Food Ingredient Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 205-0080.

SUPPLEMENTARY INFORMATION:

Regulatory Impact Analysis

This proposed action has been reviewed under USDA procedures established to implement Executive Order 12291 and has been classified as a major rule pursuant to section 1(b)(1) of that order because it is likely to result in an annual effect on the economy of $100 million or more. The Department's review is reported in its Preliminary Regulatory Impact Analysis (PRIA), which is published in its entirety as an appendix to this proposal. The PRIA also satisfies the analysis requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601 *et seq.*), which deals with the effect on small entities.

Paperwork Requirements

This proposal would require manufacturers to maintain records supporting the validity of nutrient information on the labels of meat and poultry products, and to make such records available to FSIS upon request. This proposal would require establishments to establish and maintain a partial quality control program for products labeled with nutrient content claims. Furthermore, the proposal would require most currently approved labels for all meat and poultry products, except for single-ingredient, raw products, to be revised and submitted to FSIS for approval, which would impact substantially on all such manufacturers. Manufacturers of single-ingredient, raw meat and poultry products opting to use nutrition labeling would also be required to revise their labels and comply with requirements of the mandatory program. The PRIA, attached as an appendix to this proposal, includes a cost analysis of nutrition labeling. The paperwork requirements contained in this proposal have been submitted to the Office of Management and Budget for approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). If you wish to comment on the paperwork burden of this proposed rule, send your comments to: Office of Management and Budget, Desk Officer for FSIS, Office of Information and Regulatory Affairs, room 3208, New Executive Office Building, Washington, DC 20503 and to the Clearance Office, Room 404-W, Administration Building, Washington, DC 20250.

Comments

Interested persons are invited to submit written comments concerning this proposal and the Preliminary Regulatory Impact Analysis (PRIA). FSIS plans to publish a supplement to the PRIA for public comment within 60 days of this proposal. The Agency is particularly interested in receiving early comments on the original PRIA and on the questions raised on alternatives later in this document to facilitate formulation of the supplementary document.

Written comments should be sent to the Policy Office at the address shown above and should refer to Docket Number 91-006P. Any person desiring an opportunity for an oral presentation of views as provided by the Poultry Products Inspection Act should make such request to Mr. Edwards so that arrangements can be made for such views to be presented. A transcript will be made of all views orally presented. All comments submitted in response to this proposal will be available for public inspection in the Policy Office from 9 a.m. to 12:30 p.m., and from 1:30 p.m. to 4 p.m., Monday through Friday.

Background

Introduction

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) authorize the Secretary of Agriculture to establish and maintain inspection programs designed to assure consumers that meat and poultry products distributed in commerce or within designated States are wholesome, not adulterated, and are properly marked, labeled, and packaged.

FSIS regulates the labeling of meat and poultry products while FDA has responsibility over all other food labeling. FSIS conducts a prior label approval program under which labeling to be used on, or in conjunction with, meat and poultry products must be approved by the Agency prior to their use. FDA, on the other hand, relies primarily upon food manufacturers to comply with prescribed labeling regulations and to ensure that information contained on food labels is truthful and not misleading.

FSIS also develops standards of identity or composition for certain meat and poultry products under section 7(c) of the FMIA (21 U.S.C. 607(c)) and section 8(b) of the PPIA (21 U.S.C. 457(b)). Under these authorities, FSIS has promulgated regulations prescribing standards of identity and composition. FSIS also has promulgated regulations

prescribing the content and design of labels.

In 1973, FDA adopted a regulation, recodified in 1977 as 21 CFR 101.9, prescribing a specific labeling format to be included on food product labels when voluntary or mandatory nutrition information is provided. Currently required components that must be addressed include calories, protein, carbohydrates, fat, sodium, two mineral elements (calcium and iron), and five vitamins (vitamin A, vitamin C, thiamin, riboflavin, and niacin). FSIS disseminates its nutrition labeling guidelines for meat and poultry products through the issuance by its Standards and Labeling Division of various policy memoranda.[1] One policy memorandum provides that nutrition information for nutrient content may be presented in the format and style described in 21 CFR 101.9 for the required components. This memorandum also permits an abbreviated labeling format for the nutrient content of meat and poultry products that includes calories, protein, carbohydrates, fat and/or sodium. In addition, FSIS permits other types of nutrition information to be presented, such as percentage fat-free claims. All policies on nutrition information outlined in these memoranda would no longer be in effect upon promulgation of this proposed regulation as a final rule. The policy memoranda that would require rescindment or revision include the following:

1. Policy Memo 46, April 1982, Percent Fat Free Label Declarations
2. Policy Memo 39, January 1982, Caloric Claims/Weight Reduction
3. Policy Memo 49c, June 1984, Sodium Labeling Guidelines
4. Policy Memo 69, March 1984, Labeling for Substitute Products
5. Policy Memo 70B, November 1987, Fat and Lean Claims
6. Policy Memo 71A, March 1986, Lite and Similar Terms
7. Policy Memo 74A, November 1986, Exemptions from NLV or PQC
8. Policy Memo 78, November 1984, Potassium Labeling Guidelines
9. Policy Memo 85B, January 1988, NLV Procedures
10. Policy Memo 86, May 1985, Nutrition Labeling
11. Policy Memo 114, July 1988, Point of Purchase Materials

Marketing Trends

Consumers are becoming increasingly aware of diet, health, and nutrition, and are concerned about the nutrient content of their foods. As a result, food manufacturers are adding nutrient content claims to allow consumers to make more informed food purchases. Claims such as "lean", "low fat", and "low cholesterol" have become common in today's marketplace. The use of such terms is subject to various interpretations and may mislead the consumer when purchasing products so labeled.

Nutrition Labeling Endeavors

The issue of providing consumers with more accurate and informative labeling has prompted a series of undertakings by various segments of the Federal government to provide more nutrition information on the labels of all foods. These endeavors are summarized below, most of which are further addressed in this document under the major issues of nutrition labeling.

1. Congressional Action

On November 8, 1990, the Nutrition Labeling and Education Act of 1990 (NLEA), which amended certain provisions of the Federal Food, Drug, and Cosmetic Act, was enacted (Pub. L. 101-535; 104 Stat. 2353).[2] The NLEA requires mandatory nutrition labeling for most FDA-regulated packaged food products. It also requires FDA to issue voluntary nutrition guidelines to food retailers for providing nutrition information on 20 of each of the most frequently consumed, during a year, varieties of raw vegetables, raw fruits, and raw fish. Should food retailers fail to comply substantially with the guidelines, the NLEA requires FDA to issue mandatory requirements for these commodities.

2. FDA Regulatory Initiatives

In August 1989, FDA issued an advance notice of proposed rulemaking (ANPR) requesting comments on a wide range of labeling issues to determine what changes, if any, should be made on the labeling of foods regulated by FDA (54 FR 32610). In September 1989, FDA issued a notice of an extension of the comment period on the ANPR and announced a series of public hearings to be held throughout the Nation on food labeling (54 FR 38806). FSIS participated in these hearings, which were conducted by FDA in the fall of 1989. Issues discussed at the hearings related to nutrition labeling, ingredient labeling, descriptions of food, health messages, and nutrition label format.

After consideration of various comments received, FDA published a reproposed rule on February 13, 1990, on health messages (55 FR 5176), and three proposed rules on July 19, 1990, that would establish provisions on daily values for use in declaring nutrient content in nutrition labeling (55 FR 29476), require mandatory nutrition labeling on most food products that are meaningful sources of calories or nutrients (55 FR 29487), and define serving and portion sizes (55 FR 29517). FDA also published a tentative final rule on July 19, 1990 (55 FR 29456), prescribing regulations that define and provide for the use of the terms "cholesterol free", "low cholesterol", and "reduced cholesterol" in the labeling of foods.

The NLEA, as previously discussed, was enacted in November 1990, several months after FDA published its proposed rules and tentative final rule on food labeling. As a result, on January 11, 1991, FDA published a notice (56 FR 1151) recognizing the impact of the NLEA on its pending rulemaking proceedings dealing with food labeling. FDA announced its plans to obtain comments in some form, or issue reproposals or supplemental proposals in some form, to ensure that all such regulations are consistent with the NLEA. These reproposals and supplement proposals are discussed in detail in this document.

3. NAS Study

In 1989, FSIS and the Public Health Service, U.S. Department of Health and Human Services (HHS), which includes FDA, jointly sponsored a study by the Institute of Medicine (IOM) of the National Academy of Sciences (NAS), to provide options for improving food labeling. In its 1990 final report, NAS recommended that FSIS and FDA mandate nutrition labeling for all packaged foods under their respective jurisdictions, except for certain exemptions.[3] In addition, NAS presented recommendations on various facets of nutrition labeling including nutrition label content, serving sizes, U.S. Recommended Daily Allowances, adjectival descriptors, and ingredient labeling.

4. Serving Size Meeting

On April 4, 1991, FSIS participated in a FDA public meeting on food labeling

[1] Copies of FSIS policy memoranda on nutrition labeling are available for public review in the FSIS Hearing Clerk's office. Copies may be obtained, without charge, from the FSIS Hearing Clerk.

[2] The NLEA is available for public review in the FSIS Hearing Clerk's office. Copies may be obtained, without charge, from the FSIS Hearing Clerk.

[3] The NAS final report titled "Nutrition Labeling: Issues and Directions for the 1990s" is available for public review in the FSIS Hearing Clerk's office. Copies of the report are available for sale from the National Academy Press, 2101 Constitution Avenue, NW., Washington, DC 20418.

to discuss five major issues relating to serving size: (1) The basis for determining serving size, (2) units of measure to be used, (3) deviation allowed from standard serving sizes, (4) dual nutrition labeling with the second column on the basis of uniform weight, and (5) the definition of single-serving container. One recommendation expressed by all the participants was that USDA and FDA should work in harmony to establish uniform serving sizes for the foods the agencies regulate. In response to this, FSIS participated as a member of an Interagency Committee on Serving Sizes formed by FDA to ensure consistency in serving size requirements for all foods. The committee's recommendations and objectives are further discussed in this document under section V, Serving Sizes.

Advance Notice of Proposed Rulemaking

On April 2, 1991, FSIS published an ANPR to solicit comments and recommendations from consumers, industry, public health officials, and other interested parties to assist the Agency in developing proposed regulations for nutrition labeling of meat and poultry products (56 FR 13564). In the ANPR, the Agency announced its intent to propose mandatory nutrition labeling regulations for most processed meat and poultry products and a voluntary program for fresh meat and poultry products. FSIS identified the following eight major food labeling issues that are of particular concern to the Agency: (1) Mandatory nutrition labeling, (2) nutrition label content, (3) U.S. Recommended Daily Allowances, (4) serving size, (5) descriptors and health messages, (6) food ingredients and standards of identity, (7) compliance and analytical methods, and (8) economic impact.

FSIS received 197 comments in response to the ANPR. The majority of these comments (96) were submitted by food manufacturers and distributors, while 30 comments were received from trade associations; 21 from consumers and consumer groups; 8 from State governments; 7 from health professionals; 6 from Congressional offices on behalf of small businesses; 5 from professional organizations; 5 from academia; 5 from consultants; 3 from retailers; 2 from import/export manufacturers; 2 from foreign governments; 1 from the Federal Government; and 1 from a local government. Five other comments received did not address the scope of the ANPR. The following discussion includes a summary of the comments received and the Agency's proposed regulations on each major issue.

It must be noted that because of the distinct labeling responsibilities of FSIS and FDA and the differences in the products regulated by each, some labeling differences between the two agencies continue to exist, thereby making absolute uniformity impossible. Furthermore, FSIS has attempted to parallel its proposed regulations as closely as possible to FDA's proposed regulations on nutrition labeling. This proposal was based primarily in response to comments from consumers and the industry to provide consistent nutrition labeling for all foods. Nonetheless, FSIS is interested in receiving comments addressing areas where the nutrition labeling of meat and poultry products should differ from other foods. For example, consumers may desire more detailed information on types of fat contained in meat and poultry products, or prefer a different threshold for descriptors such as "low fat" for meat and poultry than for other food products.

I. Alternatives Considered

FSIS considered several major alternatives during the course of its development of this proposed rule. (The Preliminary Regulatory Impact Analysis contains a more indepth discussion of these alternatives.) Each alternative is presented below with the Agency's reasons for selecting the favored alternative.

FSIS is interested in receiving comments on all alternatives discussed below, and on the issues that will be important on its choice among these alternatives. Such comments will be given serious consideration in the Agency's decision on a final rule. The first key issue is whether to make labeling mandatory for all or part of the industry. Mandatory labeling imposes certain costs on manufacturers, but may or may not confer benefits on consumers. For example, full mandatory labeling will ensure that all foods are labeled, but the increase in labeling may be of little value given that only a fraction of consumers currently read labels. Requiring labeling may force manufacturers to upgrade the quality of their foods rather than to reveal their poor nutrition content. On the other hand, the existence of a label may serve as a convenient and efficient signal that nutritional quality is higher for labeled foods than for unlabeled foods.

Another major issue is the extent to which special circumstances in the markets for meat and poultry relative to foods regulated by FDA might suffice to justify a difference between the regulatory approach pursued by FSIS and that pursued by FDA. The absence of a statutory mandate for this rule gives FSIS an opportunity to craft rules which serve the special needs of consumers and producers in meat and poultry markets. To exploit such an opportunity, FSIS would like to know whether special circumstances might suggest an independent approach on a variety of issues such as definitions for descriptors, relative claims, and comparative claims.

A third issue is the extent to which the issue of labeling reform is complicated by the USDA's system of prior label approval. The costs of labeling reform for the Department of Agriculture may be different than those for FDA, even correcting for the number of labels and the value of the potential dietary changes, because of the prior label approval. Could the cost effectiveness of this proposed rule be improved by abandoning the requirement of prior label approval?

1. Maintain Existing Policy

Approximately 35 to 50 percent of the meat and poultry firms voluntarily provide nutrition labeling on their products. FSIS currently approves labels that contain nutrition labeling in the format and style provided by FDA regulations or in an abbreviated format that includes calories, protein, carbohydrates, and fat in a specified serving of the product.

This alternative would result in the presence of two labeling schemes, three counting the abbreviated format. This alternative is provided to serve as a baseline for considering the other alternatives.

2. Establish a Voluntary Program Parallel to FDA

The second alternative was to establish a voluntary nutrition labeling program that parallels FDA regulations. Under such a program, meat and poultry firms would have the continued option of providing nutrition labeling, but would be required to follow FDA regulations on all elements of nutrition labeling. This alternative would require those firms opting to provide nutrition labeling to revise their labels according to FDA's proposed regulations on nutrition labeling.

3. Establish Voluntary Program With Incentives

This alternative involved the establishment of a voluntary nutrition labeling program for all meat and poultry products with incentives to offer those firms that choose to participate.

FSIS considered incentives such as use of an abbreviated nutrition label format, free or subsidized product analyses to small businesses, and centrally printed standardized materials.

FSIS seeks input as to other incentives that may be considered under a voluntary program.

4. Establish Mandatory/Voluntary Programs Parallel to FDA

The fourth alternative was the tentative position presented in FSIS's April 2, 1991, advance notice of proposed rulemaking on nutrition labeling. The alternative would require nutrition labeling for all meat and poultry products, except single-ingredient, raw products, which could contain nutrition labels at the firm's discretion. All nutrition labeling, whether mandatory or voluntary, would be required to follow FSIS's and FDA's proposed regulations on nutrition labeling.

This is the alternative selected by the Agency in this proposed rulemaking. FSIS has tentatively concluded that consumers should be provided nutrition labeled products to the extent possible for all foods. Because the nutrient values of single-ingredient, raw meat and poultry products are not modified through various stages of preparation, such as cooking and heat processing, FSIS believes that consumers have reasonable expectations as to the nutritional qualities of such products. However, the nutrient content of other products vary significantly depending upon the method of preparation and the addition of ingredients, such as preservatives and spices.

5. Establish a Mandatory Program For All Products

The final alternative considered was to establish a mandatory program for all meat and poultry products consistent with FDA's regulations. This alternative would provide consistent nutrition labeling for all foods. FSIS believes that a mandatory program for single-ingredient, raw meat and poultry products would not be necessary for the reasons set forth in the preceding section.

II. Mandatory Nutrition Labeling

A. Background

FSIS requires food manufacturers to obtain prior approval for the content and design of labeling for meat and poultry products before the products may be marketed. FSIS permits and encourages voluntary nutrition labeling using formats set forth in Agency policy memoranda. Approximately 35 to 50 percent of processed, packaged meat and poultry products currently bear nutrition labeling. FSIS requires manufacturers to provide nutrition data to substantiate nutrition claims. Additional information, when necessary to facilitate consumer understanding of these claims, is required.

NAS recommended that FSIS promulgate regulations that require nutrition labeling for most packaged foods under USDA's jurisdiction, including institutional-size packages and commodities distributed through USDA food programs, and the 20 to 30 top items of fresh/frozen meat and poultry products. NAS suggested that values for the latter be provided by using point-of-purchase information developed from data base values. Among exemptions from mandatory nutrition labeling specified in the NLEA are persons who offer food for sale and have annual gross sales to consumers which are not more than $500,000 or have annual gross sales made or business done in sales of food to consumers of not more than $50,000, with respect to food offered by such person to consumers.

The NLEA further exempts manufacturers from providing nutrition information on the label of certain small packages and food which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate food consumption and does not manufacture, process, or repackage the food it sells. NAS suggests excluding only small packages, and foods that have no nutritional significance and that do not make a claim with respect to nutritional value.

B. Discussion of Comments and Proposal

FSIS proposes to establish nutrition labeling regulations for meat, poultry, and products therefor to be as similar as possible to those established by FDA, which regulates all other foods. As previously discussed, FDA is undertaking various regulatory proceedings to comply with the NLEA, which requires mandatory nutrition labeling of most foods under FDA's jurisdiction. FSIS is proposing to: (1) Establish mandatory nutrition labeling on an "as packaged" basis for meat and poultry products, except single-ingredient, raw products; (2) permit voluntary nutrition labeling on single-ingredient, raw meat and poultry products on an "as packaged" or "as consumed" basis; (3) permit nutrition labeling information on the package or by alternate means for products, except single-ingredient, raw products, packaged in small packages and in other than consumer-size packages; (4) exempt meat and poultry products intended for further processing from nutrition labeling requirements; (5) incorporate point-of-purchase materials in the voluntary program; and (6) evaluate significant participation by food retailers in the voluntary nutrition labeling program.

1. Mandatory Nutrition Labeling

FSIS has determined that it has statutory authority to require nutrition labeling based on the Secretary of Agriculture's determination that meat and poultry products, other than single-ingredient, raw products, would be misbranded in the absence of such information on the label, under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) and section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)).

In the ANPR, the Agency announced its intention to establish mandatory nutrition labeling for most processed meat and poultry products, and to permit voluntary nutrition labeling for major cuts of fresh meat and poultry products. FSIS considered processed meat and poultry products and fresh meat and poultry products separately because of differences in the production and marketing practices of the two types of products.

A majority of the commenters supported the Agency's position. Commenters that did not support the Agency's position were equally divided in supporting either a total mandatory program or a total voluntary program. Manufacturers and distributors tended to support a total voluntary program while consumer advocate groups tended to support a total mandatory program. Small manufacturers expressed opposition to nutrition labeling because of concern regarding the expenditures for analysis and relabeling.

After reviewing the various comments received, FSIS is proposing to permit voluntary nutrition labeling on single-ingredient, raw meat and poultry products, including those that have been previously frozen, and to establish mandatory nutrition labeling on all other meat and poultry products, except products intended for further processing. Products such as ground beef, chicken breasts, and whole turkey would be in the voluntary program. Other products such as pumped turkey, chicken franks, corned beef, and meat burritos would be in the mandatory program.

2. Exemptions

In the ANPR, the Agency's tentative position was to exempt small

businesses, very small packages, and foods that are to be used in further processing. Commenters strongly supported the Agency's position on providing exemptions for all of these situations.

The NLEA exempts a food from nutrition labeling if it is offered for sale by a person who has annual gross sales to consumers which are not more than $500,000, or annual gross sales made or business done in sales of food to consumers of not more than $50,000. However, FSIS believes that the principal issue involves costs associated with compliance of nutrition labeling, and, in lieu of a small business exemption, is considering various mechanisms to minimize compliance costs for all businesses. This may include provisions for the combined use of data base and theoretical calculations of nutrient content for lines of products with minor formulation differences. FSIS seeks comments on any other mechanisms which could minimize the cost of providing nutrition labeling, especially for small businesses.

Several commenters recommended using net weight as the standard to define small packages. FSIS currently allows certain exemptions for individually wrapped packages of less than 1/2 ounce net weight. Therefore, FSIS believes it is appropriate to define small packages as individually wrapped packages of less than 1/2 ounce net weight.

The NLEA provides an exemption from nutrition labeling on the labels of foods that are in packages so small that it is impractical to comply with the statutory requirements, and that do not contain any nutrition information. The NLEA says nothing about the labeling. FDA proposes to require that nutrition information for food in very small packages be provided through alternative means, such as on placards or through display of the label for the container in which small packages are shipped.

FSIS believes it is desirable to provide consumers with nutrition information on all meat and poultry products, except for single-ingredient, raw products. Provided that no nutrition claim is made on the label, FSIS is proposing to allow nutrition information for small packages and for other than consumer-size packages to be provided by labeling means other than a nutrition panel on the package. A nutrition claim is any word or phrase, in a location on the label other than in the nutrition panel, that expressly or by implication characterizes the level of a nutrient contained in a product. If a nutrition claim is made on the label of small packages or other than consumer-size packages, all nutrition labeling requirements must be satisfied by printing the information on the label.

FSIS is proposing to exempt from nutrition labeling requirements those meat and poultry products intended for further processing, such as bulk sliced pepperoni to be used on pizza. The rationale for this exemption is that household consumers will not see nutrition information appearing on these products because such products are not sold directly to household consumers.

3. Voluntary Nutrition Labeling

FSIS is proposing to permit voluntary nutrition labeling on single-ingredient, raw meat and poultry products, including those that have been previously frozen. When manufacturers elect to provide nutrition information on the label of these products, such products and their labels would be subject to all requirements prescribed for the mandatory nutrition labeling program, except that nutrition labeling for the voluntary program may be declared on the basis of "as consumed" or "as packaged." FSIS believes that a voluntary nutrition labeling program for single-ingredient, raw meat and poultry products may be the best approach. Single-ingredient, raw products undergo minimal preparation, such as cut up, and contain no added ingredients. In addition, nutrition information on such products is available to consumers through other means such as the Extension Service, grocery stores, and trade associations.

In the ANPR, FSIS requested comments on whether it should incorporate point-of-purchase materials in its voluntary program. Commenters supported incorporating point-of-purchase materials. Therefore, FSIS is proposing to include point-of-purchase materials in the evaluation of significant participation in the voluntary program. Examples of the use of point-of-purchase materials to display nutrition information may include large placards (e.g., wall posters, signs, aisle hangings), pamphlets, brochures, and notebooks. The nutrition information may be supplemented by videos, live demonstrations or other media. For point-of-purchase materials, FSIS urges retailers to provide nutrition information in accordance with the mandatory requirements in this proposal. FSIS believes that point-of-purchase materials offer an acceptable method of presenting nutrition information to consumers.

The NLEA requires FDA to issue a report by May 8, 1993, on actions taken to comply with its voluntary guidelines. If FDA finds substantial compliance, FDA will reevaluate for substantial compliance every 2 years from the issuance of its May 1993 report; i.e., May 1995, May 1997, and so forth. If substantial compliance is not found during its initial evaluation or subsequent reevaluations, the NLEA requires FDA to mandate nutrition labeling for those products under the voluntary program.

FSIS proposes to survey food retailers on actions taken to provide consumers with nutrition information on products described in the voluntary program. As required by the NLEA, FDA will implement (1) the voluntary part of its nutrition labeling program in November of 1991 and (2) the mandatory part of its nutrition labeling program in May 1993. FSIS proposes to implement both the voluntary and mandatory nutrition labeling programs in May 1993. Should the regulation be finalized as proposed, FSIS would not begin surveying for significant participation in its voluntary program until after May 1993. FSIS would be surveying for "significant participation" rather than follow FDA's review for "substantial compliance". FSIS does not have a statutory mandate, as provided to FDA under the NLEA, to review for "substantial compliance" of the voluntary guidelines. Because of the lack of such a mandate, FSIS is proposing different terminology to refer to its review of the voluntary program.

However, FSIS proposes to follow FDA's planned 2-year evaluation cycle of the voluntary program. Thus, FSIS would issue its first report of survey findings on the voluntary program by May 1995. FSIS would reevaluate for significant participation every 2 years thereafter. If FSIS determines, during any evaluation of its voluntary guidelines, that significant participation does not exist, FSIS would initiate proposed rulemaking to determine whether it would be beneficial to require nutrition labeling on single-ingredient, raw meat and poultry products. The guidelines would remain in effect, however, as long as significant participation exists.

FSIS is proposing that individual stores that are selected for evaluation of the guidelines will be found to be participating at a significant level if (1) the store provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw meat and poultry products, including those that have been previously frozen, listed in Table 1, that it sells; and (2) nutrition labeling information is in accordance with the guidelines described in the regulations.

FSIS proposes to use a representative sample of stores to obtain the information necessary to assess participation. The distribution of the sample of stores would cover all chain companies and a representative sample of independent companies. FSIS further proposes that significant participation by food retailers exists if at least 60 percent of the companies that are evaluated are participating in accordance with the guidelines. The 60 percent cut-off value for measuring participation is consistent with FDA. The FDA proposal published July 2, 1991, sets forth its rationale for determining that substantial compliance would occur when at least 60 percent of the companies evaluated provide nutrition information for at least 90 percent of the major products identified as participating in the study.

FSIS has identified major cuts of meat and poultry, as listed in Table 1 below. These 45 major cuts would be used to measure significant participation of the voluntary program. Identification of these cuts is based on USDA nutritional studies, Poultry Nutri-Facts and Meat Nutri-Facts programs.[4] FSIS believes these cuts are representative of the market and that industry can provide data for these products. FSIS requests comments on these popular cuts and any suggestions on revising this list.

TABLE 1.—MAJOR CUTS OF MEAT AND POULTRY

1. Whole Chicken
2. Chicken Breast
3. Chicken Wing
4. Chicken Drumstick
5. Chicken Thigh
6. Whole Turkey
7. Turkey Breast
8. Turkey Wing
9. Turkey Drumstick
10. Turkey Thigh
11. Beef Chuck Blade Roast
12. Beef Loin Top Loin Steak
13. Beef Rib Roast Large End
14. Beef Round Eye Round Steak
15. Beef Round Top Round Steak
16. Beef Round Tip Roast
17. Beef Chuck Arm Pot Roast
18. Beef Loin Sirloin Steak
19. Beef Round Bottom Round Steak
20. Beef Brisket (Whole, Flat Half, or Point Half)
21. Beef Rib Steak Small End
22. Beef Loin Tenderloin Steak

TABLE 1.—MAJOR CUTS OF MEAT AND POULTRY—Continued

23. Ground Beef Regular, w/o added seasoning
24. Ground Beef Extra Lean, w/o added seasoning
25. Pork Loin Chop
26. Pork Loin Country Style Ribs
27. Pork Loin Top Loin Chop Boneless
28. Pork Loin Rib Chop
29. Pork Spareribs
30. Pork Loin Tenderloin
31. Pork Loin Sirloin Roast
32. Pork Shoulder Blade Steak
33. Pork Loin Top Roast Boneless
34. Ground Pork
35. Lamb Shank
36. Lamb Shoulder Arm Chop
37. Lamb Shoulder Blade Chop
38. Lamb Rib Roast
39. Lamb Loin Chop
40. Lamb Leg (Whole, Sirloin Half, or Shank Half)
41. Veal Shoulder Arm Steak
42. Veal Shoulder Blade Steak
43. Veal Rib Roast
44. Veal Loin Chop
45. Veal Cutlets

III. Nutrition Label Content

A. Background

The NLEA mandates that the amount of the following food constituents be included on the labeling of non-exempted food products: Calories derived from any source, calories derived from the total fat, total fat, saturated fat, cholesterol, total carbohydrates, complex carbohydrates, sugars, dietary fiber, protein, and sodium. Also required to be included is any mineral, vitamin, or other nutrient required to be placed on the label or labeling before October 1, 1990, if the Secretary of HHS determines that such information will assist consumers in maintaining healthy dietary practices. The NLEA allows FDA, by regulation, to add other nutrients to the list of nutrients that should be included on the labeling of foods subject to the NLEA, if this will help consumers to maintain healthy dietary practices. It allows FDA, by regulation, to remove nutrients required to be listed, if the Secretary of HHS determines that the information relating to the nutrient is not necessary to assist consumers in maintaining healthy dietary practices. The NLEA specifies that a simplified nutrition label format is to be used when a food contains insignificant amounts of more than one-half of the nutrients required to be listed.

During consideration of the NLEA, Congress had received testimony that certain saturated fatty acids, such as stearic acid, do not increase blood cholesterol and, thus, should not be counted as saturated fat on the nutrition label (H. Rep. No. 101-538, 101st Cong. 2nd Sess. 14). In the House Report on the NLEA, H. Rep. No. 101-538, 101st Cong, 2nd Sess. 14, Congress confirmed FDA's authority under the Act to provide definitions for nutrients, such as saturated fat, to be included on the label. Congress indicated that these definitions would give manufacturers a precise definition of the nutrients so that they would know the type of analysis to conduct on the food. Congress further stated that FDA "has the discretion to define saturated fat in a way that excludes specified fatty acids, such as stearic acid, if the Secretary determines that such an exclusion is consistent with the public health and is based on sound scientific principles" (H. Rep. No. 101-538, 101st Cong. 2nd Sess. 14).

In its July 19, 1990, proposal on mandatory nutrition labeling, FDA proposed to add calories from total fat, amounts of saturated fatty acid, cholesterol, and total dietary fiber, except if a serving (portion) contains less than a specified amount, to the list of nutrients it currently requires to be listed, and to remove the requirement that thiamin, riboflavin, and niacin be declared except in certain circumstances, because public health concerns for deficient intakes of these B vitamins has lessened considerably in the last 20 years. It proposed to permit voluntary disclosure of complex carbohydrates and sugars, unless a claim is made with respect to sugar, because dietary guidance recommendations for these food components are not quantified by consumption goals. FDA also recognized that there is a general consensus that the cholesterol-raising fatty acids are primarily lauric, myristic, and palmitic, and that current evidence indicates that stearic acid does not raise serum cholesterol. FDA requested comments as to which fatty acids should be classified as saturated.

NAS recommended optional disclosure of complex carbohydrates and sugars stating that "foods containing high proportions of complex carbohydrates are highly desirable for overall good health, not necessarily because of their specific contribution to chronic disease prevention but because these foods are usually low in fat and calories and are high in fiber." It argued that legitimate concerns about simple sugars center on dental caries, nutrient dilution, and excess calories, as opposed to their contribution to disease conditions. NAS also noted that many industry groups have raised questions

[4] *Poultry Nutri-Facts* is prepared jointly by and available from the Food Marketing Institute, the National Broiler Council, and the National Turkey Federation. Meat Nutri-Facts is prepared jointly by and available from the Food Marketing Institute, the National Live Stock and Meat Board, and the American Meat Institute.

about whether current analytical methods are adequate to support mandatory disclosure of complex carbohydrates and sugars. Besides recommending compulsory disclosure of the other food constituents listed by name in the NLEA, NAS favored required disclosure of unsaturated fat, calcium, and iron. It proposed that listing of vitamins, including vitamins A and C, be allowed as an option. In regard to saturated fat, NAS noted that a substantial body of scientific evidence has confirmed that the serum cholesterol-raising fatty acids are primarily lauric, myristic, and palmitic acids and that, unlike these saturated fatty acids, stearic acid does not elevate serum cholesterol levels. However, it now is currently classified as saturated for purposes of nutrition labeling.

B. Discussion of Comments and Proposal

In the ANPR, FSIS anticipated it would adopt FDA's July 1990 proposed list of required nutrients, which includes calories, calories from total fat, total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron, and incorporate complex carbohydrate and sugars as required by the NLEA. Commenters were generally in support of this list of required nutrients; however, there was strong opposition to requiring complex carbohydrate and sugars on the label. Various food manufacturers and distributors and trade associations opposed to the mandatory listing of complex carbohydrates and sugars on the label. Opposition was also expressed by consultants, a consumer, a professional organization, an import/export manufacturer, a State government, a consumer advocate organization, and a foreign government. These commenters stated that in most of the FSIS-regulated products, complex carbohydrates and sugars are present in small amounts or not at all. The commenters expressed the view that inclusion of these components on the label would be of little use to the consumer. There was also strong opposition to requiring dietary fiber. Those against the mandatory listing of dietary fiber were food manufacturers and distributors, trade associations, and a consultant. Because meat and poultry products are not generally meaningful sources of dietary fiber, the commenters contend that disclosure would be of limited value to the consumer. While some meat and poultry products, such as whole muscle cuts, may contain little or no dietary fiber, breaded and meal-type products may contain substantial amounts of dietary fiber.

FSIS requested comments on the inclusion of stearic acid in the definition of saturated fat. Comments indicated greater support for excluding stearic acid than including it in the definition. Several commenters recommended that FSIS and FDA harmonize on whatever decision is made. FDA's proposal defines saturated fat as the sum of lauric, myristic, palmitic, and stearic acids. This definition is consistent with the current definition of saturated fat for the purposes of nutrition labeling. Retention of this definition would avoid confusion and analytical costs that would result if the definition were changed. FDA and USDA also recognized that there is a general consensus that cholesterol-raising fatty acids are primarily lauric, myristic, and palmitic, and that stearic acid does not raise serum cholesterol. FSIS, like FDA, requested comments as to which fatty acids should be classified as saturated.

In the ANPR, the FSIS tentative position was to require that, at a minimum, the label include calories, total fat, saturated fat, cholesterol, total carbohydrate, protein, and sodium when the abbreviated format is used. Commenters supported allowing an abbreviated format. However, there was not a general consensus on what core nutrients should be required.

FSIS is proposing to: (1) Establish a list of 15 required nutrients, definition of nutrients, increments for declaring values, methods of calculation, and definition of insignificant amounts; (2) require an abbreviated format when more than one-half of the required nutrients are present in insignificant amounts; and (3) require, at a minimum, the declaration of calories, total fat, total carbohydrate, protein, and sodium when the abbreviated format is used.

1. List of Required Nutrients and Components. FSIS proposes to adopt FDA's current proposed list of nutrients as mandatory or voluntary components of nutrition labeling, definition of nutrients, and increments for declaring nutrients, in the interest of harmonizing with FDA. A more extensive discussion of FDA's proposed list of nutrients can be found in the preamble of FDA's proposed rule "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision" dated July 19, 1990, and the Supplementary to that proposal published elsewhere in this issue of the **Federal Register** (see docket 90N-0134 and 90N-0135, Section III, Content of Nutrition Labeling). Based on the Agency's review of FDA's analysis and the recommendations from "The Surgeon General Report on Nutrition and Health", issued in 1988,[5] the Agency is proposing the following rules for the listing of nutrients and food components.

a. Calories. FSIS proposes to require the declaration of the caloric content of a food, and to use the term "calories" rather than the more precise terms "kilocalories" or "energy." The use of the term calories is more readily understood by consumers. FSIS is proposing to allow, on a voluntary basis, declaration of the number of kilojoules (kJ) in addition to calories and to allow the use of the term "energy" parenthetically as a synonym for calories.

b. Calories from total fat, saturated and unsaturated fat, carbohydrate, and protein. FSIS is proposing to require that when the caloric contributions of the energy nutrients, fat, saturated fat, unsaturated fat, carbohydrate, and protein are declared, they be expressed as calories from the nutrient rather than as a percent of total calories.

(1) Calories from total fat. FSIS is proposing to require the declaration of calories contributed by total fat. The most common and consistent dietary recommendation for the general population is for calories from total fat to be reduced to less than or equal to 30 percent of calories. To enable consumers to follow this recommendation that applies to the total diet, FSIS is proposing that the number of calories from total fat be listed on the nutrition label.

(2) Calories from saturated and unsaturated fat. Information on the contribution from the content of saturated and unsaturated fat declared in the nutrition label may be of interest to consumers. Accordingly, FSIS is proposing to permit the voluntary declaration of the calories from saturated and unsaturated fat. The Agency will not allow declaration of calories from polyunsaturated and monounsaturated fat because the definition of these two types of fat is limited to the *cis* form, with the *trans* form being excluded, so that declaration of calories would underrepresent total caloric value and therefore could be misleading to consumers.

(3) Calories from total carbohydrate. FSIS is proposing to permit the voluntary declaration of calories from carbohydrate. FSIS believes that information about the caloric

[5] The referenced portion of this report is available for public review in the FSIS Hearing Clerk's Office. Copies of that portion are available, without charge, from the FSIS Hearing Clerk.

contribution of carbohydrate in foods can be useful to consumers trying to replace fat in their diet with carbohydrate and therefore should be permitted in nutrition labeling.

(4) Calories from complex carbohydrate and sugars. FSIS is proposing that calories from complex carbohydrate and sugars not be declared on the label. The Agency believes this information would be of no value to consumers because there is currently no general consensus statements from the medical and scientific community concerning the caloric contributions of these components of total carbohydrates.

(5) Calories from protein. Because information on calories from protein may be useful to consumers in planning dietary changes, FSIS is proposing to permit voluntary declaration of calories from protein.

c. Amount of total fat, fatty acids, and cholesterol—(1) Amount of total fat. FSIS proposes to require the declaration of total fat in grams, to the nearest half gram. High dietary intakes of total fat are associated with an increased risk of atherosclerotic cardiovascular disease. High fat intake may also be associated with an increased risk of some types of cancer, gall bladder disease, and obesity.

(2) Amount of saturated fat. FSIS proposes to require the declaration of saturated fat in grams, to the nearest half gram. As previously discussed, FSIS proposes to adopt FDA's definition of saturated fat as the sum of lauric, myristic, palmitic, and stearic acids.

(3) Amount of unsaturated fat. Information on levels of unsaturated fat in a food could assist consumers in monitoring their intakes of various types of fat throughout the day. FSIS is proposing to permit the voluntary declaration of the amount of unsaturated fat in grams, to the nearest half gram. FSIS is proposing to make declaration of unsaturated fat mandatory if claims are made on the label about fatty acid or cholesterol content, or if the manufacturer chooses to declare calories from unsaturated fat.

FSIS is also proposing the use of the collective term "unsaturated fat" to present content information for the two types of unsaturated fat, polyunsaturated and monounsaturated fat, instead of requiring separate declarations of each of these two types of unsaturated fat. The use of this collective term will simplify the presentation of information and allow manufacturers to conserve space. Because the definition of unsaturated fat will include all unsaturated fatty acid isomers (i.e., *cis* and *trans* isomers) rather than specific isomers of the unsaturated fatty acids, it provides an appropriate basis for voluntary declaration of calories from unsaturated fat.

(4) Amounts of polyunsaturated and monounsaturated fat. As an alternative to using the collective term "unsaturated fat", FSIS is proposing to permit the voluntary declaration of the amounts of polyunsaturated or monounsaturated fat, in grams to the nearest half gram. However, if label claims are made about polyunsaturated or monounsaturated fat, amounts of these fatty acids would be required to be listed. If a manufacturer chooses to list polyunsaturated or monounsaturated fat, or if the declaration is required because of a label claim, under this proposal, both polyunsaturated and monounsaturated fat will have to be declared so that complete information will be provided.

When polyunsaturated and monounsaturated fat are declared, FSIS is proposing to limit these fatty acids to *cis*, *cis*-methylene-interrupted polyunsaturated fatty acids and *cis*-monounsaturated fatty acids. The Agency is proposing to exclude the *trans* isomers. Thus, the definition for polyunsaturated and monounsaturated fat is less inclusive than the definition of unsaturated fat which includes both *cis* and *trans* isomers.

(5) Amount of *trans* isomers of fatty acids. FDA received comments suggesting that *trans* isomers of fatty acids behave similarly in the diet to saturated fat in that they are associated with increased serum cholesterol levels, and therefore FDA should require that levels of *trans* fatty acids be declared as a separate entity on the nutrition label. However, FDA tentatively concluded that there was no basis for declaring *trans* isomers. In its supplemental to its proposal entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Content Revision" (July 19, 1990), FDA acknowledged that new research and commentary had been published concerning the effect of *trans* isomers of fatty acids on serum cholesterol levels. FDA is requesting comments on the significance of the new findings. Therefore, FSIS will address the issue of *trans* isomers of fatty acids once FDA has made a determination in this area.

(6) Amount of cholesterol. FSIS is proposing to require the declaration of cholesterol and that it be declared in milligrams. Given the scientific consensus on the benefits of reducing dietary cholesterol as well as the availability of quantitative intake recommendations, the Agency concludes that mandatory declaration of cholesterol content of foods is warranted.

d. Amount of total carbohydrate, complex carbohydrate, dietary fiber, sugars, and sugar alcohols—(1) Amount of total carbohydrate. FSIS is proposing to require the declaration of total carbohydrate and that it be declared in grams. FSIS is proposing to define total carbohydrate to exclude dietary fiber. Because dietary fiber includes components of carbohydrate that cannot be digested by humans, the proposed definition of total carbohydrate does not include the components of carbohydrate that generally do not contribute calories to the diet. Thus, the proposed definition encompasses only the metabolizable energy of carbohydrate.

(2) Amount of complex carbohydrate. FSIS is proposing to require the declaration of complex carbohydrate and that it be declared in grams in the interest of harmonizing with FDA. FSIS proposes that complex carbohydrate be defined as the sum of dextrins and starches. Thus, complex carbohydrate, as defined, includes those carbohydrate components that contain 10 or more saccharide units (exclusive of dietary fiber). The Agency recognizes that many consumers are interested in these components but it also believes required nutrients should be those with demonstrated health implications and those that can be accurately determined.

(3) Amounts of sugars and sugar alcohols. FSIS is proposing to require the declaration of sugars content and continues to seek comments on this issue in the interest of harmonization with FDA. FSIS proposes to define sugars as the sum of all free mono- and oligosaccharides (and their derivatives) that contain four or fewer saccharide units. This definition includes tri- and tetrasaccharides. Considering that sugar alcohols behave metabolically like sugars and are used as nutritive sweeteners in foods, FSIS is proposing to include sugar alcohols in the definition of "sugars" for labeling purposes. Although sugar alcohols are included in the definition of sugars, FSIS is proposing to allow, on a voluntary basis, separate declaration of sugar alcohols. Under the proposal, declaration would become mandatory if claims are made relative to sugar alcohols or to sugar when sugar alcohols are present.

(4) Amount of dietary fiber. FSIS is proposing to require the declaration of total dietary fiber content in the interest of harmonization with FDA. Different physiological effects are associated with soluble and insoluble dietary fibers, and consumers have expressed interest in

knowing the amounts of these types of fiber in foods. However, no quantitative guidelines for daily intakes of soluble and insoluble fiber components have been provided. Thus, FSIS is proposing to permit the voluntary declaration of insoluble and soluble fiber components, unless a claim for either fiber content is made, in which case declaration would be required. If one fiber component is declared, FSIS is proposing that for completeness, both must be declared.

e. Protein. (1) Quantitative protein content. FSIS proposes to require the declaration of protein content as the number of grams of protein per serving. In addition, the Agency is proposing to require that the label for any food contain the statement "not a significant source of protein" immediately adjacent to the protein content regardless of the actual amount of protein present if the food (1) intended for adults and children 4 or more years of age, has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 percent of casein, (2) intended for children greater than 1 but less than 4 years of age, has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 percent of casein, or (3) intended for infants, has a protein quality, as measured by protein efficiency ratio, of less than 40 percent of casein.

(2) Protein content as a percentage of the Reference Daily Intakes (RDI). FSIS is proposing that declaration of protein content calculated as a percent of the RDI be voluntary for foods intended for consumption by adults and children 4 or more years of age unless a protein claim is made for the food. However, the Agency is also proposing that nutrition labeling on foods intended for infants and children less than 4 years of age contain a mandatory statement of protein content expressed as a percent of the RDI. The Agency considers this action to be warranted because of the importance of the quality of protein in diets derived from a limited number of foods, as is the case for infants and young children.

When the percent RDI for protein is declared, FSIS is proposing that this information be placed adjacent to the declaration of the quantitative amount of protein and expressed as "Percent of Daily Value." Use of the terminology "Percent of Daily Value" is discussed below under "Amounts of vitamins and minerals."

f. Amount of sodium. The Agency is proposing to require the declaration of sodium content in milligrams. FSIS believes it is prudent to recommend caution concerning sodium intake for the general population.

g. Amount of potassium. FSIS is proposing to permit the voluntary declaration of the amount of potassium in milligrams.

h. Amounts of vitamins and minerals. FSIS is proposing to require that vitamin A, vitamin C, calcium, and iron be declared in the nutrition label and that they be declared as a percent of the RDI. This proposal is based on the continuing public health concerns relative to inadequate dietary intakes of these nutrients by specific portions of the population, as well as possible association between several of these nutrients and risk of chronic disease. FSIS is also proposing to require the presentation of this information as a percentage of the reference standard (i.e., RDI) rather than as a quantitative amount, such as grams or milligrams. FSIS is proposing to use the terminology, "Percent of Daily Value," to head the list of vitamins and minerals.

FSIS believes it is beneficial to have a general term such as "Daily Value" that can apply to both types of reference standards, RDI's and Daily Reference Values (DRV's), so that consumers are not confused by the list of two different sets of values. While amounts of vitamins and minerals are to be expressed as a percent of the RDI, the Agency believes that declaration on food labels does not require exact specificity.

(1) Vitamin A. FSIS is proposing to require the declaration of vitamin A. Information about the vitamin A content of foods is important to consumers because the limited number of foods rich in vitamin A requires selective choices by consumers.

(2) Vitamin C. FSIS is proposing to require the declaration of vitamin C based on its well established role in non-heme iron absorption.

(3) Calcium. FSIS is proposing to require the declaration of the calcium content of foods. The Agency is proposing to do so based on (1) the limited number of calcium-rich foods in the U.S. food supply, (2) current concerns that calcium intakes are generally marginal, and (3) evidence that adequate calcium intakes are needed to allow for optimal bone mass development during childhood and young adulthood which in turn may reduce the risk for osteoporosis.

(4) Iron. Iron deficiency remains a risk for certain segments of the U.S. population, notable among young children, adolescents, and women of childbearing age. Pregnant women, especially those with low incomes, are also a group at risk. Therefore, FSIS is proposing to require the mandatory declaration of the iron content of foods.

(5) Thiamin, riboflavin, and niacin. FSIS is proposing to make the declaration of thiamin, riboflavin, and niacin voluntary.

(6) Other vitamins and minerals. FSIS is also proposing that declarations concerning the content of the remaining vitamins and minerals for which RDI's have been proposed may continue to be listed in nutrition labeling on a voluntary basis, unless claims are made about them. The complete list of vitamins and minerals for which RDI's have been proposed can be found in FDA's proposed rule "Food Labeling: Reference Daily Intakes and Daily Reference Values" (July 19, 1990, 55 FR 29485).

(7) Synonyms. The terms "folacin" and "folate" are currently used interchangeably, and the term "ascorbic acid" is the commonly used chemical name for vitamin C. Therefore, the Agency is proposing to permit the use of the term "ascorbic acid" parenthetically as a synonym for vitamin C and the term "folacin" parenthetically for "folate."

2. *Abbreviated format.* The use of an abbreviated format helps to keep space requirements to a minimum. The NLEA requires the use of an abbreviated format if a food contains insignificant amounts of more than one-half of the required nutrients. FDA considered all 15 nutrients in its supplementary proposal as "required nutrients". The 15 nutrients to be included are: Calories, calories from total fat, total fat, saturated fat, cholesterol, total carbohydrate, complex carbohydrate, sugars, dietary fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron.

FSIS recognizes that many meat and poultry products will likely contain more than one-half of the required nutrients. However, in the interest of nutrition labeling harmonization, FSIS believes it should apply FDA's threshold criteria for an abbreviated format for meat and poultry products. Therefore, FSIS is proposing that if a meat and poultry product contains eight or more required nutrients in insignificant amounts, it is subject to an abbreviated format.

a. Minimum nutrients declared on label. In the ANPR, FSIS's tentative position was to require that the label include, at a minimum, calories, total fat, saturated fat, cholesterol, total carbohydrate, protein and sodium. Although the commenters supported allowing an abbreviated format, there was no consensus on what core nutrients should be required. The current abbreviated format includes the

number of calories, protein, carbohydrates, and fat and or sodium. Consumers are familiar with this format and are interested in the continued listing of these nutrients. FSIS is proposing to require that, at a minimum, calories, total fat, total carbohydrate, protein, and sodium be declared, in the interest of harmonizing with FDA's proposed core nutrients. In addition, FSIS is proposing that all nutrients or food components that are required components of the full nutrition label be declared if less than one-half of them are present in insignificant amounts. As long as no additional nutrients (e.g., potassium) are declared, the nutrients or food components (other than the core requirements) that are required parts of the full nutrition label but that are present in insignificant amounts would not be identified on the simplified label. However, if manufacturers voluntarily choose to declare additional nutrients or food components that are not among the 15 required nutrients (e.g., potassium), they will then be required to use the statement "Not a significant source of ," with the blank filled in with the name of any required nutrients or food components that are missing or present in insignificant amounts.

b. Products voluntarily enriched or fortified. The Agency is also proposing that if the product is voluntarily enriched or fortified with added vitamins or minerals, any such nutrients must be declared within the abbreviated format and followed by the above statement. However, as an exception, standardized enriched foods that qualify for the use of the abbreviated format may use this format without the added statement, even though they include nutrients that are required by the standard to be added but are not among the 15 required nutrients.

c. Definition of "insignificant amount". FSIS is proposing to define "insignificant amount" as that amount which may be rounded to zero in nutrition labeling. For consistency, FSIS is proposing to use the same definition as FDA for insignificant amounts as described below. Very low levels of nutrients or food components may be rounded to zero, the Agency is proposing to indicate precisely what analytical amounts may be rounded down to zero: Calories; calories from total fat; calories from saturated fat, unsaturated fat, total carbohydrate, and protein; total fat; saturated fat; unsaturated fat; polyunsaturated fat; monounsaturated fat; total carbohydrate; complex carbohydrate; sugars; sugar alcohols; dietary fiber; soluble fiber; insoluble fiber; and protein. In the case of calories, which are proposed to be declared to the nearest 5-calorie increment in nutrition labeling (up to 50 calories), the amount specified that would be expressed as zero is "less than 5 calories." For total fat, total carbohydrate, sugars, sugar alcohols, dietary fiber, soluble fiber, insoluble fiber, and protein, FSIS is proposing less than 0.5 grams as the amount that can be expressed as zero. For saturated fat, unsaturated fat, polyunsaturated fat, and monounsaturated fat, FSIS is proposing less than 0.25 grams as the amount that can be expressed as zero. For sodium, FSIS is proposing that sodium content may be expressed as zero when less than 5 mg are present per serving (portion). For cholesterol, FSIS is proposing that a zero declaration be allowed when the cholesterol content of a food is less than 2 mg per serving (portion). FSIS is proposing that for vitamins and minerals, a value of less than 2 percent of the RDI be considered insignificant.

3. Packages with variable contents. In its July 19, 1990, proposal on mandatory nutrition labeling (55 FR 29505), FDA proposed that where assortments of food are packaged, firms would be required to express nutrient content based on the package as a whole (e.g., the entire product contents may be combined for a nutrient analysis). However, many meat and poultry manufacturers currently provide nutrition information in their "variety packs" (e.g., a package containing sliced ham, bologna, and pickle loaf) on the individual foods. In order to provide greater flexibility, FSIS is proposing to allow packages with variable contents to declare the nutrient content on the entire package contents or on each individual food.

IV. U.S. Recommended Daily Allowances

A. Background

FSIS proposes to follow current FDA requirements, set forth in 21 CFR 101.9, concerning use of the U.S. Recommended Daily Allowances (U.S. RDA's) in nutrition labeling. FDA established this single set of values in 1973 for regulatory use in declaring contents of vitamins and minerals (38 FR 2125).

On July 19, 1990, FDA published a proposed rule on Reference Daily Intakes (RDI's) and Daily Reference Values (DRV's) (55 FR 29476). The proposal discusses various issues such as the need for change in reference values for nutrition labeling, development of the RDI, DRV values, and the units of measures.

FDA proposed to update and expand the current U.S. RDA's with RDI's to provide a basis for consumers to compare the protein, vitamin, and mineral contents of foods. FDA proposed to establish RDI's for protein and 26 vitamins and minerals, and to focus on five specific consumer groups: Adults and children 4 or more years of age, children less than 4 years of age (13 through 47 months), infants, pregnant women, and lactating women. FDA noted that its proposal to revise the U.S. RDA's was based primarily on the 1989 Recommended Dietary Allowances and Estimated Safe and Adequate Daily Dietary Intakes (ESADDI's) of the National Research Council of NAS (except for chloride) (55 FR 29478).

In addition, FDA proposed DRV's for adults and children 4 or more years of age for eight other food components including total fat, saturated fatty acids, unsaturated fatty acids, cholesterol, carbohydrate, fiber, sodium, and potassium for which RDA's and ESADDI's have not been established but that are important in diet and health interrelationships (55 FR 29478). The RDI's and DRV's are meant to serve as reference values for labeling purposes only, as opposed to dietary intake recommendations. They are intended to help consumers compare how nutrient levels in various foods contribute toward general recommendations for a total diet and to facilitate graphical presentations of nutrient information.

In an effort to clarify the manner of declaring amounts of DRV's, FDA published a proposed supplemental rule in this issue of the **Federal Register** (see dockets 90N-0134 and 90N-0135, Section VI, Other Nutrition Labeling Provisions). This proposal would require that, when a nutrition profile is given, the percent DRV's be expressed in 2-percent increments up to and including the 10-percent level, 5-percent increments above 10 percent and up to and including the 50-percent level, and 10-percent increments above the 50-percent level.

It is necessary to differentiate between RDI's and DRV's for regulatory purposes. The term "daily value" will be used for food labeling. The term distinguishes the reference value as a daily intake level and will enable the consumer to understand the relative significance of the information presented in the context of a total daily diet.

B. Discussion of Comments and Proposal

In its April 2, 1991, ANPR, FSIS requested comments on its tentative

position to adopt FDA's reference values. The majority of the commenters concurred that FSIS should adopt the values being proposed by FDA to provide consumers with a basis to compare the protein, vitamin, and mineral content of all foods.

Some concerns were expressed that FDA's RDI values had not been completed. A few others wrote that a consumer education program was not in place. After giving all comments careful consideration, it remains the interest of FSIS to be consistent with past practice, and, in the interest of nutrition label harmonization, to adopt FDA's RDI values.

The majority of the comments received on the DRV's agree that FSIS should adopt the values being proposed by FDA to provide a basis for consumers to compare nutrients and food components (fat, fatty acids, cholesterol, carbohydrate, fiber, sodium, and potassium) that have been identified as important to diet and health interrelationships.

FSIS is proposing to parallel FDA by requiring that DRV's become a part of nutrition labeling. FSIS also proposes to adopt FDA's proposed format for the "daily value", as presented in the proposed 21 CFR 101.9(c)(12)(i).

V. Serving Sizes

A. Background

The definition of a product's serving size is an essential element of a uniform nutrition labeling system. A product's serving size is used as the basis for reporting that product's nutrient values and serves as the reference point for using descriptors. FSIS is aware of public concern that the serving sizes on many products are misleading. In many cases, serving sizes currently in use are neither reasonably consumed amounts of a product nor are they consistent for similar food products. This makes it very difficult to compare products and to select the one that fits an individual consumer's needs. FDA regulations stipulate that a "serving" is a reasonable quantity of food suited for consumption as part of a meal, and "portion" as the amount of food customarily used only as an ingredient in the preparation of other foods (21 CFR 101.9(b)(1)). FSIS permits nutrient values to be listed per serving with the size of the serving expressed in common household measures. Alternatively, FSIS allows use of portion sizes for foods that are not used only as ingredients in the preparation of other foods, but also for foods in which the manufacturer's serving size is less than that commonly accepted for a serving of the particular food. Industry generally determines the serving or portion sizes stated for their products. FSIS exercises control over the use of the terms "serving" versus "portion" during the prior label approval process. FSIS's "Standards and Labeling Policy Book" currently defines a "dinner" as a product with a minimum serving size of 10 ounces, a minimum of three components, and a minimum meat or poultry content requirement depending on the product name.[6]

To make nutrition information on food labels meaningful, the NLEA requires FDA to establish standards to ensure that nutrition labeling provide the serving size which is an amount customarily consumed and is expressed in a common household measure appropriate to the food. NAS recommended that FDA and USDA jointly establish sizes for limited, broad categories of foods to help consumers make product comparisons. NAS suggested basing them on standard serving sizes as specified by dietary guidance recommendations to make their use in educational programs less difficult and to permit consistency among serving sizes shown in dietary guidance material and on the food label. NAS also advocated a petition process for desired deviations from the serving size set by FDA and USDA or for creation of different food subcategories with other serving sizes.

B. Discussion of Comments and Proposal

In order to establish standards for nutrition labeling of meat and poultry products which are in harmony with the NLEA and with regulations and guidelines being established by the FDA to administer the Act, and in response to comments on the ANPR issued on April 2, 1991, the FSIS is proposing to: (1) Create Reference Amounts for serving sizes for 23 food Product Categories; (2) establish guidelines for converting Reference Amounts to serving sizes; (3) define serving sizes for meal-type products and food products in pieces or units; (4) require presentation of nutrition information based on serving size "as packaged" for the mandatory labeling program and allow nutrition information for single-ingredient, raw meat and poultry to be declared "as packaged" or "as consumed" under a voluntary nutrition labeling program; (5) require the use of both common household and metric measures to declare serving size; (6) define serving size and single-serving container; (7) establish guidelines for declaring the number of servings per container; (8) require the use of serving size and Reference Amounts to evaluate nutrition claims; and (9) allow for petitions for changes in Product Categories and Reference Amounts.

In the ANPR issued by FSIS on April 2, 1991, four major areas of concern related to serving sizes were discussed and tentative positions were presented. These areas addressed (1) standardized size unit for presenting nutrition information, (2) serving sizes for meal-type products and food products in pieces or units, (3) product state for presenting nutrition information, e.g., "as packaged" or "as consumed," and (4) unit of measure most readily understandable to the public.

On April 4, 1991, FSIS participated in a public meeting conducted by FDA to discuss issues on serving sizes. This open meeting provided an additional opportunity for interested parties to submit both oral and written comments. A copy of the transcript of the meeting is on file with the FSIS Hearing Clerk, Room 3171, South Building, USDA, Washington, DC 20250. Oral presentations were made at the public meeting on serving sizes by representatives of food industries and trade organizations, professional nutrition organizations, and consumer organizations.

1. *Reference Amounts for serving sizes for 23 food Product Categories.* In the ANPR, FSIS discussed three options for establishing standardized reference serving sizes: (1) 1 ounce or 100 grams, (2) a single, uniform Reference Standard serving size using food consumption data, and (3) a Reference Standard serving size based on dietary recommendations.

Option 1 would establish a single, uniform standard size unit such as 1 ounce or 100 grams. Fresh meat and poultry products and some processed products are packaged in an infinite variety of sizes, and are packaged and then weighed, rather than weighed and then packaged. It is difficult for such products to have an integral number of standardized servings.

A 1-ounce serving size would provide the easiest method for conversion to multiples, and allow consumers to make comparisons between meat and poultry products easily and readily. A possible problem with this option is that consumers may not realize that the information has to be converted to be meaningful in terms of the amounts they eat.

[6] The referenced portion of the "Standards and Labeling Policy Book" is available for public review in the FSIS Hearing Clerk's Office. Copies of that portion may be obtained, without charge, from the FSIS Hearing Clerk.

There was some support for a uniform standardized size unit of 1 ounce because it is easily multiplied and can be used for most meat and poultry products. Those opposed expressed concern that the consumer may not easily be able to make the conversions to larger serving sizes and that one ounce is not a "commonly consumed amount" for meat and poultry products.

Some commenters preferred presenting nutrition information per 100 grams, but also preferred that metric units be required either in addition to or instead of the U.S. measure of the ounce. They cited international harmonization, trade concerns, and the need to respond to requirements of the Omnibus Trade and Competitiveness Act which requires use of the metric system in doing business by 1992.

Option 2 considered establishing a standard serving size for meat and poultry products using food consumption data. This would be more consistent with FDA's July 19, 1990, proposal and the NLEA. FDA proposed to establish standard serving sizes for 159 categories of foods, whereas FSIS would establish a single one standard serving size for the general category of meat and poultry products. FDA considered establishing 159 food product category serving sizes because they regulate a wide diversity of food and food products (55 FR 29530).

There was virtually no support for establishing a single uniform serving size based on food consumption data. FSIS decided not to adopt this approach because of lack of support from commenters. There was, however, support for using food consumption data as the basis for establishing serving size categories similar to those proposed by FDA in the July 19, 1990, proposal.

Option 3 would establish a standard serving size for meat and poultry products using dietary recommendations. This would provide nutrition information on the recommended portions of foods. However, it would not provide information on what is actually being consumed.

There was limited support from nutrition educators and health professionals to provide nutrition information using dietary recommendations. Although the advantages presented by the supporters of this concept have merit for nutrition education purposes, FSIS believes the problems with this approach outweigh the advantages. FSIS has the following concerns: (1) The NLEA defines serving size as an "amount customarily consumed"; that is, the Act links serving size to the amount consumed and not to an amount recommended by the dietary guidance recommendations or any other system; (2) many serving sizes in dietary guidance recommendations are for very narrow food categories, e.g., the recommendation is for lean cooked meat, whereas many meat products such as beef patties may contain ingredients other than meat; and (3) there are no dietary guidance recommendations for many product categories, particularly further processed packaged products for which nutrition labeling is mandatory (e.g., frozen entrees and dinners; snack foods; infant and toddler foods).

There was no strong support for any of the three options proposed. The comments in favor of any of the three options proposed for establishing serving sizes were split approximately evenly. However, virtually all comments supported harmonization with FDA. Comments stated that harmonization with FDA should be an overriding factor when resolving issues between the two agencies. The vast majority of comments echoed the contention that without a single, uniform set of nutrition labeling regulations for all foods, confusion will continue to exist. In addition, the NAS report recommended that USDA and FDA jointly establish serving sizes for a limited number of different food categories to allow ready product comparison.

In an effort to harmonize the serving sizes for all foods, FDA established the Interagency Committee on Serving Sizes. The committee consisted of representatives from FDA and USDA's Food Safety and Inspection Service and Human Nutrition Information Service. FSIS and FDA will continue to cooperate throughout the rulemaking process to assure the best possible uniform food labeling system.

The committee's major goal was to establish standards that could be used by manufacturers to determine: (1) Label serving sizes in household measures most appropriate to their specific products, and (2) whether a claim such as "low sodium" meets criteria for the claim.

Using the principles set forth in the preamble of FDA's proposed rule on serving sizes (see docket 90N-0165, published elsewhere in this issue of the **Federal Register**), the Interagency Committee established 131 Product Categories and Reference Amounts for each category. These 131 Product Categories were representative of all food products regulated by both USDA and FDA. A detailed discussion of the Interagency Committee's work and the principles, methodology, and procedures used to develop the Reference Amounts is contained in the preamble of FDA's reproposal on serving sizes (see docket 90N-0165, Section IV, The Proposed Regulation, D. Proposed Reference Amounts for Serving Sizes, Sections 2 and 3).

Of the 131 Product Categories and Reference Amounts set up by the committee, 23 apply to meat products and 22 apply to poultry products which are regulated by USDA. Therefore, FSIS is proposing to establish 23 Product Categories and Reference Amounts for meat products and 22 Product Categories and Reference Amounts for poultry products which will provide a uniform food labeling system for the consumer so that similar foods such as vegetarian vegetable soup and beef vegetable soup will have the same reference standard. A discussion of the formation of the Product Categories and Reference Amounts and the guidelines for converting Reference Amounts to serving sizes follows.

FSIS is also proposing, along with FDA, that petitions may be submitted to amend the Reference Amounts and the Product Categories through the rulemaking process. Any such petitions for changes to the Reference Amounts and Product Categories for meat and poultry products would be submitted to the Administrator, FSIS. FSIS solicits public comments on the proposed Reference Amounts and any product or Product Category that should be added to the Reference Amounts, with supporting documentation. FSIS is also requesting comments on additional product examples that should be listed in the proposed Product Categories. Examples listed under Product Category are not all inclusive, and are provided to assist manufacturers in identifying the appropriate Reference Amount to use for their products.

2. *Procedures for converting Reference Amounts to Serving Sizes.* Procedures are needed by manufacturers so they can convert the Reference Amounts to serving sizes in common household measures that are most appropriate for their products. FDA is proposing guidelines for converting Reference Amounts to serving sizes for (1) products in discrete individual units, e.g., hot dogs and slices of meat; (2) products in large discrete units that are usually divided for consumption, e.g., pizza (when not marketed as a serving for one); and (3) non-discrete bulk products, e.g., beef stew and meat chili (see docket 90N-0165, Section IV, E. Procedures for Converting the Reference Amount to Serving Size, published elsewhere in this issue of the **Federal Register**).

These procedures would help to assure uniformity in the declared serving size within a Product Category and allow flexibility in the serving size to account for differing characteristics of diverse food products. As a member of the Interagency Committee, FSIS participated fully in establishing the criteria as published in the preamble of FDA's rationale. Therefore, FSIS is proposing to adopt the procedures as published in the proposed 21 CFR 101.9(b)(2).

3. *Serving Sizes for Meal-type Products and Food Products in Pieces or Units.* In the ANPR, FSIS discussed its plan to propose nutrition labeling for meal-type products, and for piece or unit products. A meal-type product is any product that is intended for consumption by one person. Under the ANPR, FSIS proposed that meal-type products would be labeled on the basis of the entire contents of the package, and pieces and units would be labeled based on each piece or unit.

There was strong support for nutrition labeling for meal-type products in their entirety. Several commenters suggested criteria for establishing serving sizes for meal-type products.

Because meal-type products are typically consumed by one person and make up the major portion of a meal, it is more meaningful to provide consumers with nutrition information on these products in terms of the entire product. A consumer would have nutrition information on exactly what he or she purchases and typically consumes. Therefore, the consumer would be able to evaluate how the product fits into his or her total diet. FSIS plans to propose nutrition labeling for meal-type products, based on the contents of the entire package. Comments supported nutrition information on products in discrete individual units (e.g., hot dogs). They contend that these products should be labeled per unit because that is how these foods are customarily eaten and the measure consumers most prefer for nutrition information on these products. Other products that belong in this category include sliced or individually shaped mini pizzas and individually wrapped or packaged products in multi-serving containers such as individually wrapped sausage, egg and biscuit breakfast buns packaged eight to a box.

A number of comments on bite-sized products suggested that the serving size should be the number that would make a "logical serving" or a "customarily consumed amount." One comment suggested a dual nutrition label format that would show both the amount customarily consumed as well as pieces or units. FSIS does not believe that dual listing would be useful to consumers. Rather, it believes that presenting the number of bite-size or very small pieces that make up a customarily consumed amount, as discussed further in this document, appears to be more useful to consumers for making product comparison.

FSIS believes that the common household unit most meaningful for products in discrete units would be the unit itself (e.g., piece). However, these products come in many different sizes. For example, the size of hot dogs ranges from .5 ounce cocktail franks to 4 ounce dinner franks. If nutrition information for these products is expressed on a single unit basis, there would be no uniformity in serving sizes declared on these products and consumers would have to compare, for example, the nutritional value of a .5 ounce cocktail frank with a 4 ounce dinner frank.

To assure uniformity in the serving size used for different sizes of similar products, FSIS is proposing that serving sizes for products in discrete units be the number of units most closely approximating the Reference Amount for the Product Category, which was established by the Interagency Committee. Provisions for converting Reference Amounts to serving sizes are set forth in FDA's proposed 21 CFR 101.9(b)(2) (see docket 90N-0165 published elsewhere in this issue of the **Federal Register**).

4. *Nutrition Information Based on Serving Size "as packaged" or "as consumed."* FSIS's tentative position in the ANPR was to require nutrition labeling on products "as consumed." The Agency recognized that preparation and cooking methods can significantly alter the nutrient composition of a food and that it might be necessary to provide nutrition information on foods as cooked using recommended methods without the use of salt, flour, cooking oil, or other such added ingredients.

Many comments addressed the issue of presenting nutrition information "as consumed" or "as packaged." There were slightly more comments favoring nutrition information being presented on products "as packaged."

Comments that advocated providing nutrition information on the "as consumed" basis stated that meat and poultry products are rarely eaten raw. Nutritional information based on the raw product, therefore, would be of little advantage to consumers. Some commenters felt the nutritional information should be educational and relevant to the diet as consumed, therefore supporting that "as consumed" labeling information would be most useful to consumers.

Those urging FSIS to require nutrition labeling on foods "as packaged" rather than "as consumed" thought the accounting for nutrient content changes which occur during the cooking process would be impossible. Factors such as time, temperature, humidity, altitude, microwave wattages, and cooking surfaces influence nutrient content changes during cooking. Some commenters stated that the chemical analysis requirements for these products would require substantial investment as well.

FSIS, consistent with FDA's mandatory and voluntary nutrition labeling scheme, is proposing to require nutrient values "as packaged" for products, except that products under the voluntary program may list nutrient values on an "as consumed" basis rather than an "as purchased" basis. Products covered by the mandatory program, required to list the "as purchased" nutrient values, have the option of also presenting "as consumed" values. The preparation method upon which the "as consumed" values are determined must be clearly indicated on the package.

5. *Units of Measure for Declaring the Serving Size.* In the ANPR, FSIS discussed the importance of establishing a standard unit of measure that would be readily understandable by consumers. FSIS's tentative position was that the use of weight as expressed in ounce(s) for meat and poultry products would be useful to consumers. In fact, the common household unit of measure for most meat and poultry products is ounces. FSIS believes that the use of the ounce as the unit measure on the nutrition label will be meaningful to consumers. However, in the interest of promoting free trade and international harmonization of nutrition labeling, FSIS's tentative position was that the use of grams should be optional.

The majority of the commenters agreed with the Agency's tentative position that the use of the ounce as the unit measure in nutrition labeling will be meaningful to consumers and that grams should be optional. However, there were a significant number of comments pointing out the importance of promoting free trade and international harmonization of nutrition labeling. Several comments cited the Omnibus Trade and Competitiveness Act of 1988 which requires use of the metric system in doing business after 1992.

To provide a uniform labeling system, FSIS is proposing to require the use of common household and metric measures

to declare serving sizes. In addition, FSIS will adopt FDA definitions and rules for declaring household measures. FDA is proposing that, whenever possible, cups, tablespoons or teaspoons should be used. Cups should be expressed in ¼ cup increments, tablespoons in whole number of tablespoons for quantities less than ¼ cup but greater than or equal to 1 tablespoon, teaspoons in whole number of teaspoons for quantities less than 1 tablespoon but greater than or equal to 1 teaspoon, and in ¼ teaspoon increments for quantities less than one teaspoon.

If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction of the whole piece or package should be used.

If neither of the above is applicable, ounces may be used. Ounce measurements should be expressed in 0.5 ounce increments most closely approximating the Reference Amount.

FSIS is also proposing to allow an additional column of figures to be declared on the nutrition label based on 100 grams or 100 milliliters of the food as packaged or purchased. For products that are in units or pieces, the label may optionally declare the number of units or pieces in the serving size.

6. *Definition of Serving Size and Single-Serving Container.* FSIS is proposing to define a serving or serving size in the same manner as FDA (docket 90N-0165, section IV). A serving or serving size will mean an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the food. When the article is represented to be for infants or for toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants through 12 months of age or by children 1 through 3 years of age. The term "portion" means an amount of food that is not typically expressed in a serving size, i.e., a food customarily used only as an ingredient in the preparation of other foods.

FSIS is proposing to define a single-serving container as a container or package containing less than 200 percent of the Reference Amount. The nutrition profile on the single-serving container will be declared on the total content of the container.

7. *Declaration of Number of Servings Per Container.* FSIS, like FDA, is proposing that the number of servings per package or container be declared to the nearest whole or approximate whole number. Manufacturers would be allowed to either declare the approximate serving size in household measure that results in a whole number of servings per package (e.g., serving size: approximately 3 oz.; number of servings per container: 10) or to declare the exact serving size in household measures and the approximate number of servings per container (e.g., serving size: 3 oz.; number of servings per container; approximately 10) (see FDA's docket 90N-0165, proposed 21 CFR 101.9 (b)(8)(i) and (ii)).

Regulations for the number of servings per package must be flexible enough to accommodate products in random weight packages. For random weight products such as kielbasa, manufacturers would have problems in declaring the number of servings per package. As a means of addressing this problem, FSIS is proposing to accommodate random weight packages by allowing manufacturers to declare the number of servings per container as "varied" provided the nutrition information is based on the Reference Amount expressed in ounces. The Agency is soliciting comments on whether this exception is a reasonable provision for this type of package.

8. *Use of Serving Size to Evaluate Nutrition Claims.* This issue is discussed in detail in Part VI, Descriptors.

VI. Descriptors

A. Background

The Standards and Labeling Division of FSIS has issued several policy memoranda, in connection with its label approval system, outlining quantitative criteria for permitting the use of selected descriptors such as "low calorie", "low sodium", "low fat", and "lean".[7] For many years, the Agency's definition for "lean", except as applied to ground beef, hamburger, and products containing added substances, such as water or extenders, has been no more than 10 percent fat content. The memoranda currently require at least a 25 percent reduction from specific reference points for comparative expressions such as "lower." FSIS also uses informal working policies for descriptors for some food constituents, such as cholesterol in meals and fiber. FSIS has no regulatory definitions for any descriptive terms.

To alleviate widespread public confusion associated with descriptors, the NLEA contains requirements regarding nutrient content claims. It precludes, except for specified limited exceptions, the use of any nutrient content term that characterizes the level of any nutrient that has not been defined by FDA by regulation, and requires FDA to define "free", "low", "light" or "lite", "reduced", "less", and "high". The NLEA places limitations on cholesterol, saturated fat, and dietary fiber claims for a food by requiring these claims to be accompanied by prominent disclosure of the food's level of fat or saturated fat, cholesterol, and total fat, respectively, on the label. The NLEA does not address the use of cholesterol claims based on threshold criteria for fat or saturated fat content.

Currently, FDA has regulatory definitions for descriptors about calories and sodium (21 CFR 101.13 and 105.66, respectively). On July 19, 1990, FDA published a tentative final rule, "Food Labeling; Definitions of the Terms Cholesterol Free, Low Cholesterol, and Reduced Cholesterol," to amend its food labeling regulations in order to define and provide for the proper use of these cholesterol descriptors (55 FR 29456). In the document, FDA tentatively proposed threshold levels for fat that establish conditions for the use of cholesterol content claims. FDA has developed informal policy for trial shelf-labeling programs covering descriptors for fat, fiber, calcium, and for defining "* * * source of," such as "good source of."

"The Surgeon General's Report of Nutrition and Health," issued in 1988, states that descriptive terms such as "low calorie," in compliance with FDA's regulations, may be helpful in informing people about the nutrient content of foods and encouraging their expanded use.[8]

B. Discussion of Comments and Proposal

In the ANPR, FSIS stated that uniform descriptors, when coupled with nutrition education efforts, could facilitate dietary improvement. FSIS anticipated adopting FDA developed descriptors. In addition, the ANPR proceeded to state that the definitions established by FDA were likely to be so restrictive that many meat and poultry products would be unable to use these descriptors. Therefore, FSIS suggested establishing some unique terms such as "lower" and "extra lean" that would be used only for meat and poultry products and to consider the use of other descriptors on a case-by-case basis under the prior label approval system.

There was overwhelming support for FSIS to adopt the same terminology and

[7] Copies of these policy memoranda are available for public review in the FSIS Hearing Clerk's office. Copies may be obtained, without charge, from the FSIS Hearing Clerk.

[8] The referenced portion of this report is available for public review in the FSIS Hearing Clerk's Office. Copies are available, without charge, from the FSIS Hearing Clerk.

definitions as FDA for descriptors for meat and poultry products. The majority of commenters believed that inconsistencies in nutrient content claims between meat and poultry products and all other foods would contribute to consumer confusion, and could create barriers to informed dietary choices.

Many manufacturers contended that it was important for product lines containing both FDA and USDA regulated products to be labeled in a similar or identical manner with descriptive terms that meet the same criteria. They further stated that differing descriptor definitions between the two agencies would not only confound their efforts in labeling conformity, but cause unnecessary confusion for the consumer and hinder any consumer education efforts.

FSIS agrees that inconsistent use of the same descriptive terms on USDA and FDA regulated products could lead to consumer confusion and nonuniformity in the marketplace. FSIS also acknowledges that different definitions would defeat the purpose of providing an effective nutrition education tool.

Based upon the review of the comments, FSIS is proposing the adoption of most of FDA's proposals, published elsewhere in this issue of the **Federal Register**, for 21 CFR 101.13, Nutrient Content Claims—General Principles; 21 CFR 101.54, Nutrient Content Claims for "Source" and "High"; 21 CFR 101.56, Nutrient Content Claims for "Light" or "Lite"; 21 CFR 101.60, Nutrient Content Claims for the Calorie Content; 21 CFR 101.61, Nutrient Content Claims for the Sodium Content of Foods; 21 CFR 101.62, Nutrient Content Claims for the Fat, Fatty Acids, and Cholesterol Content of Foods; and 21 CFR 101.69, Petitions for Nutrient Content Claims. In these documents, FDA has set forth proposals required by legislation in the NLEA.

FSIS has reviewed the rationale used by FDA for establishing the criteria for the regulations mentioned above and agrees with its approach, as discussed in the preamble to the nutrient content claims general principals, petitions, definition of terms proposal (91N-0384) and the definitions of nutrient content claims for the fat, fatty acids and cholesterol content of food proposal (84N-0153).

Since many products regulated by FSIS contain descriptive terms in the brand name ("brand name" is a generic term FSIS will use to define a fanciful name, trademark, etc.), FSIS believes a brief discussion to call attention to the use of descriptors in brand names is warranted. If a brand name includes a descriptive term which has been defined by FSIS, the product must meet the definition set for that term, and will have to bear an appropriate referral statement. The referral statement instructs the consumer to see the appropriate panel for more nutrition information; e.g., "See back panel for nutrition information."

Nutrient content claims not defined by regulation that appear as part of the brand name may be used on the label or in labeling if they are not false or misleading and only if the brand name was in use prior to November 27, 1991. The Agency specifically solicits comments on how best to determine when a term incorporated into a brand name should be regulated as a nutrient content claim.

FSIS is providing a petition process, consistent with FDA's, to permit certain types of claims, without requiring approval by regulation. Such claims would include terms that are consistent with a defined term (synonym) or implied claims made as part of the brand name. The approved synonyms would appear in a list and would be updated in the annual issuance of the CFR.

FDA is also proposing a separate document on health claims. In that document FDA states that it believes that the term "healthy" would be an inappropriate implied health claim for an individual food commodity. FDA is considering the possibility that the term "healthy" may be useful to the consumer in selecting meals that are helpful in achieving a total diet that conforms to the dietary guidelines. FDA is requesting comments and specific information on circumstances under which the term "healthy" on the label of a meal-type product would assist consumers in maintaining healthy dietary practices. If comments persuade FDA that the term "healthy" is an appropriate nutrient content claim for meal-type products, and provide criteria for the use of the term, they may provide for the term in a final regulation.

Likewise, FSIS is soliciting comments on the appropriateness and usefulness of the term "healthy" on the label of a meal-type product, and requests specific information on the criteria for the use of the term.

FSIS has compiled the following list of brand names from labels on file with the Standards and Labeling Division that include descriptive terms. Although the list is not all inclusive, the Agency believes it is useful to provide specific examples of some of the products that may be affected:

Brand Names, Trade Names and Product Lines Including Nutrient Content Claims

Lean, Light, Natural, Less, Reduced, High

Lean Cuisine
Dining Lite
Light Balance

Sizzlean
Lean and Light
Lean & Low
Lean Pockets
Naturalean
Lite & Low
Natural Lite
Lean & Free
Lite & Free
UltraLean
Diet Lite
D'Lite
deLight
AgriLite

Health

Light & Healthy
Hearty & Healthy
Healthy Choice
LeMenu Healthy
Healthy Request Soups
Weight Watchers—Health Watchers
Health Selection
HealthCheck
Chef's Healthy Entrees
Lite & Healthier
Healthy Deli
Health Valley
Health is Wealthy
Featherweight Healthy Recipes
Health Menu
Fast & Healthy
Health Watchers
Health Plus
Lean & Healthy

Others

Eating Right
Right Course
Smart Meat
Better For You
Slim Selects
Lil' Salt Brand
Tasty Slim Brand Beef
NutraMeal
Nutra System
Right For You
Omega—3 Pork Products
Pinch O'Salt
Diet Center

FDA is also proposing to address terms used for purposes other than making nutrient content claims, namely "fresh", "natural", and "organic." FSIS will accept any comments offered for the use and criteria for these terms; however, the Agency is concentrating its efforts on terms that characterize the level of a nutrient.

In the proposed 21 CFR 101.62, FDA defines terms that describe the fat, fatty acid, and cholesterol content of food, provides for the proper use of these terms, and provides for the use of comparative claims. FDA is proposing to require that fat, fatty acid, and

cholesterol content claims comply with the provisions of 21 CFR 101.13 as well as the provisions of 21 CFR 101.62. FSIS has examined the scientific background, the provisions of FDA's proposed regulation, the use of defined terms and comparative statements, and the conditions of use of defined terms as outlined in the document and supports its approach and justification (see docket 84N-0153 published elsewhere in this issue of the **Federal Register**).

FSIS realizes that by adopting FDA's proposed regulations, a few defined terms, such as "Cholesterol Free" and "Fat Free", may not be applicable at the present time to meat and poultry products. However, the Agency believes the best approach is to adopt FDA's proposed regulations in their entirety to minimize confusion and to provide for possible technological advances in the future.

Numerous comments from consumers, health professional trade organizations, trade associations, and the food industry urged FSIS to develop unique descriptors for meat and poultry products since they play a special role in the diet. There was overall support for the development of descriptors unique to meat and poultry products to help consumers differentiate products with lower levels of fat and cholesterol.

A few comments specifically addressed the adoption of the FDA "low fat" definition as excluding many FSIS regulated products and not allowing consumers to distinguish between products of varying fat content. Many comments supported the use of the terms "lean" and "extra lean" as unique descriptors since they are already in use, are readily identified as characterizing meat and poultry products, and are distinctly different from the terms defined by FDA.

There was opposition to establishing a definition for the term "lower" as a possible unique descriptor for meat and poultry products, as was suggested in the ANPR. Comments indicated that the descriptor "lower" is too close to the descriptor "low" and could be confusing.

The American Heart Association (AHA) submitted a letter to FSIS in response to the ANPR in which they propose fat, saturated fatty acids, and cholesterol thresholds for the term "lean" and "extra lean":

The term "lean" should be used to describe fresh and processed cooked meat and poultry (cut or ground) that meets the following thresholds (representing approximately 7% fat in raw and 10% fat in cooked meat by weight):

	Fat	Saturated fatty acids	Cholesterol
1 oz. cooked	<3 g	<1 g	<27 mg
3 oz. cooked	<8 g	<3 g	<80 mg

* * * the term "extra lean" should be used to describe fresh and processed cooked meat (cut or ground) that meet the following thresholds (representing approximately 5% fat by weight):

	Fat	Saturated fatty acids	Cholesterol
1 oz. cooked	<1.4 g	<0.5 g	<27 mg
3 oz. cooked	<4.3 g	<1.4 g	<80 mg

FSIS has considered these suggested values and has determined that the values have merit. As a criteria for establishing nutrient content claims, FDA based their calculations on the proposed Dietary Reference Values (DRV's) for that nutrient, average food consumption servings per day (16–20), and dietary guidance recommendations.

For meat and poultry products, Dietary Guidelines published by the Department of Agriculture and dietary recommendations published by the National Cholesterol Education Program suggest 6 ounces of these products per day, or two 3-ounce servings.

For purposes of nutrition labeling, the value of 75 g has been proposed as the DRV for fat, as discussed in the FDA's proposed supplemental rule 90N-0134 and 90N-0135. This value was derived from current dietary guidelines that recommend a person consume a maximum of 30 percent of calories from fat, which in a diet of 2,350 calories per day would allow for consumption of a maximum of 75 g of fat per day.

The proposed fat criteria for "lean" is <8 g per 3 ounces of cooked product. Two meat and poultry servings of the average 16–20 servings of food per day would account for <16 g of fat, or less than one-fourth of the DRV for fat. The remaining 14–18 servings of food, to meet the recommendation of no more than 75 g DRV for fat, could contain at least 59 g of fat.

The proposed fat criteria for "extra lean" is <4.3 g per 3 ounces of cooked product. Two meat and poultry servings of the average 16–20 servings of food per day would account for <8.6 g of fat, or less than one-seventh of the DRV for fat. The remaining 14–18 servings of food, to meet the recommendation of no more than 75 g DRV for fat, could contain at least 66.4 g of fat.

For purposes of nutrition labeling, the value of 25 g has been proposed as the DRV for saturated fat, as discussed in the FDA's proposed supplemental rule 90N-0134 and 90N-0135. This value was derived from current dietary guidelines that recommend a person consume less than 10 percent of calories from saturated fat, which in a diet of 2,350 calories per day would allow for consumption of about 25 g of saturated fat per day.

The proposed saturated fat criteria for "lean" is <3 g per 3 ounces of cooked product. Two meat and poultry servings of the average 16–20 servings of food per day would account for <6 g of saturated fat, or less than one-fourth of the DRV for saturated fat. The remaining 14–18 servings of food, to meet the recommendation of no more than 25 g DRV for saturated fat, could contain 19 g of saturated fat.

The proposed saturated fat criteria for "extra lean" is <1.4 g per 3 ounces of cooked product. Two meat and poultry servings of the average 16–20 servings of food per day would account for <2.8 g of saturated fat, or less than one-seventh of the DRV for saturated fat. The remaining 14–18 servings of food, to meet the recommendation of no more than 25 g DRV for saturated fat, could contain 22.2 g of saturated fat.

The value of 300 mg has been proposed as the DRV for cholesterol, as discussed in the FDA's proposed supplemental rule. This value was derived from recommendations from a wide variety of public health groups and organizations.

The proposed cholesterol criteria for "lean" and "extra lean" is <80 mg per 3 ounces of cooked product. Since cholesterol is only found in foods of animal origin, FSIS believes that the same value for both terms, with differing criteria for the fat and saturated fat, is required. Two meat and poultry servings of the average 16–20 servings of food per day would account for <160 mg of cholesterol slightly more than one-half of the DRV for cholesterol. The remaining 14–18 servings of food, to meet the recommendation of no more than 300 mg DRV for cholesterol, could contain 140 mg of cholesterol.

Fat, saturated fat, and cholesterol are not ubiquitous in the food supply. As mentioned previously, cholesterol is only found in foods of animal origin, and very little fat and saturated fat is found in most fruits, vegetables, and grains. Meat and poultry provide more of the fat, saturated fat, and cholesterol in the adult American diet than any other food group.

Therefore, FSIS finds merit in these suggested values, and believes these numbers recognize the practice of

dietary planning in which a person consumes servings of a variety of foods that contain different levels of fat, saturated fat, and cholesterol, and allow for a diet that will meet the dietary guidelines. FSIS believes, however, that the quantitative values should be proposed per 100 grams of product. Extrapolating the 1 ounce values which AHA suggested to 100 grams would yield the following values:

	Fat	Saturated fatty acids	Cholesterol
Lean	<10.5 g	<3.5 g	<94.5 mg
Extra Lean	<4.9 g	<1.8 g	<94.5 mg

The values for the fat content of 10.5 and 4.9 grams approximate the Agency's current definitions for the terms "lean" and "extra lean". Therefore, FSIS is proposing the above-listed values as the definitions for the terms "lean" and "extra lean" per 100 grams of product. FSIS is soliciting comments specifically on the appropriateness of these values and criteria for the definitions of the terms "lean" and "extra lean".

The Agency believes that, since FDA's proposed definitions for the descriptive terms "low fat" and "low cholesterol" are so restrictive, the unique descriptors should be applied to all meat and poultry products. Accordingly, the terms "lean" and "extra lean" could be used as descriptive terms on multi-ingredient meal-type products as well as muscle cuts of meat. Ground beef and hamburger would also be subject to the proposed definitions for the terms "lean" and "extra lean". Currently, FSIS extends special exception to ground beef and hamburger for the purposes of "lean" and "extra lean" labeling. "Lean" and "extra lean" ground beef and hamburger can contain up to 22.5 percent fat, a 25 percent reduction from the regulatory standard of 30 percent fat for these products. The Agency believes, however, that there is a need for definitions to be standardized and that these terms should be applied equally across all meat and poultry foods, with no exceptions granted.

Many comments recommended that FSIS not approve other descriptors on a case-by-case basis under the prior label approval process but establish definitions through a petition and rulemaking process that would provide full opportunity for public comment and would place the definitions in regulations. FSIS finds merit in these comments and is proposing a petition process to issue regulatory definitions for descriptors, approve the use of synonyms, and approve the use of implied nutrition content claims in fanciful names, brand names, and trademarks.

Descriptors relating to nutrition, other than those identified in this proposal, would require approval through the Agency's petition process as set forth in this proposal. The rulemaking process would furnish the Agency with the opportunity to carefully evaluate each petition, and allow a sufficient time for assessment and comment periods.

Several comments addressed the issue of "_____ percent fat free" claims. Comments were varied on this issue. A few comments suggested that the labeling of percentage of fat by weight is very deceptive and is of no use or value to the consumer in evaluating a product. A few comments suggested that "_____ percent fat free" labeling is a useful tool to consumers in appraising the fat content at a glance.

The Agency believes that "_____ percent fat free" claims can be useful and appropriate if used in the proper manner. The "_____ percent fat free" claims are generally used to indicate a relatively small amount of fat in a product. The impression that a product contains a small amount of fat is not necessarily reflected by a percent fat by weight statement. In FDA's proposed definitions of nutrient content claims for the fat, fatty acid, and cholesterol content of food (proposed 21 CFR 101.62), the issue of "_____ percent fat free" claims is discussed. FDA is proposing to prohibit the claim in those circumstances in which it would be misleading. To ensure that the consumer is not deceived, FDA is proposing that "_____ percent fat free" claims meet several criteria, discussed in FDA's docket 84N-0153, Section III, B(1), Amount and Percentage of Nutrient Claims. The FDA criteria is that the product has to meet the definition for "low fat" and the label or labeling discloses the amount of total fat per serving of the product. FSIS has reviewed the discussion and basis for the criteria and fully agrees with FDA's rationale, and is therefore proposing to adopt FDA's definition for "_____ percent fat free" claims.

VII. Compliance and Analytical Methods

A. Background

As part of its prior label approval process, FSIS requires manufacturers to submit analytical data to support nutrient values and content claims on food labels. The Agency processed approximately 180,000 requests for label approvals in 1990, of which 35 to 50 percent contained nutrition information. FSIS conducts a nutrition labeling verification program to ensure the continued accuracy of label information after initial approval. Under the program, manufacturers periodically submit analytical data on their products for Agency review. FSIS nutrition labeling guidelines for meat and poultry products, which address requirements for initial label approval and continuing accuracy of labels, are contained in Policy Memoranda 85B and 86.

FDA does not conduct prior label approval but places the responsibility for truthful labeling on industry. It set forth procedures for determining labeling compliance in its mandatory labeling proposal of July 19, 1990 (55 FR 29487). These procedures do not encompass determinations of substantial compliance with the voluntary labeling program for fresh produce and raw fish as described in FDA's proposed rule on nutrition labeling of raw fruit, vegetables, and fish (56 FR 30468). However, FDA proposed to exempt raw fruit, vegetables, and fish from its compliance procedures as described in the FDA booklet, "Compliance Procedures for Nutrition Labeling," [9] when the nutrition information is in accordance with an FDA-accepted data base, the nutrient values have been computed following FDA guidelines, and the food has been handled in accordance with current good manufacturing practices to prevent nutrient loss. Label nutrient values based on the FDA procedures give 95 percent assurance that for each nutrient contained in the labeled packages of a production lot from which samples were taken, nutrient values are at least equal to, and no less than, 80 percent of the label nutrient value for protein, vitamins, and most minerals and at least equal to, and no more than, 120 percent of the label nutrient value for calories, cholesterol, fat, and sodium. FDA has accepted a number of data bases for use in nutrition labeling of raw fruit and vegetables.

NAS generally addressed compliance issues in terms of the adequacy of analytical methods for nutrient analyses. It recognized that current methods of food analysis do not permit precise measurement of nutrient values for many food components and that the limitations of certain methods hinder the analytical process due to the volume of analyses that would be required under a mandatory nutrition labeling scheme. NAS recommended flexibility in selection of analytical methods for label

[9] This booklet, is available for public review in the FSIS Hearing Clerk's office.

verification and stated that "[a]lthough there are clear merits of the USDA system of label verification in terms of ensuring accuracy, management of the FDA system seems much less costly." It favored FDA and USDA certification of data bases containing representative values for use in labeling fresh food products. The NAS argued that, if compliance procedures applied to the labeling of fresh foods required adherence to 20 percent tolerances as are currently applied to the labeling of packaged foods, the labeling, in order to be in regulatory compliance, might grossly distort the average composition of the products.

In the ANPR, FSIS stated that it concurred with FDA's approach to labeling of fresh fruits and vegetables when such labeling is performed under voluntary guidelines, and that it supported the NAS recommendations on use of representative data base values for labeling of fresh products. The Agency also stated its belief that manufacturers of processed products, when such products are subject to mandatory nutrition labeling requirements, should certify that information submitted on requests for nutrition label approval complies with FSIS requirements. FSIS indicated that it assigns each manufacturer the responsibility for assuring the validity of a product's stated nutrient content by stating that "compliance with nutrition labeling requirements rightfully should be ensured by each establishment" through its quality control system, taking into account nutrient variability and adequacy of testing methods. FSIS specifically sought comments on reasonable tolerance levels which can reduce costs and frequency of testing.

B. Discussion of Comments and Proposal

The majority of the comments received in response to the ANPR regarding compliance and analytical method issues addressed the following areas: (1) The label approval requirements and nutrition labeling verification program, (2) use of data bases in labeling, and (3) the tolerance level compliance parameters.

1. *Label Approval and Nutrition Labeling Verification.* Most commenters expressed the opinion that FSIS should adopt a compliance program similar to that of FDA. There was almost no support for either the submission at the time of initial label approval of a specified number of analytical results that establish the initial nutrient data base for a product or for the nutrition labeling verification program. The most frequently cited reasons for these positions were the high cost of testing and the burden the requirements imposed.

FSIS maintains that the manufacturer is responsible for insuring the validity of nutrient content expressed on the food label in conformance with the requirements set forth in these regulations. The Agency believes that its approach to inspection, which calls for an inspector in every federally inspected establishment and prior approval of labels before use, allows FSIS employees the opportunity to observe plant controls over product formulation and processing and to review the nutrition panel and claims while having a product's quantitative ingredient listing on hand. Therefore, the Agency concludes that the requirements for submission of laboratory data with requests for initial label approvals, the submission of periodic data to support the continuing accuracy of food labels, and maintenance of FSIS-approved nutrition labeling verification procedures are unnecessary. Instead, FSIS will require manufacturers to maintain records to support the nutritional values on the nutrition panel of food labels and to make this information available for review by Agency personnel upon request. The frequency of testing for nutrient content to support nutritional values may vary with the identity of the nutrients to be tested, sample size and number of samples, nature of the product, and the like.

The Agency is especially concerned about the accuracy of nutrient content claims, such as "low sodium" and "low fat", and percentage labeling on food labels. These claims are very visible types of information that are often used for marketing purposes, may readily affect consumers' purchasing decisions, and carry potential for public harm should they be false. Consequently, the Agency concludes that, when labeling material containing nutrient content claims is submitted for approval, FSIS would require that a plant operated partial quality control (PQC) program (9 CFR 318.4 (d) and (e) and 381.145 (d) and (e)) be established for the nutrients which are the subject of such claims, as well as any other nutrients conditioning the use of such claims, as a necessary source of information in determining label compliance. The PQC program will provide the controls and information necessary to give a high degree of assurance that the products will meet the labeling claims and that the variability of the products will remain within the limits defined in these regulations. Monitoring of these inplant PQC programs by inspection personnel will serve as a tool to help to ensure labeling compliance.

2. *Use of Data Bases.* Respondents to the ANPR voiced almost unanimous support for use of representative data base values for labeling of fresh meat and poultry products. Many expressed the opinion that use of data base values, either FSIS-approved or private, be extended to processed products as well as to reduce analytical costs. FSIS considers use of data base values for single-ingredient, raw products (fresh) and their use for all other products as two distinct issues.

a. Single Ingredient Products. NAS recommended that USDA promulgate regulations that mandate nutrition labeling for the 20 to 30 top items of fresh/frozen meat and poultry products and suggested that values be provided using point-of-purchase information developed from data base values. It recognized that USDA's National Nutrient Data Bank (NNDB), whose published form is the AH–8 series, is the authoritative source of data on the nutrient composition of foods in the United States. NAS stated that USDA food composition data are relatively complete for a variety of cuts and grades of beef, and fairly complete for poultry products, pork products, lamb, and veal. Some of these data on beef, fresh pork, and lamb were used in developing Meat Nutri-Facts. FSIS is aware that information on beef and lamb products has been updated in the AH–8 series since Meat Nutri-Facts was published; that pork products are currently being updated using results from a nationwide survey on retail cuts of pork; and that information on poultry products is being updated to include new data developed for use with Poultry Nutri-Facts and other research. Many of the studies conducted to generate these food composition values were large in scope and involved the collaborative efforts of USDA, industry, and academia. The Agency accepts the results of the research efforts as adequately characterizing the nutrient profiles of retail cuts of beef (including ground beef), fresh pork, lamb, veal, chicken, and turkey. FSIS concludes that the representative values for these foods as contained in the NNDB or its published form, the AH–8 series, are appropriate for generic labeling of single-ingredient, raw meat and poultry products under the voluntary guidelines set forth in these regulations.

FSIS believes that use of nationally representative, year-round nutritional values for single-ingredient, raw meat and poultry products will be of most use

in assisting consumers in maintaining healthy dietary practices. Use of representative mean values averages out the nutrient variability of these products and more accurately represents their nutrient content over time. Composite labeling takes into consideration the factors responsible for nutrient variation, examples of which include quality grades for beef and classes for turkey. The Agency's position on the labeling of single-ingredient, raw meat and poultry products is supported by NAS which recommended flexibility in the nutrition information required for labeling fresh foods. NAS stated that "[r]egulatory compliance could be accomplished through less stringent regulations that permit the use of representative data (e.g., the mean or the mean ± one standard deviation) instead of the tolerances currently applied to nutrition labeling of packaged food."

As discussed under the Guidelines for Voluntary Nutrition Labeling elsewhere in this preamble, representative data base values may be used for generic labeling of single-ingredient, raw meat and poultry products either on the label of the product or through use of point-of-purchase materials. FSIS considers appropriate generic labeling values to be those from the NNDB or AH-8 for the six species discussed above. A list of 45 cuts which the Agency considers as the most popular cuts that fairly represent different anatomical locations of poultry and primal cuts of meat is included under the Guidelines. Data for additional cuts of the six species also may be used in labeling. Considering industry's past efforts in developing and providing nutritional information on cooked meat and poultry products through the Nutri-Facts programs, FSIS believes it is appropriate that nutritional information be presented on either a cooked basis or a raw basis for single-ingredient, raw products under the voluntary program. If information is presented on a cooked basis, the cooking methods should be recommended methods commonly used for the product by consumers and should not add fat, flour, salt, or other ingredients which could alter nutritional profiles.

FSIS believes that use of composite data is appropriate because their use reduces the burden for retailers and provides uniform and consistent data for consumers. FDA presents a detailed discussion, with which FSIS concurs, of the advantages and disadvantages of the use of composite nutrient values in its proposal on nutritional labeling of raw fruits, vegetables, and fish (56 FR 30475). FSIS believes that when representative data base values are used on a label applied to a product which is also labeled as a component food of a composite value as shown in AH-8, the representative values for the component food should be used instead of composite values. Thus, if a nutrition label is applied to a cut of beef labeled Choice grade, representative values from AH-8 for the appropriate Choice grade cut as opposed to values for the same cut designated as "all-grades" should be used. Values for "all-grades" are composite values derived by weighting representative values for Select, Choice, and Prime grades for each grade's market share. FSIS invites comments on the aptness of this approach.

The Agency received several comments to the ANPR regarding the use of data for separable lean of red meat and skinless poultry meat, which was the approach used in the Nutri-Facts programs. The Agency has no evidence to support the appropriateness of using values for separable lean tissue instead of total edible tissue for red meat or values for skinless poultry meat instead of poultry meat with skin. Therefore, FSIS concludes that appropriate nutritional values for single-ingredient, raw meat and poultry products are those for meat cuts with external cover fat at trim levels reflecting current market practices and for poultry cuts with skin. The additional, optional listing of nutrients for the separable lean cuts of meat and skinless poultry also would be appropriate because it gives consumers comparative information for use in deciding to trim fat from meat and take skin off poultry before eating, as is recommended in the Dietary Guidelines for Americans. If nutrition labels bearing representative data base values are applied to packages of cuts of meat or poultry, FSIS believes the values selected must be those that represent the meat or poultry tissues in the package, i.e., values for a skinless cut of poultry must only be used on labels of packages containing poultry cuts from which the skin has been removed.

When representative data base values from the NNDB or AH-8 are used on the labeling or labels of single-ingredient, raw products, FSIS is proposing that such products will not be subject to Agency compliance review as established for the mandatory program. If a nutrient content claim is made on the basis of representative data base values, products must meet the criteria for such claims as set forth in FSIS regulations and be produced under a PQC program. These products will be sampled to measure compliance with the regulations and such claims will not be allowed on the labels of products which fail to meet the criteria. If industry practices change or FSIS monitoring suggests that the representative nutrient values have changed, the Agency will object to the use of claims based on these values and will work with USDA's Human Nutrition Information Service and affected parties to update the representative data base values used for generic labeling of fresh products. FSIS does not discourage the use of private data base values for single-ingredient, raw meat and poultry products. These are especially relevant when producers want to point out unique nutritional characteristics of their products. However, products so labeled would be subject to all of the requirements of the mandatory labeling program as set forth in these regulations and Agency compliance procedures, except that data may be presented on either a raw or cooked basis. FSIS believes this exception is necessary to provide flexibility and to reduce the economic impact on the affected industry.

b. All Other Products. As indicated before, a number of commenters expressed the opinion that use of data base values be extended to processed products to reduce testing costs. The issue is whether FSIS should continue to require that food labels reflect the nutrient composition of the specific products as determined by analysis of individual lots of products or whether use of representative data base values could be substituted for actual analyses. Likewise, an issue is whether nutrition profiles should be developed for multicomponent products using calculations or recipe programs based on data base values as a substitute for actual analyses.

The Agency is not convinced that blanket approval of the use of data base values for processed products with elimination of compliance requirements and review is warranted. The use of data base values and calculations is likely useful in predicting nutrient profiles, especially when products are reformulated, but such use as the sole basis for nutrition profiles of individual food items may present a risk to manufacturers. Generally, data base values reflect a diverse food supply and, in many instances, can only approximate the nutrient content of specific product samples. Their use, however, might result in decreased testing costs because a smaller number of analyses might serve to assure

applicability of data base values to specific products or to corroborate the accuracy of calculated values than would need to be performed to establish an initial data base in the absence of such information.

3. Compliance Parameters. The adequacy of the 80/120 tolerance levels for naturally occurring nutrients was supported by most commenters who addressed this issue. The overall theme of the responses was that FSIS compliance requirements should track those of FDA. The Agency proposes to retain the 80/120 tolerance levels, which it currently uses, for naturally occurring nutrients and to define these as Class II nutrients in determining compliance with the regulations. FSIS has little experience with nutrients added in fortified or fabricated foods unless specific regulations permit their addition, as in the case of adding vitamin A to margarine (9 CFR 319.700). FDA defines such added nutrients for purposes of compliance as Class I nutrients under 21 CFR 101.9(e)(3). FSIS proposes to define added nutrients as Class I nutrients and establish tolerance levels for purposes of compliance which are identical to those of FDA.

FSIS leaves it to the company to determine label declarations. FSIS will take random samples for checking compliance, and the composite values must fall within 80/120 percent of the stated nutrient value in each case.

FSIS current nutrition labeling guidelines state that ideally analyses should be performed on a composite of 12 units, one from each of 12 consecutive production lots. FDA currently determines compliance on 12 units taken one from each of 12 randomly chosen shipping cases, to be representative of a lot. In describing how it will determine compliance with its nutrition labeling requirements, FSIS is proposing that analyses be conducted on a composite consisting of a minimum of six units selected within or across lots. FSIS will monitor a minimum of six units for compliance. In most cases, the number of samples taken will be 12, whenever it is feasible and not too costly. However, for various products, such as large samples of ham, FSIS believes a composite of six units will contribute to cost and logistical efficiency. The Agency believes that within lot sampling within an establishment and across lot sampling outside an establishment are both valuable options. FSIS personnel will not be limited to collection of samples during production of products at an establishment. They will have the added flexibility to draw samples at the wholesale and retail levels.

The USDA methodology and procedures used to determine compliance with the regulations are those approved by the Administrator in accordance with the "Chemistry Laboratory Guidebook." If the Department does not have an analytical method approved by the Administrator in each case, it shall determine compliance using methods prescribed in the current edition of the Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC), or those specified under 21 CFR 101.9(c) when neither USDA nor AOAC methods are available. If the use of a method will result in a significant (10 percent or greater) under representation of caloric value or misrepresentation of an available nutrient (e.g., mono- and diglycerides are not detected with the AOAC methods for fat), such that the nutrients whose intakes should be limited appear to be present at lower levels than is actually the case, then a more appropriate method of analysis should be used. This concern raised about the applicability of methods in certain circumstances is discussed further in FDA's mandatory labeling proposal of July 19, 1990. USDA is also concerned about the analytical methodologies for sugars and concurs with FDA's discussion of the problems as presented in the same proposal. Both the FDA and FSIS proposed definitions for sugars include tri- and tetrasaccharides; however, the widely used laboratory methods employing high performance liquid chromatography measure mono- and disaccharides. This poses a compliance problem because there is no AOAC laboratory method to measure tri- and tetrasaccharides. FSIS seeks comments on appropriate methods for the analysis of sugars as they are defined in these proposed regulations.

In the event that FSIS employees, through FSIS monitoring of samples, determine that products do not meet the compliance parameters set forth in these proposed regulations, the establishments would be notified to take whatever corrective actions are necessary for the nutrient content of a subsequent production to be in accordance with labeling declarations. Failure to provide a response within 30 days may cause approval to use the labeling material in official establishments to be withdrawn. Before approval to use a labeling material is finally withdrawn by the Administrator, the affected establishment would be given notice and the opportunity to present its views to the Administrator in accordance with the applicable rules of practice as established in 9 CFR 335.12.

References

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4. Buege, D.R., J.E. Held, C.A. Smith, L.K. Sather, and L.V. Klatt. 1990. A Nationwide Survey of the Composition and Marketing of Pork Products at Retail. Serial #R3509. Department of Meat and Animal Science, University of Wisconsin, Madison, WI.
5. Poultry Nutri-Facts. Fresh Poultry Nutrition Information Program Manual. 1987. Food Marketing Institute, National Broiler Council, National Turkey Federation. Washington, D.C., 27 pp.
6. U.S. Department of Agriculture and U.S. Department of Health and Human Services. 1990. Nutrition and Your Health: Dietary Guidelines for Americans, 3rd ed. Home and Garden Bulletin No. 232. U.S. Government Printing Office, Washington, DC, 27 pp.

VIII. Health Messages

FSIS does not permit health claims, i.e., those explicitly linking food attributes to disease or health-related conditions. However, FSIS does permit the inclusion on labels of health recommendations from authoritative sources such as the National Cholesterol Education Program and references on how a food can fit into general recommendations for a total diet.

The NLEA requires FDA to adopt health-claim regulations prohibiting health claims for foods which FDA determines to contain any nutrient in an amount that increases the risk of persons in the general population to a diet-related disease, taking into account the contribution of the food in the daily diet.

On February 13, 1990, FDA published a reproposal on health messages and label statements to protect consumers from false or misleading health claims and to ensure provisions of accurate information (55 FR 5176). The health claims issue is still under study by FDA and FSIS. Upon completion of these studies, FSIS will publish a separate proposed regulation on health claims in line with FDA's proposal.

IX. Format

The format in which nutrition labeling is presented is an important topic being

investigated by FDA and the industry. FDA has initiated a pilot program to test alternative nutrition label formats. FDA experts will use the results of this program to propose changes to the format of the nutrition label. FSIS is working closely with FDA to ensure that the same format will be used by both agencies.

FDA's preliminary review of comments received on the mandatory nutrition labeling and RDI/DRV proposal indicate a great consumer interest in having reference values become a part of nutrition labeling. FDA believes that the use of the DRV's will help meet the 1990 amendments and is therefore proposing to make them mandatory in some form. In the interest of harmonization, FSIS is also proposing to make the DRV's mandatory. How they will be expressed within nutrition labeling and in what form is the subject of further format research. FSIS will propose a nutrition label format in a separate document after the results of current studies are received.

X. Food Ingredients and Standards of Identity

In the ANPR, FSIS addressed its belief that concerns relating to ingredients and standards, which currently attract the most attention, include possibly incomplete ingredient statements on packaged products, including standardized foods; the impact of "and/or" labeling of fats and oils on consumers' ability to judge the amount of saturated fat in a product; and the concern that existing food standards may impede development of substitute products that are lower in calories, fat, cholesterol, and sodium. Since FSIS requires full ingredient labeling on all meat and poultry products, including standardized products, this issue may not present a problem for the labeling of meat and poultry products.

The Agency believes that concerns about disjunctive labeling of fats and oils can be resolved by proper labeling of saturated fat. Because USDA standards of identity and composition do not require minimum fat contents, development of products with desirable characteristics is not hampered by minimum fat criteria. However, levels for minimum amounts of meat and poultry are a part of most standards. These criteria protect consumers against economic fraud and dilution of beneficial micronutrients and protein expected in certain products. Due to the shift of concern from problems connected to underconsumption to those associated with overconsumption of certain food components such as fat, FSIS plans to reassess this matter after completing its rulemaking on nutrition labeling.

XI. Prior Label Approval

FSIS requires that all labels proposed for use on meat and poultry products be approved under the Agency's prior label approval process before their use on such products. Conversely, FDA does not administer a prior label approval system, but monitors labeling of other foods primarily through periodic surveillance at the marketplace.

Concerns have been expressed by various affected parties as to the divergence between FSIS and FDA regarding the monitoring of labeling compliance. As a result, efforts are underway to assess the Agency's prior label approval process in terms of internal management, organizational structure, and program effectiveness. The Department has commissioned an evaluation of all aspects of FSIS's organization and management systems, including prior label approval, and their ability to assure a safe, wholesome supply of meat and poultry to consumers. The evaluation will include alternatives which could increase the Agency's effectiveness and efficiency. Results of this evaluation will provide FSIS the information necessary to consider possible changes in the prior label approval process.

FSIS has also initiated a plan to modernize internal systems and procedures for the prior label approval process. Every aspect of prior label approval is being assessed to identify those areas where modifications may be made to facilitate a more efficient label process while responding to consumers' demand for more informative labels.

If adopted, this nutrition labeling rulemaking would require the labels for meat and poultry products, except single ingredient, raw products and products used for further processing, to be revised and submitted for review by the Agency. FSIS acknowledges the significant economic impact that would be imposed upon the affected meat and poultry industry, as well as the need for substantive resources from the Agency to review all such revised labels.

FSIS is interested in receiving comments through this rulemaking proceeding as to whether modifications should be made to the Agency's label approval process and, if so, how such changes should be accomplished. FSIS is also seeking comments on whether the prior approval process should be eliminated. Such comments would assist FSIS in its assessment of label procedures.

XII. Implementation

The NLEA mandates deadlines for FDA's publication and implementation of mandatory nutrition labeling regulations. The implementation date, except for a few exceptions, set by the NLEA for mandatory nutrition labeling and health claims is May 1993. In order to provide consumers with a complete nutrition labeling program, FSIS plans to follow FDA's mandated timeframe.

FSIS also examined several alternative implementation timeframes for companies complying with the nutrition labeling regulations and the costs associated with each. The compliance periods examined were 6, 12, and 24 months with single- and multi-analytical tests per product. The results indicate that the longer the compliance period, the lower the per-company compliance costs. (Refer to the Preliminary Regulatory Impact Analysis for further discussion on compliance costs.) FSIS is interested in receiving comments from industry concerning the implementation period for the nutrition labeling regulation.

FSIS also seeks comments on whether companies should be permitted to use existing labels, especially those labels containing nutrition information, for some period of time beyond the implementation date in order to exhaust existing label inventory.

Within 6 months of the publication of this document, FSIS intends to publish a notice in the **Federal Register** announcing the intended implementation date.

Proposal

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR parts 317, 320, and 381 of the Federal meat and poultry products inspection regulations to read as follows:

List of Subjects

19 CFR Part 317

Food labeling, Meat inspection.

9 CFR Part 320

Reporting and recordkeeping.

9 CFR Part 381

Food labeling, Poultry and poultry products, Reporting and recordkeeping.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for part 317 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Part 317 would be amended by redesignating the current § § 317.1 through 317.24 as subpart A—General, and by adding a new subpart B—Nutrition Labeling to read as follows:

Subpart A—General

Sec.
317.1–317.24
* * * * *

Subpart B—Nutrition Labeling

317.300 Nutrition labeling of meat products.
317.301 [Reserved]
317.302 Location of nutrition information.
317.303–317.307 [Reserved]
317.308 Labeling of meat products with number of servings.
317.309 Nutrition label content.
317.310 [Reserved]
317.311 [Reserved]
317.312 Reference amounts customarily consumed per eating occasion.
317.313 Nutrient content claims; general principles.
317.314–317.342 [Reserved]
317.343 Significant participation for voluntary nutrition labeling.
317.344 Identification of major cuts of meat products.
317.345 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.
317.346–317.353 [Reserved]
317.354 Nutrient content claims for "source" and "high".
317.355 [Reserved]
317.356 Nutrient content claims for "light" or "lite".
317.357–317.359 [Reserved]
317.360 Nutrient content claims for calorie content.
317.361 Nutrient content claims for sodium content.
317.362 Nutrient content claims for fat, fatty acids, and cholesterol content of meat products.
317.363–317.368 [Reserved]
317.369 Petitions for nutrient content claims.
317.370–317.379 [Reserved]
317.380 Label statements relating to usefulness in reducing or maintaining body weight.
317.381–317.399 [Reserved]
317.400 Exemption from nutrition labeling.

Subpart B—Nutrition Labeling

§ 317.300 Nutrition labeling of meat products.

(a) Nutrition labeling shall be provided for all meat products, except single-ingredient, raw products, in accordance with the requirements of § 317.309, unless the product is used for further processing as provided in § 317.400 of this subpart.

(b) Nutrition labeling may be provided for single-ingredient, raw meat products in accordance with the requirements of § 317.309 and § 317.345. Significant participation in voluntary nutrition labeling shall be measured by the Agency in accordance with § § 317.343 and 317.344 of this subpart.

§ 317.301 [Reserved]

§ 317.302 Location of nutrition information.

(a) Nutrition information on a label of packaged meat products shall appear on the label's principal display panel or on the information panel, except as provided in paragraph (b) of this section.

(b) Nutrition labeling information for individually wrapped packages of meat products of less than ½ ounce net weight and products packaged in other than consumer-size packages may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claims. In lieu of on the product label, nutrition information may be displayed as follows:

(1) Product label inserts, as provided in § 317.4(c), and

(2) Point of purchase information supplied by the manufacturer.

§ § 317.303–317.307 [Reserved]

§ 317.308 Labeling of meat products with number of servings.

The label of any package of a meat product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 317.2(h)(10).

§ 317.309 Nutrition label content.

(a)(1) All nutrient and product component quantities shall be declared in relation to a serving or, where the product is customarily not consumed directly, to a portion, as defined in 21 CFR 101.9(b) (1) through (3) and 21 CFR 101.9(b) (5) through (8).

(2) The declaration of nutrient and product component content shall be on the basis of the product "as packaged" for all products, except that single-ingredient, raw products may be declared on the basis of the product "as consumed" as set forth in § 317.345(a)(1). In addition to the required declaration on the basis of "as packaged" for products other than single-ingredient, raw products, the declaration may also be made on the basis of "as consumed."

(3) Another column of figures may be used to declare the nutrient and product component information on the basis of 100 grams or 100 milliliters of the product. This information shall be shown as required in paragraph (a)(2) of this section.

(b) The declaration of nutrition information on the label shall contain the following information, except for that which is identified as "VOLUNTARY" or for those meat products where an abbreviated format must be used as provided for in paragraph (e) of this section. Information shall be presented in the following order, using the headings, specified and displayed with equal type size under the overall heading of "NUTRITION INFORMATION PER SERVING (PORTION)." Alternatively, the terms "PER SERVING (PORTION)" may be placed directly below the terms "NUTRITION INFORMATION." Definitions, units of measure, increments for declaring values, and methods of calculation shall be in accordance with 21 CFR 101.9(c) (1) through (10).

(1) "Serving (portion) size",

(2) "Servings (portions) per container",

(3) "Caloric content" or "Calories",

(i) "Calories from total fat",

(ii) "Calories from saturated fat", "Calories from unsaturated fat", "Calories from total carbohydrate", and "Calories from protein" (VOLUNTARY),

(A) "Calories from saturated fat" or "Calories from saturated",

(B) "Calories from unsaturated fat" or "Calories from unsaturated",

(C) "Calories from total carbohydrate",

(D) "Calories from protein",

(4) "Total fat content" or "Total fat",

(i) "Saturated fat content", "Saturated fat", or "Saturated",

(ii) "Unsaturated fat content", "Unsaturated fat", or "Unsaturated" (VOLUNTARY),

(A) "Polyunsaturated fat" or "Polyunsaturated",

(B) "Monounsaturated fat" or "Monounsaturated",

(5) "Cholesterol content" or "Cholesterol",

(6) "Total carbohydrate content" or "Total carbohydrate",

(i) "Complex carbohydrate content" or "Complex carbohydrate",

(ii)(A) "Sugars content" or "Sugars",

(B) "Sugar alcohol content" or "Sugar alcohol" (VOLUNTARY),

(7) "Dietary fiber content" or "Dietary fiber",

(i) "Soluble and insoluble fiber" (VOLUNTARY),

(A) "Soluble fiber",

(B) "Insoluble fiber",

(ii) "Total dietary fiber," "soluble dietary fiber", and "insoluble dietary fiber content",

(8) "Protein content" or "Protein",

(i) A statement of the corrected amount of protein per serving calculated as a percentage of the Reference Daily Intake (RDI) for protein and expressed as "Percent of Daily Value",

(ii) The "Corrected amount of protein (gram) per serving (portion)", and

(iii) For the purpose of labeling with a percent of the RDI, a value of 50 grams of protein shall be the RDI for adults and children 4 or more years of age, 16 grams of protein for children less than 4 years of age, and 14 grams of protein for infants.

(9) "Sodium content" or "Sodium",

(10) "Potassium content" or "Potassium" (VOLUNTARY),

(11) Under the heading "Percent of Daily Value": A statement of the amount per serving (portion) of the vitamins and minerals expressed as a percent of the RDI, in accordance with 21 CFR 101.9(c)(11), and

(12) "Nutrition Profile" in accordance with 21 CFR 101.9(c)(12).

(c) [Reserved]

(d)(1) If a product consists of assortments of meat products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(2) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided*, That, the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(e) The abbreviated format shall be in accordance with 21 CFR 101.9(f) (1) through (4).

(f) The Reference Daily Intakes and Daily Reference Values used shall be in accordance with 21 CFR 101.9(c)(8) (i) and (iii), 11(iv), and (12)(i).

(g) Compliance with this section shall be determined as follows:

(1) A production lot is that product from one production shift. Alternatively, a collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six finished production units, one from each of six production lots. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six subsamples (consumer units), each taken from a randomly chosen shipping case, to be representative of a lot. Composites shall be analyzed by appropriate methods and procedures used by the Department for each nutrient in accordance with the "Chemistry Laboratory Guidebook," or, if no USDA method is available or appropriate in each case, by appropriate methods for each nutrient in accordance with the 1990 edition of the "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC), 15th ed., which is incorporated by reference, unless a particular method of analysis is specified in 21 CFR 101.9(c), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures. Copies of the AOAC Methods are available from the Association of Official Analytical Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, or potassium shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) unless it meets the following requirements:

(i) Class I vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) Class II vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label: *Provided*, That no regulatory action will be based on a determination of a nutrient value which falls below this level by a factor less than the variability generally recognized for the analytical method used in that product at the level involved.

(5) A product with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, or potassium may vary from the labeled amounts within good manufacturing practice.

(7) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(8) A prerequisite for obtaining approval for labeling containing nutrient content claims as defined in these regulations is that an establishment has an approved partial quality control program as provided in § 318.4(d) to result in compliance with these provisions.

(9) The compliance provisions set forth in paragraph (g) (1) through (7) of this section shall not apply to single-ingredient, raw meat (including ground beef) products, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series.

(h) Nutrition information provided by a manufacturer or distributor directly to professionals (e.g., physicians, dietitians, and educators) may vary from the requirements of this section, but shall also contain or have attached to it the nutrition information as required by this section.

§ 317.310 [Reserved]

§ 317.311 [Reserved]

§ 317.312 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the Reference Amounts for serving (portion) sizes set forth in paragraph (b) of this section are found in 21 CFR 101.12 (a) through (g), except paragraph (b).

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION INFANT AND TODDLER FOODS [1 2 3]

Product category	Reference amount
Infant and toddler foods:	
Dinner dry mix	15 g
Dinner, ready-to-serve, strained type.	60 g
Dinner, soups, ready-to-serve junior type.	110 g
Dinner, stew or soup ready-to-serve toddlers.	170 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION GENERAL FOOD SUPPLY [1 2 3]

Product category [4]	Reference amount
Egg Mixtures, e.g., western style omelet, souffle, egg foo young.	110 g
Lard, lard, margarine, shortening	1 tbsp
Salad and potato toppers, e.g., bacon bits.	7 g
Bacon, e.g., bacon, beef breakfast strips, pork breakfast strips.	15 g
Dried, e.g., jerky, dried beef, sausage products with a moisture/protein ratio of less than 2:1, e.g., pepperoni.	30 g
Snacks, e.g., meat snack food sticks, pork rinds.	30 g
Luncheon meat, bologna, Canadian style bacon, Vienna sausages, frankfurters, pork pattie crumbles, beef pattie crumbles, blood pudding, pork sausage, luncheon loaf, old fashioned loaf, berlinger, imitation frankfurters, bangers, brotwurst, kielbasa, minced luncheon roll, Polish sausage, summer sausage, thuringer, liver sausage, mortadella, liverwurst, uncured sausage (franks), ham and cheese loaf, P & P loaf, scrapple, souse, head cheese, pizza loaf, olive loaf, pate, deviled ham, sandwich spread, mettwurst, smoked country sausage, teawurst, cervelet, Lebanon bologna, potted meat food product, taco fillings, meat pie fillings.	55 g
Smoked or pickled, meat pickled pigs feet, smoked sausage.	55 g

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION GENERAL FOOD SUPPLY [1 2 3]—Continued

Product category [4]	Reference amount
Entrees without sauce, cuts of meat including marinated, tenderized, injected cuts of meat, beef patty, corn dog, bagel dog, croquettes, fritters, cured ham, dry cured ham, dry cured cappicola, Parma ham, corned beef, pastrami, country ham, pork shoulder picnic, meatballs, pureed adult foods.	85 g
Canned meats, canned beef, canned pork.	85 g
Entrees with sauce, barbecued meats in sauce.	140 g
Mixed dishes, NOT measurable with a cup, e.g., burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches, cracker and meat lunch-type packages, gyro, stromboli, burger on a bun, frank on a bun, calzone, taco, pockets stuffed with meat, foldovers, meat lasagna, stuffed vegetables with meat, shish kabobs, empanada.	140 g (plus 55 gms for products with sauce toppings)
Mixed dishes, measurable with cup, e.g., meat casserole, macaroni and cheese with meat, pot pie, spaghetti with sauce, meat chili, chili with beans, meat hash, creamed chipped beef, beef ravioli in sauce, beef stroganoff casserole, Brunswick stew, goulash, meat stew, ragout.	1 cup
Salads pasta or potato, potato salad with bacon, macaroni and meat salad.	140 g
Salads—all other meat, salads, ham salad.	100 g
Soups—all varieties	1 cup
Major main entree type sauce, e.g., spaghetti sauce with meat, spaghetti sauce with meatballs.	1/2 cup
Minor main entree sauce, e.g., pizza sauce with meat, gravy.	1/4 cup
Seasoning mixes dry, freeze dry, dehydrated, concentrated soup mixes, bases, extracts, dried broths and stock/juice, freeze dry trail mix product with meat	
As reconstituted: Amount to make one Reference Amount of the final dish e.g., gravy—1/4/cup, major main entree type sauce—1/2 cup, soup—1 cup, entree measurable with a cup—1 cup	

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated meat dinner) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

[4] Examples listed under Product Category are not all inclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.

(c) The Reference Amounts set forth in paragraph (b) of this section shall be used to determine whether a product meets the USDA criteria for nutrient content claims such as "Low Calorie." If the serving size declared on the product label differs from the Reference Amount, both the Reference Amount and the serving size declared on the product label shall be used to determine whether the product meets the criteria for a claim.

(d) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section. A petition to establish or amend a Product Category or Reference Amount shall include information as identified in 21 CFR 101.12(h) (1) through (11) and (13).

§ 317.313 Nutrient content claims; general principles.

(a) This section applies to meat products that are intended for human consumption and that are offered for sale, except that nutrient content claims may not be made on products intended specifically for use by infants and toddlers less than 2 years of age.

(b) A claim, which expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 317.309, may not be made on a label or in labeling of that product unless the claim is made in accordance with this Subpart.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium."

(2) An implied nutrient content claim is any claim that describes the product or an ingredient therein in such a manner that leads a consumer to assume that a nutrient is absent or present in a certain amount (e.g., "high in oat bran") or that the food may be useful in selecting foods that are helpful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy").

(c) Information required or permitted by § 317.309 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) An individual product bearing a nutrient content claim shall meet the criteria for that claim on the basis of the reference amount customarily consumed

(RACC) and the amount per labeled serving as specified in § 317.312(b).

(e)(1) A nutrient content claim may state the absence of a nutrient (e.g., Sodium free) if that nutrient is usually present in the product or in product for which the product is a substitute and the substitute food resembles the product for which it substitutes, i.e., is organoleptically, physically and functionally similar (including shelf life) and may be used interchangeably.

(i) If there is a difference in performance characteristics, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(ii) of this section, informing the consumer of such difference.

(ii) This disclaimer must be in easily legible print or type and in a size no less than one-half the size of the type of the descriptive term but in no case less than one-sixteenth of an inch in height.

(2) Any claim for the absence of a nutrient in a product that has not been specially processed, altered, formulated or reformulated so as to eliminate the nutrient from the product shall indicate that the product inherently meets the criteria for that descriptor and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches. It shall not bear the descriptive term immediately preceding the name of the product because such terminology would imply that the product has been altered compared to other products of the same type.

(f) A nutrient content claim shall be, in type size and style, no larger than that of the statement of identity.

(g) The label or labeling of a product for which a nutrient content claim is made shall contain prominently and in immediate proximity to such claim the following referral statement: "See _____ for nutrition information" with the blank filled in with the identity of the panel on which nutrition labeling is located.

(1) The referral statement "See [*appropriate panel*] for nutrition information" shall be in easily legible boldface print or type in distinct contrast to other printed or graphic matter and no less than one-half the size of the type of the descriptive term but in no case less than one-sixteenth of an inch in height.

(2) The referral statement shall be immediately adjacent to the descriptive term and may have no intervening material other than the statement of identity. If the descriptive term appears on more than one panel of the label, the referral statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information.

(3) If a single panel of a label or labeling contains multiple nutrient content claims or a single claim repeated several times, a single referral statement may be made. The statement shall be adjacent to the claim that is printed in the largest type on that panel.

(h) In place of the referral statement described in paragraph (g) of this section, if a product contains more than 11.5 grams of fat, 4.0 grams of saturated fat, 45 milligrams of cholesterol, or 360 milligrams of sodium per reference amount customarily consumed (RACC), labeled serving size or per 100 grams, then that product must disclose, as part of the referral statement, that the nutrient exceeding the specified level is present in the product as follows: "See [*appropriate panel*] for information about [*nutrient requiring disclosure*] and other nutrients"; e.g., "See side panel for information about fats and other nutrients."

(i) The label or labeling of a product may contain a statement about the amount or percentage of a nutrient which implies that the product is high or low in that nutrient if the product actually meets the definition for either "high" or "low" as defined for the nutrient which the label addresses. Such a claim might be "Contains 100 mg of sodium per serving."

(j) Products may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference food. These statements shall be known as "relative claims" and include "reduced", "light", and comparative claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the product must be compared as specified below to a reference food. Such products are:

(i) For all relative claims, an industrywide norm, i.e., a composite value weighted according to a national market share on a unit or tonnage basis of all the products of the same type as the product for which the claim is made, or

(ii) For reduced and comparative claims only, a manufacturer's regular product which has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name.

(iii) For comparative claims only, a product or class of product whose composition is reported in a current valid data base such as U.S. Department of Agriculture's Handbook 8, *Composition of Foods, Raw, Processed, Prepared.*

(2) For products bearing relative claims:

(i) The label must bear immediately adjacent to such claim in the most prominent location and in type no less than half the size of the type of the claim but no less than one-sixteenth inch, the following accompanying information:

(A) The percentage (or fraction) of the amount of the nutrient in the reference food by which the nutrient has been modified, (e.g., "50% less fat," "⅓ fewer calories"), and

(B) The identity of the reference food, and

(C) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that of the reference food.

(ii) The most prominent location shall be determined by the following order:

(A) A claim on the principal display panel adjacent to the statement of identity,

(B) A claim elsewhere on the principal display panel,

(C) A claim on the information panel, or

(D) A claim elsewhere on the label.

(iii) Relative claims for decreased levels of nutrients may be made on the label or in labeling of a product only if the nutrient content for that nutrient differs from that of the reference food by more than the amount specified in the definition of "low" for that nutrient.

(k) The term "modified" may be used in the statement of identity of a product that bears a comparative claim in conformance with the requirements of this Subpart, followed immediately by the name of the nutrient whose content has been altered; e.g., "Modified fat ground beef." This statement of identity must be immediately followed by the comparative statement such as "Contains 35% less fat than _____" and all other information required in paragraph (j)(2) of this section for comparative claims.

(l) For purposes of making a claim, a "meal-type product" shall be defined as a product that:

(1) Makes a significant contribution to the diet by:

(i) Providing at least 200 calories per serving (container), or

(ii) Weighing at least 6 ounces per serving (container), and

(2) Contains ingredients from two or more of the following four food groups:

(i) Bread, cereal, rice and pasta group,

(ii) Fruits and vegetables group,

(iii) Milk, yogurt, and cheese group, and

(iv) Meat, poultry, fish, dry beans, eggs, and nuts group.

(3) Is represented as, or is in a form commonly understood to be a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Such representations may be made either by statements, photographs, or vignettes.

(m) [Reserved]

(n) Compliance with requirements for nutrient content claims will be determined using analytical methodology prescribed for determining compliance with nutrition labeling in § 317.309(g) of this subpart.

(o) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991 may continue to be used as part of that brand name, provided they are not false or misleading under section 1(n) of the Act (21 U.S.C. 601(n)(1)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food in relation to a reference daily intake (RDI) as defined in 21 CFR 101.9(c) may be made on the label.

(4) The requirements of this section do not apply to products for special dietary use as described in § 317.2(j)(2).

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991 are not subject to the requirements of paragraphs (b), (g), and (h) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by USDA. Petitions requesting approval of such a claim (e.g., healthy) may be submitted pursuant to § 317.369.

§§ 317.314-317.342 [Reserved]

§ 317.343 Significant participation for voluntary nutrition labeling.

(a) In evaluating significant participation for voluntary nutrition labeling, FSIS will consider only the major cuts of single-ingredient, raw meat products, as identified in § 317.344, including those that have been frozen.

(b) FSIS will judge a food retailer to be participating at a significant level if the retailer provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw meat products, listed in § 317.344, that it sells, and if the nutrition label is consistent in content and format with the mandatory program, or nutrition information is displayed at point-of-purchase in an appropriate manner.

(c) To determine whether there is significant participation by retailers under the voluntary nutrition labeling guidelines, FSIS will select a representative sample of companies allocated by type and size.

(d) FSIS will find that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated are participating in accordance with the guidelines.

(e) FSIS will evaluate significant participation of the voluntary program every 2 years beginning in May 1995.

(1) If significant participation is found, the voluntary nutrition labeling guidelines shall remain in effect.

(2) If significant participation is not found, FSIS shall initiate rulemaking to require nutrition labeling on those products under the voluntary program.

§ 317.344 Identification of the major cuts of meat products.

The major cuts of single-ingredient, raw meat products are: Beef chuck blade roast, beef loin top loin steak, beef rib roast large end, beef round eye round steak, beef round top round steak, beef round tip roast, beef chuck arm pot roast, beef loin sirloin steak, beef round bottom round steak, beef brisket (whole, flat half, or point half), beef rib steak small end, beef loin tenderloin steak, ground beef regular, ground beef extra lean, pork loin chop, pork loin country style ribs, pork loin top loin chop boneless, pork loin rib chop, pork spareribs, pork loin tenderloin, pork loin sirloin roast, pork shoulder blade steak, pork loin top roast boneless, ground pork, lamb shank, lamb shoulder arm chop, lamb shoulder blade chop, lamb rib roast, lamb loin chop, lamb leg (whole, sirloin half, or shank half), veal shoulder arm steak, veal shoulder blade steak, veal rib roast, veal loin chop, and veal cutlets.

§ 317.345 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.

(a) Nutrition information on the cuts of single-ingredient, raw meat products, including those that have been previously frozen, shall be provided in the following manner:

(1) If a retailer chooses to provide nutrition information on the label of these products, these products shall be subject to all requirements of the mandatory nutrition labeling program, except that nutrition labeling may be declared on the basis of either "as consumed" or "as packaged." In addition, the declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw meat products (including ground beef), including those that have been previously frozen.

(2) If a retailer chooses to provide nutrition information at the point-of-purchase by an appropriate means, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food, nutrition information shall be provided as specified in this Subpart for the mandatory nutrition labeling program. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(b) The declaration of nutrition information shall be presented in an abbreviated format as specified in § 317.309(e) of this subpart for the mandatory nutrition labeling program.

(c) The nutrition label data should be based on either raw or cooked edible portions of meat cuts with external cover fat at trim levels reflecting current market practices. If data are based on cooked portions, the methods used to cook the products must be specified and should be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the cooked edible portions of the separable lean of meat cuts.

(d) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series, may be used for nutrition labeling of single-ingredient, raw meat products (including ground beef), including those that have been previously frozen. These data may be composite data that reflect different quality grades of beef or other variables affecting nutrient content. Alternatively, data that reflect specific grades or other variables may be used, except that if data are used on labels attached to a product which is labeled as to grade of meat or other variables, the data must represent the product in the package when such data are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible meat tissues present in the package.

(e) If the nutrition information is in accordance with paragraph (d) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 317.309(g), unless a nutrition claim is made on the basis of the representative data base values.

(f) Retailers may use data bases that they believe reflect the nutrient content

of single-ingredient, raw meat products (including ground beef), including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (d) of this section and the requirements specified in this subpart for the mandatory nutrition labeling program.

§§ 317.346–317.353 [Reserved]

§ 317.354 Nutrient content claims for "source" and "high".

(a) *General requirements.* Except as provided in paragraph (e) of this section, the following nutrient content claims about a nutrient in a product in relation to the Reference Daily Intake (RDI) established for that nutrient in 21 CFR 101.9(c)(11)(iv) or Daily Reference Value (DRV) established for that nutrient in 21 CFR 101.9(c)(12)(i), excluding total carbohydrates and unsaturated fatty acids, may be used on the label or in labeling, provided that:

(1) The product is labeled in compliance with § 317.309, and

(2) The nutrient content claim complies with the requirements of § 317.313.

(b) *High.* The term "high" may be used on the label or in labeling of a product:

(1) When the product (except meal-type products as described in § 317.313(l)) contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed (RACC) and per labeled serving, or

(2) If it is a meal-type product as described in § 317.313(l) and it contains per 100 grams of product, an amount of the nutrient that is equal to 20 percent or more of the RDI or DRV.

(c) *Source.* The term "source" may be used on the label or in labeling of a product:

(1) When the product (except meal-type products as described in § 317.313(l)) contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed (RACC) and per labeled serving, or

(2) If it is a meal-type product as described in § 317.313(l) and it contains per 100 grams of product, an amount of the nutrient that is equal to 10–19 percent of the RDI or DRV.

(d) *Fiber claim.* If a nutrient content claim is made with respect to the level of dietary fiber, that is, the product is high in fiber or a source of fiber and the product is not low in total fat as defined in § 317.362(b), then the label must disclose the level of total fat as part of the referral statement, e.g., "See [*appropriate panel*] for nutrition information. Contains [*x amount*] of total fat per serving."

(e)(1) *More.* A comparative claim using the term "more" may be used to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, provided that:

(i) The product contains at least 10 percent of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber, or potassium more than the reference food that it resembles and for which it substitutes; and

(ii) As required in § 317.313(j) for relative claims, the percentage (or fraction) that the nutrient was increased relative to the RDI or DRV; the identity of the reference food; and clear and concise quantitative information comparing the level of the nutrient in the product per labeled serving, with that of the reference food it replaces are declared in immediate proximity to the most prominent such claim.

(2) A comparative claim using the term "more" may be used to describe the level of carbohydrates in a product, provided that the product contains at least 10 percent of the DRV for carbohydrates more than the reference food and the difference between the two products is only complex carbohydrates as defined in 21 CFR 101.9(c)(6)(i). The product must also meet the requirement of subparagraph (e)(1)(ii) of this section.

(3) A comparative claim using the term "more" may be used to describe the level of unsaturated fat in a product, provided that the level of total fat is not increased and the level of trans fatty acids does not exceed 1 percent. The reference food must also meet the requirements of paragraph (e)(1)(ii) of this section.

§ 317.355 [Reserved]

§ 317.356 Nutrient content claims for "light" or "lite".

(a) *General requirements.* The following nutrient content claims using the term "light" or "lite" to describe a product may be used on the label and in labeling, provided that:

(1) The product is labeled in compliance with § 317.309, and

(2) The nutrient content claim complies with the requirements of § 317.313.

(b) The terms "light" or "lite" may be used without further qualification to describe a product, provided that:

(1) The product has at least a one-third (33⅓%) reduction in the number of calories compared to a reference food as specified in § 317.313(j)(1)(i) with a minimum reduction of more than 40 calories per reference amount customarily consumed (RACC) and per labeled serving;

(2) If it derives more than 50 percent of its calories from fat; its fat content is reduced by 50 percent or more compared to the reference food that it resembles or for which it substitutes as specified in § 317.313(j)(1)(i) with a minimum reduction of more than 3 grams per reference amount customarily consumed (RACC) and per labeled serving; and

(3) As required in § 317.313(j) for relative claims, the percent (or fraction) that the calories, and, if appropriate, the fat, were reduced; the identity of the reference food; and clear and concise quantitative information comparing the level of calories and, if appropriate, fat content, in the product per labeled serving, with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., "⅓ fewer calories and 50% less fat than our regular Italian sausage: Lite Italian sausage 200 calories, 4 grams fat; regular Italian sausage 300 calories, 8 grams fat per serving.").

(c) A product, other than a salt substitute, that is low, reduced or otherwise altered in sodium content cannot use the term "light" solely because of this alteration but rather must use, as appropriate, the term "reduced sodium" or "low sodium".

(d) The term "light" or "lite" may be used to describe a salt substitute if the sodium content of the product has been reduced by at least 50 percent compared to ordinary table salt.

(e) The term "light" or "lite" may not be used to refer to a product that is not reduced in calories by one-third, and, if applicable, fat by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the product such as texture or color and the qualifying information, so stated, clearly conveys the nature of the product, and

(2) The qualifying information is in the same type size, style, color and prominence as the word "light" and in immediate proximity thereto.

(f) [Reserved]

§§ 317.357–317.359 [Reserved]

§ 317.360 Nutrient content claims for calorie content.

(a) *General requirements.* The following nutrient content claims about the calorie content of a product may be used on the label or in labeling, provided that:

(1) The product is labeled in compliance with § 317.309, and

(2) The nutrient content claims comply with the requirements of § 317.313.

(b) *Calorie content claims.* (1) The terms "calorie free", "free of calories", "no calories", or "zero calories" may be used on the label or in labeling of a product that usually contains or substitutes, as specified in § 317.313(e)(1), for a product that usually contains calories, provided that:

(i) The product contains less than 5 calories per reference amount customarily consumed (RACC) and per labeled serving.

(ii) If a product meets this condition without the benefit of special processing, alteration, formulation or reformulation to lower the caloric content, it is labeled to disclose that calories are not usually present in the product.

(2) The terms "low calorie", "low in calories", or "a low calorie food" may be used on the label or in labeling of products (except meal-type products as described in § 317.313(1)), provided that:

(i) The product does not provide more than 40 calories per reference amount customarily consumed (RACC) and per labeled serving, and

(ii) The product does not provide more than 40 calories per 100 grams or is a sugar substitute.

(iii) If a product meets these conditions without the benefit of special processing, alteration, formulation or reformulation to vary the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The term "low calorie", "low in calories", or "low calorie meal" may be used on the label or in labeling of meal-type products, provided that the meal contains 105 calories or less per 100 grams of product and meets the requirement of paragraph (b)(2)(iii) of this section.

(4) The terms "reduced calorie", "reduced in calorie", or "calorie reduced" may be used to describe a product (except meal-type products as described in § 317.313(l)), provided that:

(i) The product has been specifically formulated or processed to reduce its calorie content by 33⅓ percent or more, with a minimum reduction of more than 40 calories per reference amount customarily consumed (RACC) and per labeled serving from the reference food that it resembles and for which it substitutes as specified in § 317.313(j)(1) (i) and (ii); and

(ii) As required in § 317.313(j) for relative claims, the percent (or fraction) that the calories were reduced; and the identity of the reference food is declared; and clear and concise quantitative information comparing the level of the nutrient in the product per labeled serving with that of the reference food that it replaces in immediate proximity to the most prominent such claim (e.g., "33⅓ percent fewer calories than regular salami. Calorie content has been reduced from 150 to 100 calories per serving").

(5) A comparative claim using the term "fewer" may be used on the label or in labeling of a product, including meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent fewer calories, with a minimum reduction of more than 40 calories per reference amount customarily consumed (RACC) and per labeled serving, than the reference food that it resembles and for which it substitutes as specified in § 317.313(j)(1) (i), (ii) and (iii); and

(ii) As required in § 317.313(j) for relative claims, the percent (or fraction) that the calories were reduced; the identity of the reference food; and clear and concise quantitative information comparing the level of the calories in the product per labeled serving with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., "This Italian sausage contains 25 percent fewer calories than our regular Italian sausage. Calorie content has been lowered from 200 to 150 calories per serving.").

(c) *Use of terms such as "sugars free", "no sugars", or "zero sugars".* (1) Consumers may reasonably be expected to regard terms that represent that the product contains no sugars or sweeteners, e.g., "sugars free" or "no sugars", as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a product may not be labeled with such terms unless:

(i) The product contains less than 0.5 grams of sugars, as defined in 21 CFR 101.9(c)(6)(ii)(A) per reference amount customarily consumed (RACC) and per labeled serving;

(ii) The product contains no added ingredients that are sugars; and

(iii) (A) It is labeled "low calorie" or "reduced calorie" or bears a comparative claim of special dietary usefulness labeled in compliance with paragraph (b) (2), (3), or (4) of this section, or

(B) Such term is immediately accompanied, each time it is used, by the statement "Not a reduced calorie food", "Not a low calorie food", or "Not for weight control."

(2) The terms "no added sugars", "without added sugars", or "no sugars added" may be used, provided:

(i) No amount of sugars as defined in 21 CFR 101.9(c)(6)(ii)(A) is added during processing or packaging;

(ii) The product does not contain ingredients containing added sugars such as jam, jelly, and concentrated fruit juice;

(iii) The sugars or content has not been increased above the amount naturally present in the ingredient(s) by some means such as the use of enzymes;

(iv) The product that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement indicating that the product is not low calorie or calorie reduced (unless the product meets the requirements for a low or reduced calorie product) and directing consumers' attention to the nutrition panel for further information on sugars and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a product is unsweetened or contains no added sweeteners in the case of a product that contains apparent substantial inherent sugar content, e.g., juices.

§ 317.361 Nutrient content claims for sodium content.

(a) *General requirements.* The following nutrient content claims about the sodium content of a product may be used on the label and in labeling, provided that:

(1) The product is labeled in compliance with § 317.309; and

(2) The nutrient content claims comply with the requirements of § 317.313.

(b) *Sodium Content claims.* (1) The terms "sodium free", "free of sodium", "no sodium", or "zero sodium" may be used on the label or in labeling of a product that usually contains or substitutes as specified in § 317.313(e)(1) for a product that usually contains sodium, provided that:

(i) The product contains less than 5 milligrams of sodium per reference amount customarily consumed (RACC) and per labeled serving; and

(ii) The product contains no ingredient that is salt (sodium chloride); and

(iii) If a product meets this condition without the benefit of special processing, alteration, formulation or reformulation to lower the sodium content, it is labeled to disclose that sodium is not usually present in the product, e.g., "_____, a sodium free food."

(2) The terms "very low sodium", "very low in sodium", and "a very low sodium food" may be used on the label or in labeling of products (except meal-

type products as described in § 317.313(l)), provided that:

(i) The product does not provide more than 35 milligrams of sodium per reference amount customarily consumed (RACC) and per labeled serving, and

(ii) The product does not provide more than 35 milligrams of sodium per 100 grams.

(iii) If a product meets these conditions without the benefit of special processing, alteration, formulation or reformulation to vary the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches (e.g., "_____, a very low sodium food").

(3) The term "very low sodium", "very low in sodium", or "very low sodium meal" may be used on the label or in labeling of meal-type products as defined in § 317.313(l), provided that the meal contains 35 milligrams or less of sodium per 100 grams of product and meets the requirement of paragraph (b)(2)(iii) of this section.

(4) The terms "low sodium", "low in sodium", or "a low sodium food" may be used on the label or in labeling of products (except meal-type products as described in § 317.313(l)), provided that:

(i) The product does not provide more than 140 milligrams of sodium per reference amount customarily consumed (RACC) and per labeled serving; and

(ii) The product does not provide more than 140 milligrams of sodium per 100 grams.

(iii) If a product meets these conditions without the benefit of special processing, alteration, formulation or reformulation to vary the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches (e.g., "_____, a low sodium food").

(5) The term "low sodium", "low in sodium", or "low sodium meal" may be used on the label or in labeling of meal-type products as described in § 317.323(l), provided that the meal contains 140 milligrams or less sodium per 100 grams of product and meets the requirement of paragraph (b)(4)(iii) of this section.

(6) The term "reduced sodium", "reduced in sodium", or "sodium reduced" may be used to describe a product (except meal-type products as discussed in § 317.313(l)), provided that:

(i) The product has been specifically formulated or processed to reduce its sodium content by 50 percent or more with a minimum reduction of more than 140 milligrams per reference amount customarily consumed (RACC) and per labeled serving from the reference food that it resembles and for which it substitutes as specified in § 317.313(j)(1)(i) and (ii); and

(ii) As required in § 317.313(j) for relative claims, the percent (or fraction) that the sodium was reduced; the identity of the reference food; and clear and concise quantitative information comparing the level of the sodium in the product per labeled serving with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium—50 percent less sodium than regular _____. Sodium content has been reduced from 300 to 150 milligrams of sodium per serving.").

(7) A comparative claim using the term "less" may be used on the label or in labeling of a product including meal-type products as described in § 317.313(l), provided that:

(i) The product contains at least 25 percent less sodium with a minimum reduction of more than 140 milligrams per reference amount customarily consumed (RACC) and per labeled serving than the reference food that it resembles and for which it substitutes as specified in § 317.313(j)(1)(i), (ii), and (iii); and

(ii) As required in § 317.313(j) for relative claims, the percent (or fraction) that the sodium was reduced; the identity of the reference food; and clear and concise quantitative information comparing the level of the sodium in the product per labeled serving with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., "This chicken noodle soup contains 25% less sodium than our regular chicken noodle soup. Sodium content has been lowered from 300 to 325 milligrams per serving.").

(c) The term "salt" is not synonymous with "sodium." Salt refers to sodium chloride. However, references to salt content such as "unsalted", "no salt", and "no salt added" are potentially misleading.

(1) The term "salt free" may be used on the label or in labeling of products only if the product is "sodium free" as defined in paragraph (b)(1) of this section.

(2) The terms "unsalted", "without added salt", and "no salt added" may be used on the label or in labeling of products, provided:

(i) No salt is added during processing;

(ii) The product that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the product is not sodium free, such claims are immediately accompanied each time they are used, by the statement, "Not a sodium free food" or "Not for control of sodium in the diet."

§ 317.362 Nutrient content claims for fat, fatty acids, and cholesterol content of meat products.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a meat product may only be made on the label and in the labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 317.313; and

(3) The meat product for which the claim is made is labeled in accordance with § 317.309.

(b) *Fat content claims.* (1) The terms "fat free", "free of fat", "no fat", "zero fat", or "nonfat" may be used on the label or in labeling of a meat product, provided that:

(i) The product contains less than 0.5 gram of fat per reference amount customarily consumed and per labeled serving size.

(ii) The product contains no added ingredient that is a fat or oil; and

(iii) As required in § 317.313(e)(2), if the meat product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to disclose that fat is not usually present in the product.

(2) The terms "low fat" or "low in fat" may be used on the label or in labeling of meat products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains 3 grams or less of fat per reference amount customarily consumed, per labeled serving size, and per 100 grams of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms "low fat" or "low in fat" may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains 3 grams or less of fat per 100 grams; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms "reduced fat", "reduced in fat", or "fat reduced" may be used on the label or in labeling of a product, except meal-type products as defined in § 317.313(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its fat content by 50 percent or more, with a minimum reduction of more than 3 grams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 317.313(j)(2)(i) and (ii); and

(ii) As required in § 317.313(j)(2) for relative claims, the percent (or fraction) that the fat has been reduced, the identity of the reference food, and quantitative information comparing the level of fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 317.313(j)(2)(ii) (e.g., "Reduced fat—50 percent less fat than our regular ground beef. Fat content has been reduced from 28 grams to 14 grams per serving").

(5) A comparative claim using the term "less" may be used on the label or in labeling of a meat product, including meal-type products as defined in § 317.313(l), provided that:

(i) The food contains at least 25 percent less fat, with a minimum reduction of more than 3 grams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 317.313(j)(1)(i), (ii), and (iii): and

(ii) As required in § 317.313(j)(2) for relative claims, the percent (or fraction) that the fat has been reduced, the identity of the reference food, and the quantitative information comparing the level of fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 317.313(j)(2)(ii) (e.g., "This hot dog contains 40 percent less fat than our regular hot dog. Fat content has been lowered from 9 grams to 5.5 grams per serving.").

(6) The term "_____ percent fat free" may be used on the label or in labeling of a meat product, provided that:

(i) The product meets the criteria for "low fat" in paragraph (b)(2) or (b)(3) of this section.

(ii) The label or labeling discloses the amount of total fat per serving (as declared on the label) of the meat product expressed in grams, to the nearest one-half gram. When the total fat content is less than 0.5 grams per serving, the amount may be declared as "0." Such disclosure shall appear in immediate proximity to the most prominent such claim as defined in § 317.313(j)(2)(ii) and in type size that shall be no less than one-half the size of the type used for such claim.

(iii) The percent of reduction and the words "fat free" are in uniform type size.

(iv) A claim for "100 percent fat free" meets all criteria for "fat free" in paragraph (b)(1) of this section.

(c) *Fatty acid content claims.* The label or labeling of meat products that bear claims with respect to the level of saturated fat shall disclose the level of total fat and cholesterol in the product in immediate proximity to such claim each time the claim is made and in type that shall be no less than one-half the size of the type used for the claim with respect to the level of saturated fat. Declaration of cholesterol content may be omitted when the product contains less than 2 milligrams of cholesterol per labeled serving size.

(1) The terms "low in saturated fat" or "low saturated fat" may be used on the label or in labeling of a meat product, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains 1 gram or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, not more than 15 percent of calories from saturated fatty acids; and

(ii) If a product meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(2) The terms "low in saturated fat" or "low saturated fat" may be used on the label or in labeling of a meal-type product, as defined in § 317.313(l), provided that:

(i) The product contains 1 gram or less of saturated fatty acids per 100 grams of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms "reduced saturated fat", "reduced in saturated fat", or "saturated fat reduced" may be used on the label or in labeling of a meat product, except meal-type products as defined in § 317.313(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its saturated fatty acid content by 50 percent or more, with a minimum reduction of more than 1 gram per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 317.313(j)(1)(i) and (ii); and

(ii) As required in § 317.313(j)(2) for relative claims, the percent (or fraction) that the saturated fat was reduced, the identity of the reference food, and the quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 317.313(j)(2)(ii) (e.g., "Reduced saturated fat. Contains 50 percent less saturated fat than the national average for pork sausage. Saturated fat reduced from 14 g to 7 g per serving").

(4) A comparative claim using the term "less" may be used on the label or in labeling of a meat product, including meal-type products as defined in § 317.313(l), provided that:

(i) The product contains 25 percent less saturated fat with a minimum reduction of more than 1 gram per reference amount customarily consumed and per labeled serving size from the reference food that it resembles and for which it substitutes defined in § 317.313(j)(1)(i), (ii), and (iii); and

(ii) As required in § 317.313(j)(2) for relative claims, the percent (or fraction) that the saturated fat was reduced, the identity of the reference food, and the quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 317.313(j)(2)(ii) (e.g., "Brand Y Italian sausage contains 40 percent less saturated fat than our regular Brand X Italian sausage. Brand Y contains 6 grams saturated fat; Brand X contains 10 grams saturated fat.").

(d) *Cholesterol content claims.* (1) The terms "cholesterol free", "free of cholesterol", "zero cholesterol", or "no cholesterol" may be used on the label or in labeling of a meat product, provided that:

(i) For products that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams of product:

(A) The product contains less than 2 milligrams of cholesterol per reference

amount customarily consumed and per labeled serving size;

(B) The product contains 2 grams or less of saturated fat per reference amount customarily consumed and per labeled serving size;

(C) As required in § 317.313(e), if the product contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size without the benefit of special processing, alteration, formulation or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the product.

(ii) For products that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of product:

(A) The product contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size;

(B) The product contains 2 grams or less of saturated fat per reference amount customarily consumed and per labeled serving size.

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the product. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 317.313(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim appears more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 317.313(e)(2), if the meat product contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the product, or

(E) If the product contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meet requirements of paragraph (d)(5)(i)(A) of this section) than the product for which it substitutes as specified in § 317.313(d) that has a significant (i.e., 5 percent or more) market share. As required in § 317.313(j)(2) for relative claims, the percent (or fraction) that the cholesterol was reduced, the identity of the reference food, and the quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 317.313(j)(2)(ii).

(2) The terms "low in cholesterol" or "low cholesterol" may be used on the label or in labeling of a meat product, except meal-type products as defined in § 317.313(l), provided that:

(i) For products that contain 11.5 grams or less of total fat, per reference amount customarily consumed, per labeled serving size, and per 100 grams of product:

(A) The product contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of product;

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size;

(C) As required in § 317.313(e), if the product contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of product without the benefit of special processing, alteration, formulation or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of that type and not merely to the particular brand to which the label attaches.

(ii) For products that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of product:

(A) The product contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of product;

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the product. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 317.313(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 317.313(e)(2), the product contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of product without the benefit of special processing, alteration, formulation or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of that type and not merely to the particular brand to which the label attaches, or

(E) If the product contains 20 milligrams or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(5)(i)(A) of this section) than the food for which it substitutes as specified in § 317.313(d) that has a significant (i.e., 5 percent or more) market share. As required in § 317.313(j)(2) for relative claims, the percent (or fraction) that the cholesterol has been reduced, the identity of the reference food, and the quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food are declared in immediate proximity to the most prominent such claim as defined in § 317.313(j)(2)(ii).

(3) The terms "low in cholesterol" or "low cholesterol" may be used on the label or in labeling of a meal-type product as defined in § 317.313, provided that the product meets the requirements of paragraph (d)(2) of this section, except that the determination as to whether paragraph (d)(2) (i) or (ii) of this section applies to the product will be made only on the basis of whether the product contains 11.5 grams or less of fat per 100 grams of product, the requirement in paragraphs (d)(2) (i)(A) and (ii)(A) of this section shall be limited to 20 milligrams of cholesterol per 100 grams, and the requirement in paragraphs (d)(2) (i)(B) and (ii)(B) of this section shall be modified to require that the product contain 2 grams or less of saturated fat per 100 grams rather than per reference amount customarily consumed and per labeled serving size.

(4) The terms "reduced cholesterol", "reduced in cholesterol", or "cholesterol reduced" may be used on the label or in labeling of a meat product or a product that substitutes for that food as specified in § 317.313(d), except meal-type products as defined in § 317.313(l), provided that:

(i) For products that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams:

(A) The product has been specifically formulated, altered, or processed to reduce its cholesterol content by 50 percent or more, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 317.313(j)(1) (i) and (ii);

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) As required in § 317.313(j)(2) for relative claims, the percent that the cholesterol has been reduced, the identity of the reference food, and the quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 317.313(j)(2)(ii).

(ii) For products that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of product:

(A) The product has been specifically formulated, altered, or processed to reduce its cholesterol content by 50 percent or more, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food (as defined in § 317.313(j)(1) (i) and (ii)) that it resembles and for which it substitutes as specified in § 317.313(d) that has a significant (i.e., 5 percent or more) market share;

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the product. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 317.313(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 317.313(j)(2) for relative claims, the percent (or fraction) that the cholesterol has been reduced, the identity of the reference food, and the quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 317.313(j)(2)(ii).

(5) A comparative claim using the term "less" may be used on the label or in labeling of a product or a product that substitutes for that product as specified in § 317.313(d), including meal-type products as defined in § 317.313(l), provided that:

(i) For products that contain 11.5 grams or less of total fat, per reference amount customarily consumed, per labeled serving size, and per 100 grams:

(A) The product contains at least 25 percent less cholesterol, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 317.313(j)(1) (i), (ii), and (iii);

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) As required in § 317.313(j)(2) for relative claims, the percent that the cholesterol was reduced, the identity of the reference food, and the quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food are declared in immediate proximity to the most prominent such claim as defined in § 317.313(j)(2)(ii).

(ii) For products that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of product:

(A) The product contains at least 25 percent less cholesterol with a minimum reduction of 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food as defined in § 317.313(j)(1)(i), (ii), and (iii) that it resembles and for which it substitutes as specified in § 317.313(d) that has a significant (i.e., 5 percent or more) market share;

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the product. Such disclosure shall appear each time the claim is made, in immediate proximity to such claim preceding the referral statement required in § 317.313(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 317.313(j)(2) for relative claims, the percent (or fraction) that the cholesterol was reduced, the identity of the reference food, and the quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food it replaces are declared in immediate proximity to the most prominent such claim as defined in § 317.313(i)(2)(ii) (e.g., "This ham omelette contains 30 percent less cholesterol than our regular omelette. Cholesterol lowered from 45 milligrams to 30 milligrams per serving. Contains 12 grams of fat per serving.").

§§ 317.363–317.368 [Reserved]

(e) *Lean and Extra Lean Claims.* (1) The term "lean" may be used on the label or in labeling of a meat product, provided that the product contains less than 10.5 grams fat, less than 3.5 grams saturated fat, and less than 94.5 milligrams cholesterol per 100 grams.

(2) The term "extra lean" may be used on the label or in labeling of a meat product, provided that the product contains less than 4.9 grams fat; less than 1.8 grams saturated fat; and less than 94.5 milligrams cholesterol per 100 grams.

§ 317.369 Petitions for nutrient content claims.

(a) This section pertains to petitions for claims, expressed or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Petitions included in this section are (1) petitions for a new (heretofore unauthorized) nutrient content claim,

(2) petitions for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and (3) petitions for the use of an implied claim in a brand name.

(c) Petitions to be filed under this section shall be submitted in quadruplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The

petition shall state the petitioner's post office address.

(d) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies are included in a petition, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter I, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations are included, the petition shall include statements regarding each such clinical investigation relied upon in the petition that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter I, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter I, title 21.

(g) The availability for public disclosure of petitions submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application from the petitioner, the present petition must provide the data.

(i) The petition must be signed by the petitioner or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The petition shall include a statement signed by the person responsible for the petition, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the petition.

(k)(1) Petitions for a new nutrient content claim shall include the following data and be submitted in the following form.

(Date)
Name of petitioner _____
Post-office address _____
Subject of the petition _____

FSIS Hearing Clerk, Regulations Development Unit, Policy Office, Food Safety and Inspection Service,
U.S. Department of Agriculture, Washington DC 20250.

Dear Sirs: The undersigned,_____ submits this petition pursuant to 9 CFR 317.369 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the descriptive term and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement should address why the use of the term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

B. A detailed explanation supported by any necessary data, of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose. The petition should also include data and information, e.g., surveys to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

C. Analytical data that demonstrates the amount of the nutrient that is the subject of the claim, that is present in the products for which the claim is intended. The assays should be performed on representative samples using the Association of Official Analytical Chemists (AOAC) methods where available. If no AOAC method is available, the petitioner shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data should include a statistical analysis of the analytical and product variability.

D. A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The latter item should specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis should specifically address the dietary practices of such group, and should include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner _____
By _____
(Indicate authority)

(2) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner (i) that the petition is undergoing Agency review and the petitioner will subsequently be notified of the Agency's decision to file or deny the petition; or (ii) that the petition is incomplete, e.g., one that lacks any of the data required by this section, one that states such data in a manner that is not readily understood, or one that has not been submitted in quadruplicate, in which case the petition will be denied and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 100 days of the date of receipt of the petition, the Administrator will notify the petitioner by letter that the petition has either been filed or denied. If denied, the notification shall state the reasons therefor. If filed, the date of the notification letter becomes the date of filing. A petition that has been denied shall not be made available to the public. A filed petition shall be available to the public as provided under paragraph (e) of this section.

(4) Within 90 days of the date of filing, the Administrator will, by letter of notification to the petitioner, (i) deny the petition, or (ii) inform the petitioner that a proposed regulation to provide for the requested use of the new term will be published in the **Federal Register**. The Administrator will publish the proposal to amend the regulations to provide for the requested use of the nutrient content claim in the **Federal Register** within 90 days of the date of filing. The proposal will also announce the availability of the petition for public disclosure.

(l)(1) Petitions for a synonymous term shall include the following data and be submitted in the following form.

(Date)
Name of petitioner _____
Post-office address _____
Subject of the petition _____

FSIS Hearing Clerk, Regulations Development Unit, Policy Office, Food Safety and Inspection Service,
U.S. Department of Agriculture, Washington DC 20250.

Dear Sirs: The undersigned, _____ submits this petition pursuant to 9 CFR 317.369 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart B of part 317).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the synonymous descriptive term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement should address why the use of the synonymous term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

B. A detailed explanation supported by any necessary data, of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This item shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing term defined by regulation. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose. This item shall also include data and information, e.g., surveys, to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

C. A detailed analysis of the potential effect of the use of the proposed claim on food consumption and any corresponding changes in nutrient intake. The latter item should specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis should specifically address the dietary practices of such group, and should include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner _____
By _____
(Indicate authority)

(2) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner (i) that the petition is undergoing Agency review and the petitioner will subsequently be notified of the Agency's decision to grant the petitioner permission to use the proposed term or to deny the petition; or (ii) that the petition is incomplete, e.g., one that lacks any of the data required by this part, one that states such data in a manner that is not readily understood, or one that has not been submitted in quadruplicate, in which case the petition will be denied and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 90 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and subsequently denied), the Administrator will notify the petitioner by letter of the Agency's decision to grant the petitioner permission to use the proposed term, with any conditions or limitations on such use specified, or to deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition.

(4) As soon as practicable following the granting of a petition, the Administrator will publish a notice in the **Federal Register** informing the public of his or her decision. If the petition is granted, the approved synonymous term will be included in the regulations listing terms permitted for use in nutrient content claims.

(m)(1) Petitions for the use of an implied nutrient content claim in a brand name shall include the following data and be submitted in the following form.

(Date)
Name of petitioner _____
Post-office address _____
Subject of the petition _____

FSIS Hearing Clerk, Regulations Development Unit, Policy Office, Food Safety and Inspection Service,
U.S. Department of Agriculture, Washington DC 20250.

Dear Sirs: The undersigned, _____ submits this petition pursuant to 9 CFR 317.369 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement should address why the use of the brand-name as proposed will not be misleading. The statement should provide examples of the types of products on which the brand name will appear. It should also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient should meet the requirements stated under petition format item C in paragraph (k)(1) of this section.

B. A detailed explanation supported by any necessary data, of why use of the proposed brand name is requested. This item shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose.

C. A detailed analysis of the potential effect of the use of the proposed brand name on food consumption, and any corresponding changes in nutrient intake. The latter item should specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet. If the branded product is intended for a specific group within the population, the analysis should specifically address the dietary practices of such group, and should include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner _____
By _____

(2) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner (i) that the petition is undergoing Agency review or (ii) that the petition is incomplete, i.e., one that lacks any of the data required by this part, one that states such data in a manner that is not readily understood, or one that has not been submitted in quadruplicate, in which case the petition will be denied and the petitioner will be notified as to what respect the petition is incomplete.

(3) The Administrator will publish a notice of the petition in the **Federal Register** announcing its availability to the public and seeking comment on the petition. The petition shall be available to the public to the extent provided under paragraph (e) of this section. The notice shall allow 30 days for comments.

(4) Within 100 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and subsequently denied), the Administrator will (i) notify the petitioner by letter of the Agency's decision to grant the petitioner permission to use the proposed brand name if such use is not misleading, with any conditions or limitations on such use specified, or (ii) deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition

to fully address the requirements of this section shall be grounds for denial of the petition. Should the Administrator not notify the petitioner of his or her decision on the petition within 100 days, the petition shall be considered to be granted.

(5) As soon as practicable following the granting of a petition, the Administrator will publish a notice in the **Federal Register** informing the public of such fact.

§§ 317.370-317.379 [Reserved]

§ 317.380 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 317.309 of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener, e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A product purporting to be "low calorie" must comply with the criteria set forth for such foods in § 317.360(b) (2) and (3).

(d) *"Reduced calorie" foods and other comparative claims.* A product purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 317.360(b) (4) and (5).

§§ 317.381-317.399 [Reserved]

§ 317.400 Exemption from nutrition labeling.

Meat products used for further processing, such as sliced pepperoni that will be used in pizza, shall be exempt from nutrition labeling, provided that the labels for these products bear no nutrition claims or nutrition information.

PART 320—RECORDS, REGISTRATION, AND REPORTS

3. The authority citation for part 320 would continue to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

4. Section 320.1 would be amended by adding a new paragraph (b)(7) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(7) Records of nutrition labeling as required by subpart B, part 317, of this subchapter.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

5. The authority citation for part 381 would continue to read as follows:

Authority: 7 U.S.C. 450, 21 U.S.C. 451-470, 7 CFR 2.17, 2.55.

6. Section 381.175 would be amended by adding a new paragraph (b)(4) to read as follows:

§ 381.175 Records required to be kept.

* * * * *

(b) * * *

(4) Records of nutrition labeling as required by subpart Y of this part.

7. Part 381 would be amended by adding a new subpart Y to read as follows:

Subpart Y—Nutrition Labeling

Sec.
381.400 Nutrition labeling of poultry products.
381.401 [Reserved]
381.402 Location of nutrition information.
381.403-381.407 [Reserved]
381.408 Labeling of poultry products with number of servings.
381.409 Nutrition label content.
381.410 [Reserved]
381.411 [Reserved]
381.412 Reference amounts customarily consumed per eating occasion.
381.413 Nutrient content claims; general principles.
381.414-381.442 [Reserved]
381.443 Significant participation for voluntary nutrition labeling.
381.444 Identification of the major cuts of poultry products.
381.445 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.
381.446-381.453 [Reserved]
381.454 Nutrient content claims for "source" and "high".
381.455 [Reserved]
381.456 Nutrient content claims for "light" or "lite".
381.457-381.459 [Reserved]
381.460 Nutrient content claims for calorie content.
381.461 Nutrient content claims for sodium content.
381.462 Nutrient content claims for fat, fatty acids, and cholesterol content of poultry products.
381.463-381.468 [Reserved]
381.469 Petitions for nutrient content claims.
381.470-381.479 [Reserved]
381.480 Label statements relating to usefulness in reducing or maintaining body weight.
381.481-381.499 [Reserved]
381.500 Exemption from nutrition labeling.

Subpart Y—Nutrition Labeling

§ 381.400 Nutrition labeling of poultry products.

(a) Nutrition labeling shall be provided for all poultry products, except single-ingredient, raw products, in accordance with the requirements of § 381.409, unless the product is used for further processing as provided in § 381.500 of this subpart.

(b) Nutrition labeling may be provided for single-ingredient, raw poultry products in accordance with the requirements of §§ 381.409 and 381.445. Significant participation in voluntary nutrition labeling shall be measured by the Agency in accordance with §§ 381.443 and 381.444 of this subpart.

§ 381.401 [Reserved]

§ 381.402 Location of nutrition information.

(a) Nutrition information on a label of packaged poultry products shall appear on the label's principal display panel or on the information panel, except as provided in paragraph (b) of this section.

(b) Nutrition labeling information for individually wrapped packages of poultry products of less than ½ ounce net weight and products packaged in other than consumer-size packages may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claims. In lieu of on the product label, nutrition information may be displayed as follows:

(1) Product label inserts, and

(2) Point of purchase information supplied by the manufacturer.

§§ 381.403–381.407 [Reserved]

§ 381.408 Labeling of poultry products with number of servings.

The label of any package of a poultry product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 381.121(c)(7).

§ 381.409 Nutrition label content.

(a) (1) All nutrient and product component quantities shall be declared in relation to a serving or, where the product is customarily not consumed directly, to a portion, as defined in 21 CFR 101.9(b) (1) through (3) and 21 CFR 101.9(b) (5) through (8).

(2) The declaration of nutrient and product component content shall be on the basis of the product "as packaged" for all products, except that single-ingredient, raw products may be declared on the basis of the product "as consumed" as set forth in § 381.445(a)(1). In addition to the required declaration on the basis of "as packaged" for products other than single-ingredient, raw products, the declaration may also be made on the basis of "as consumed."

(3) Another column of figures may be used to declare the nutrient and product component information on the basis of 100 grams or 100 milliliters of the product. This information shall be shown as required in paragraph (a)(2) of this section.

(b) The declaration of nutrition information on the label shall contain the following information, except for that which is identified as "VOLUNTARY" or for those poultry products where an abbreviated format must be used as provided for in paragraph (e) of this section. Information shall be presented in the following order, using the headings, specified and displayed with equal type size under the overall heading of "NUTRITION INFORMATION PER SERVING (PORTION)." Alternatively, the terms "PER SERVING (PORTION)" may be placed directly below the terms "NUTRITION INFORMATION." Definitions, units of measure, increments for declaring values, and methods of calculation shall be in accordance with 21 CFR 101.9(c) (1) through (10).

(1) "Serving (portion) size",

(2) "Servings (portions) per container",

(3) "Caloric content" or "Calories",

(i) "Calories from total fat",

(ii) "Calories from saturated fat", "Calories from unsaturated fat", "Calories from total carbohydrate", and "Calories from protein" (VOLUNTARY),

(A) "Calories from saturated fat" or "Calories from saturated",

(B) "Calories from unsaturated fat" or "Calories from unsaturated",

(C) "Calories from total carbohydrate",

(D) "Calories from protein",

(4) "Total fat content" or "Total fat",

(i) "Saturated fat content", "Saturated fat", or "Saturated",

(ii) "Unsaturated fat content", "Unsaturated fat", or "Unsaturated" (VOLUNTARY),

(A) "Polyunsaturated fat" or "Polyunsaturated",

(B) "Monounsaturated fat" or "Monounsaturated",

(5) "Cholesterol content" or "Cholesterol",

(6) "Total carbohydrate content" or "Total carbohydrate",

(i) "Complex carbohydrate content" or "Complex carbohydrate",

(ii)(A) "Sugars content" or "Sugars",

(B) "Sugar alcohol content" or "Sugar alcohol" (VOLUNTARY),

(7) "Dietary fiber content" or "Dietary fiber",

(i) "Soluble and insoluble fiber" (VOLUNTARY),

(A) "Soluble fiber",

(B) "Insoluble fiber",

(ii) "Total dietary fiber", "soluble dietary fiber", and "insoluble dietary fiber content",

(8) "Protein content" or "Protein",

(i) A statement of the corrected amount of protein per serving calculated as a percentage of the Reference Daily Intake (RDI) for protein and expressed as "Percent of Daily Value",

(ii) The "Corrected amount of protein (gram) per serving (portion)", and

(iii) For the purpose of labeling with a percent of the RDI, a value of 50 grams of protein shall be the RDI for adults and children 4 or more years of age, 16 grams of protein for children less than 4 years of age, and 14 grams of protein for infants.

(9) "Sodium content" or "Sodium",

(10) "Potassium content" or "Potassium" (VOLUNTARY),

(11) Under the heading "Percent of Daily Value": A statement of the amount per serving (portion) of the vitamins and minerals expressed as a percent of the RDI, in accordance with 21 CFR 101.9(c)(11), and

(12) "Nutrition Profile" in accordance with 21 CFR 101.9(c)(12).

(c) [Reserved]

(d)(1) If a product consists of assortments of poultry products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(2) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided*, That the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(e) The abbreviated format shall be in accordance with 21 CFR 101.9(f) (1) through (4).

(f) The Reference Daily Intakes and Daily Reference Values used shall be in accordance with 21 CFR 101.9(c)(8) (i) and (iii), 11(iv), and (12)(i).

(g) Compliance with this section shall be determined as follows:

(1) A production lot is that product from one production shift. Alternatively, a collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six finished production units, one from each of six production lots. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six subsamples (consumer units), each taken from a randomly chosen shipping case, to be representative of a lot. Composites shall be analyzed by appropriate methods and procedures used by the Department for each nutrient in accordance with the "Chemistry Laboratory Guidebook," or, if no USDA method is available or appropriate in each case, by appropriate methods for each nutrient in accordance with the 1990 edition of the "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC), 15th ed., which is incorporated by reference, unless a particular method of analysis is specified in 21 CFR 101.9(c), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures. Copies of the AOAC Methods are available from the Association of Official Analytical Chemists, 2200

Wilson Blvd., suite 400, Arlington, VA 22201.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods, and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, or potassium shall be deemed to be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)), unless it meets the following requirements:

(i) Class I vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) Class II vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label: *Provided*, That no regulatory action will be based on a determination of a nutrient value which falls below this level by a factor less than the variability generally recognized for the analytical method used in that product at the level involved.

(5) A product with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)), if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, or potassium may vary from the labeled amounts within good manufacturing practice.

(7) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(8) A prerequisite for obtaining approval for labeling containing nutrient content claims as defined in these regulations is that an establishment has an approved partial quality control program as provided in § 381.145(d) to result in compliance with these provisions.

(9) The compliance provisions set forth in paragraph (g)(1) through (7) of this section shall not apply to single-ingredient, raw poultry products, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series.

(h) Nutrition information provided by a manufacturer or distributor directly to professionals (e.g., physicians, dietitians, and educators) may vary from the requirements of this section, but shall also contain or have attached to it the nutrition information as required by this section.

§ 381.410 [Reserved]

§ 381.411 [Reserved]

§ 381.412 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the Reference Amounts for serving (portion) sizes set forth in paragraph (b) of this section are found in 21 CFR 101.12(a) through (g), except paragraph (b).

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1.—REFERENCE AMOUNT CUSTOMARILY CONSUMED PER EATING OCCASION INFANT AND TODDLER FOODS [1 2 3]

Product category	Reference amount
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	60 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dry cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by the regulation.

TABLE 2.—REFERENCE AMOUNT CUSTOMARILY CONSUMED PER EATING OCCASION GENERAL FOOD SUPPLY [1 2 3]

Product category [4]	Reference amount
Egg Mixtures, e.g., western style omelet, souffle, egg foo young with poultry	110 g
Salad and potato toppers, e.g., poultry bacon bits	7 g
Bacon, e.g., poultry breakfast strips	15 g
Dried, e.g., poultry jerky, dried poultry, poultry sausage products with a moisture/protein ratio of less than 2:1	30 g
Snacks, e.g., poultry snack food sticks	30 g
Luncheon products, poultry bologna, poultry Canadian style bacon, poultry franks, poultry crumbles, poultry luncheon loaf, poultry Polish sausage, potted poultry products, poultry taco fillings	55 g
Smoked or pickled, poultry smoked sausage	55 g
Entrees without sauce, poultry cuts, including marinated, tenderized, injected cuts of poultry, poultry corn dogs, poultry bagel dogs, poultry croquettes, poultry fritters, cured poultry ham products, adult pureed poultry	85 g
Canned poultry, canned chicken, canned turkey	85 g
Entrees with sauce, turkey and gravy	140 g
Mixed dishes, NOT measurable with a cup, e.g., poultry burrito, poultry enchiladas, poultry pizza, poultry quiche, all types of poultry sandwiches, cracker and poultry lunch-type packages, poultry gyro, poultry stromboli, poultry frank on a bun, poultry burger on a bun, poultry taco, chicken cordon bleu, poultry calzone, poultry lasagna, stuffed vegetables with poultry, poultry kabobs	140 g (plus 55 gms. for products with sauce toppings)
Mixed dishes, measurable with cup, e.g., poultry casserole, macaroni, cheese and poultry, poultry pot pie, poultry spaghetti with sauce, poultry chili, poultry chili with beans, poultry hash, creamed dried poultry, poultry ravioli in sauce, poultry a la king, poultry stew, poultry goulash	1 cup
Salads pasta or potato, potato salad with poultry, macaroni and poultry salad	140 g
Salads—all other, poultry salads, chicken salad, turkey salad	100 g
Soups—all varieties	1 cup
Major main entree type sauce, e.g., spaghetti sauce with poultry	½ cup
Minor main entree sauce, e.g., pizza sauce with poultry, gravy	¼ cup
Seasoning mixes dry, freeze dry, dehydrated, concentrated soup mixes, bases, extracts, dried broths and stock/juice, freeze dry trail mix product with poultry	
As reconstituted: Amount to make one Reference Amount of the final dish e.g.,	
gravy	¼ cup
major main entree type sauce	¼ cup
soup	1 cup

TABLE 2.—REFERENCE AMOUNT CUSTOMARILY CONSUMED PER EATING OCCASION GENERAL FOOD SUPPLY [1 2 3]—Continued.

Product category [4]	Reference amount
entree measurable with a cup....	1 cup

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977-1978 and the 1987-1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e. heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated poultry dinner) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the reference amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

[4] Examples listed under Product Category are not all inclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.

(c) The Reference Amounts set forth in paragraph (b) of this section shall be used to determine whether a product meets the USDA criteria for nutrient content claims such as "Low Calorie." If the serving size declared on the product label differs from the Reference Amount, both the Reference Amount and the serving size declared on the product label shall be used to determine whether the product meets the criteria for a claim.

(d) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a petition, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section. A petition to establish or amend a Product Category or Reference Amount shall include information as identified in 21 CFR 101.12(h) (1) through (11) and (13).

§ 381.413 Nutrient content claims; general principles.

(a) This section applies to poultry products that are intended for human consumption and that are offered for sale, except that nutrient content claims may not be made on products intended specifically for use by infants and toddlers less than 2 years of age.

(b) A claim, which expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 381.409, may not be made on a label or in labeling of that product unless the claim is made in accordance with this subpart.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium."

(2) An implied nutrient content claim is any claim that describes the product or an ingredient therein in such a manner that leads a consumer to assume that a nutrient is absent or present in a certain amount (e.g., "high in oat bran") or that the food may be useful in selecting foods that are helpful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy").

(c) Information required or permitted by § 381.409 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) An individual product bearing a nutrient content claim shall meet the criteria for that claim on the basis of the reference amount customarily consumed (RACC) and the amount per labeled serving as specified in § 381.412(b).

(e)(1) A nutrient content claim may state the absence of a nutrient (e.g., Sodium free) if that nutrient is usually present in the product or in product for which the product is a substitute and the substitute food resembles the product for which it substitutes, i.e., is organoleptically, physically and functionally similar (including shelf life) and may be used interchangeably.

(i) If there is a difference in performance characteristics, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(ii) of this section, informing the consumer of such difference.

(ii) This disclaimer must be in easily legible print or type and in a size no less than one-half the size of the type of the descriptive term but in no case less than one-sixteenth of an inch in height.

(2) Any claim for the absence of a nutrient in a products that has not been specially processed, altered, formulated or reformulated so as to eliminate the nutrient from the product shall indicate that the product inherently meets the criteria for that descriptor and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches. It shall not bear the descriptive term immediately preceding the name of the product because such terminology would imply that the product has been altered compared to other products of the same type.

(f) A nutrient content claim shall be, in type size and style, no larger than that of the statement of identity.

(g) The label or labeling of a product for which a nutrient content claim is made shall contain prominently and in immediate proximity to such claim the following referral statement: "See _____ for nutrition information" with the blank filled in with the identity of the panel on which nutrition labeling is located.

(1) The referral statement "See [*appropriate panel*] for nutrition information" shall be in easily legible boldface print or type in distinct contrast to other printed or graphic matter and no less than one-half the size of the type of the descriptive term but in no case less than one-sixteenth of an inch in height.

(2) The referral statement shall be immediately adjacent to the descriptive term and may have no intervening material other than the statement of identity. If the descriptive term appears on more than one panel of the label, the referral statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information.

(3) If a single panel of a label or labeling contains multiple nutrient content claims or a single claim repeated several times, a single referral statement may be made. The statement shall be adjacent to the claim that is printed in the largest type on that panel.

(h) In place of the referral statement described in paragraph (g) of this section, if a product contains more than 11.5 grams of fat, 4.0 grams of saturated fat, 45 milligrams of cholesterol, or 360 milligrams of sodium per reference amount customarily consumed (RACC), labeled serving size or per 100 grams, then that product must disclose, as part of the referral statement, that the nutrient exceeding the specified level is present in the product as follows: "See [*appropriate panel*] for information about [*nutrient requiring disclosure*] and other nutrients"; e.g., "See side panel for information about fats and other nutrients."

(i) The label or labeling of a product may contain a statement about the amount or percentage of a nutrient which implies that the product is high or low in that nutrient if the product actually meets the definition for either "high" or "low" as defined for the nutrient which the label addresses. Such a claim might be "Contains 100 mg of sodium per serving."

(j) Products may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a

reference food. These statements shall be known as "relative claims" and include "reduced", "light", and comparative claims.

(1) To bear a relative claim about level of a nutrient, the amount of that nutrient in the product must be compared as specified below to a reference food. Such products are:

(i) For all relative claims, an industrywide norm, i.e., a composite value weighted according to a national market share on a unit or tonnage basis of all the products of the same type as the product for which the claim is made, or

(ii) For reduced and comparative claims only, a manufacturer's regular product which has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name.

(iii) For comparative claims only, a product or class of product whose composition is reported in a current valid data base such as U.S. Department of Agriculture's Handbook 8, *Composition of Foods, Raw, Processed, Prepared.*

(2) For products bearing relative claims:

(i) The label must bear immediately adjacent to such claim in the most prominent location and in type no less than half the size of the type of the claim but no less than one-sixteenth inch, the following accompanying information:

(A) The percentage (or fraction) of the amount of the nutrient in the reference food by which the nutrient has been modified, (e.g., "50% less fat," "⅓ fewer calories"), and

(B) The identity of the reference food, and

(C) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that of the reference food.

(ii) The most prominent location shall be determined by the following order:

(A) A claim on the principal display panel adjacent to the statement of identity,

(B) A claim elsewhere on the principal display panel,

(C) A claim on the information panel, or

(D) A claim elsewhere on the label.

(iii) Relative claims for decreased levels of nutrients may be made on the label or in labeling of a product only if the nutrient content for that nutrient differs from that of the reference food by more than the amount specified in the definition of "low" for that nutrient.

(k) The term "modified" may be used in the statement of identity of a product that bears a comparative claim in conformance with the requirements of this subpart, followed immediately by the name of the nutrient whose content has been altered; e.g., "Modified fat ground turkey." This statement of identity must be immediately followed by the comparative statement such as "Contains 35% less fat than _____ and all other information required in paragraph (j)(2) of this section for comparative claims.

(l) For purposes of making a claim, a "meal-type product" shall be defined as a product that:

(1) Makes a significant contribution to the diet by:

(i) Providing at least 200 calories per serving (container), or

(ii) Weighing at least 6 ounces per serving (container), and

(2) Contains ingredients from two or more of the following four food groups:

(i) Bread, cereal, rice and pasta group,

(ii) Fruits and vegetables group,

(iii) Milk, yogurt, and cheese group, and

(iv) Meat, poultry, fish, dry beans, eggs, and nuts group.

(3) Is represented as, or is in a form commonly understood to be a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Such representations may be made either by statements, photographs, or vignettes.

(m) [Reserved]

(n) Compliance with requirements for nutrient content claims will be determined using analytical methodology prescribed for determining compliance with nutrition labeling in § 317.309(g) of this subpart.

(o) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991 may continue to be used as part of that brand name, provided they are not false or misleading under section 4(h) of the Act (21 U.S.C. 453(h)(4)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food in relation to a reference daily intake (RDI) as defined in 21 CFR 101.9(c) may be made on the label.

(4) The requirements of this section do not apply to products for special dietary use as described in § 381.124.

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991 are not subject to the requirements of paragraphs (b), (g), and (h) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by USDA. Petitions requesting approval of such a claim (e.g., healthy) may be submitted pursuant to § 381.469.

§§ 381.414-381.442 [Reserved]

§ 381.443 Significant participation for voluntary nutrition labeling.

(a) In evaluating significant participation for voluntary nutrition labeling, FSIS will consider only the major cuts of single-ingredient, raw poultry products, as identified in § 381.444, including those that have been frozen.

(b) FSIS will judge a food retailer to be participating at a significant level if the retailer provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw poultry products, listed in § 381.444, that it sells, and if the nutrition label is consistent in content and format with the mandatory program, or nutrition information is displayed at point-of-purchase in an appropriate manner.

(c) To determine whether there is significant participation by retailers under the voluntary nutrition labeling guidelines, FSIS will select a representative sample of companies allocated by type and size.

(d) FSIS will find that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated are participating in accordance with the guidelines.

(e) FSIS will evaluate significant participation of the voluntary program every 2 years beginning in May 1995.

(1) If significant participation is found, the voluntary nutrition labeling guidelines shall remain in effect.

(2) If significant participation is not found, FSIS shall initiate rulemaking to require nutrition labeling on those products under the voluntary program.

§ 381.444 Identification of the major cuts of poultry products.

The major cuts of poultry products are: Whole chicken, chicken breast, chicken wing, chicken drumstick, chicken thigh, whole turkey, turkey breast, turkey wing, turkey drumstick, and turkey thigh.

§ 381.445 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.

(a) Nutrition information on single-ingredient, raw poultry products, including those that have been

previously frozen, shall be provided in the following manner:

(1) If a retailer chooses to provide nutrition information on the label of these products, the products shall be subject to all requirements of the mandatory nutrition labeling program, except that nutrition labeling may be declared on the basis of either "as consumed" or "as packaged." In addition, the declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw poultry products, including those that have been previously frozen.

(2) If a retailer chooses to provide nutrition information at the point-of-purchase by an appropriate means, such as by posting a sign, or by making the information available in brochures, notebooks, or leaflet form in close proximity to the food, nutrition information shall be provided as specified in this subpart for the mandatory nutrition labeling program. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(b) The declaration of nutrition information shall be presented in an abbreviated format as specified in § 381.409(e) of this subpart for the mandatory nutrition labeling program.

(c) The nutrition label data should be based on either raw or cooked edible portions of poultry cuts with skin. If data are based on cooked portions, the methods used to cook the products must be specified and should be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the cooked edible portions of the skinless poultry meat.

(d) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series, may be used for nutrition labeling of single-ingredient, raw poultry products, including those that have been previously frozen. These data may be composite data that reflect different classes of turkey or other variables affecting nutrient content. Alternatively, data that reflect specific, classes or other variables may be used, except that if data are used on labels attached to a product which is labeled as to class of poultry or other variables, the data must represent the product in the package when such data are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible poultry tissues present in the package.

(e) If the nutrition information is in accordance with paragraph (d) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 381.409(g), unless a nutrition claim is made on the basis of the representative data base values.

(f) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw poultry products, including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (d) of this section and the requirements specified in this subpart for the mandatory nutrition labeling program.

§§ 381.446–381.453 [Reserved]

§ 381.454 Nutrient content claims for "source" and "high".

(a) *General requirements.* Except as provided in paragraph (e) of this section, the following nutrient content claims about a nutrient in a product in relation to the Reference Daily Intake (RDI) established for that nutrient in 21 CFR 101.9(c)(11)(iv) or Daily Reference Value (DRV) established for that nutrient in 21 CFR 101.9(c)(12)(i), excluding total carbohydrates and unsaturated fatty acids, may be used on the label or in labeling, provided that:

(1) The product is labeled in compliance with § 381.409, and

(2) The nutrient content claim complies with the requirements of § 381.413.

(b) *High.* The term "high" may be used on the label or in labeling of a product:

(1) When the product (except meal-type products as described in § 381.413(l)) contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed (RACC) and per labeled serving, or

(2) If it is a meal-type product as described in § 381.413(l) and it contains per 100 grams of product, an amount of the nutrient that is equal to 20 percent or more of the RDI or DRV.

(c) *Source.* The term "source" may be used on the label or in labeling of a product:

(1) When the product (except meal-type products as described in § 381.413(l)) contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed (RACC) and per labeled serving, or

(2) If it is a meal-type product as described in § 381.413(l), and it contains per 100 grams of product, an amount of the nutrient that is equal to 10–19 percent of the RDI or DRV.

(d) *Fiber claim.* If a nutrient content claim is made with respect to the level of dietary fiber, that is, the product is high in fiber or a source of fiber and the product is not low in total fat as defined in § 381.462(b), then the label must disclose the level of total fat as part of the referral statement, e.g., "See [*appropriate panel*] for nutrition information. Contains [*x amount*] of total fat per serving."

(e)(1) *More.* A comparative claim using the term "more" may be used to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, provided that:

(i) The product contains at least 10 percent of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber, or potassium more than the reference food that it resembles and for which it substitutes; and

(ii) As required in § 381.413(j) for relative claims, the percentage (or fraction) that the nutrient was increased relative to the RDI or DRV; the identity of the reference food; and clear and concise quantitative information comparing the level of the nutrient in the product per labeled serving, with that of the reference food it replaces are declared in immediate proximity to the most prominent such claim.

(2) A comparative claim using the term "more" may be used to describe the level of carbohydrates in a product, provided that the product contains at least 10 percent of the DRV for carbohydrates more than the reference food and the difference between the two products is only complex carbohydrates as defined in 21 CFR 101.9(c)(6)(i). The product must also meet the requirement of paragraph (e)(1)(ii) of this section.

(3) A comparative claim using the term "more" may be used to describe the level of unsaturated fat in a product, provided that the level of total fat is not increased and the level of trans fatty acids does not exceed 1 percent. The reference food must also meet the requirements of paragraph (e)(1)(ii) of this section.

§ 381.455 [Reserved]

§ 381.456 Nutrient content claims for "light" or "lite".

(a) *General requirements.* The following nutrient content claims using the term "light" or "lite" to describe a product may be used on the label and in labeling, provided that:

(1) The product is labeled in compliance with § 381.409, and

(2) The nutrient content claim complies with the requirements of § 381.413.

(b) The terms "light" or "lite" may be used without further qualification to describe a product, provided that:

(1) The product has at least a one-third (33⅓%) reduction in the number of calories compared to a reference food as specified in § 381.413(j)(1)(i) with a minimum reduction of more than 40 calories per reference amount customarily consumed (RACC) and per labeled serving;

(2) If it derives more than 50 percent of its calories from fat, its fat content is reduced by 50 percent or more compared to the reference food that it resembles or for which it substitutes as specified in § 381.413(j)(1)(i) with a minimum reduction of more than 3 grams per reference amount customarily consumed (RACC) and per labeled serving; and

(3) As required in § 381.413(j) for relative claims, the percent (or fraction) that the calories, and, if appropriate, the fat, were reduced; the identity of the reference food; and clear and concise quantitative information comparing the level of calories and, if appropriate, fat content, in the product per labeled serving, with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., "⅓ fewer calories and 50% less fat than our regular Italian sausage: Lite Italian turkey sausage 200 calories, 4 grams fat; regular Italian turkey sausage 300 calories, 8 grams fat per serving.").

(c) A product, other than a salt substitute, that is low, reduced or otherwise altered in sodium content cannot use the term "light" solely because of this alteration but rather must use, as appropriate, the term "reduced sodium" or "low sodium."

(d) The term "light" or "lite" may be used to describe a salt substitute if the sodium content of the product has been reduced by at least 50 percent compared to ordinary table salt.

(e) The term "light" or "lite" may not be used to refer to a product that is not reduced in calories by one-third, and, if applicable, fat by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the product such as texture or color and the qualifying information, so stated, clearly conveys the nature of the product, and

(2) The qualifying information is in the same type size, style, color and prominence as the word "light" and in immediate proximity thereto.

(f) [Reserved]

§§ 381.457–381.459 [Reserved]

§ 381.460 Nutrient content claims for calorie content.

(a) *General requirements.* The following nutrient content claims about the calorie content of a product may be used on the label or in labeling, provided that:

(1) The product is labeled in compliance with § 381.409, and

(2) The nutrient content claims comply with the requirements of § 381.413.

(b) *Calorie content claims.* (1) The terms "calorie free", "free of calories", "no calories", or "zero calories" may be used on the label or in labeling of a product that usually contains or substitutes, as specified in § 381.413(e)(1), for a product that usually contains calories, provided that:

(i) The product contains less than 5 calories per reference amount customarily consumed (RACC) and per labeled serving.

(ii) If a product meets this condition without the benefit of special processing, alteration, formulation or reformulation to lower the caloric content, it is labeled to disclose that calories are not usually present in the product.

(2) The terms "low calorie", "low in calories", or "a low calorie food" may be used on the label or in labeling of products (except meal-type products as described in § 381.413(l)), provided that:

(i) The product does not provide more than 40 calories per reference amount customarily consumed (RACC) and per labeled serving, and

(ii) The product does not provide more than 40 calories per 100 grams or is a sugar substitute.

(iii) If a product meets these conditions without the benefit of special processing, alteration, formulation or reformulation to vary the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms "low calorie", "low in calories", or "low calorie meal" may be used on the label or in labeling of meal-type products, provided that the meal contains 105 calories or less per 100 grams of product and meets the requirement of paragraph (b)(2)(iii) of this section.

(4) The terms "reduced calorie", "reduced in calorie", or "calorie reduced" may be used to describe a product (except mealtype products as described in § 381.413(l)), provided that:

(i) The product has been specifically formulated or processed to reduce its calorie content by 33⅓ percent or more with a minimum reduction of more than 40 calories per reference amount customarily consumed (RACC) and per labeled serving from the reference food that it resembles and for which it substitutes as specified in § 381.413(j)(l) (i) and (ii); and

(ii) As required in § 381.413(j) for relative claims, the percent (or fraction) that the calories were reduced; and the identity of the reference food is declared; and clear and concise quantitative information comparing the level of the nutrient in the product per labeled serving with that of the reference food that it replaces in immediate proximity to the most prominent such claim (e.g., "33⅓percent fewer calories than regular salami. Calorie content has been reduced from 150 to 100 calories per serving").

(5) A comparative claim using the term "fewer" may be used on the label or in labeling of a product, including meal type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent fewer calories, with a minimum reduction of more than 40 calories per reference amount customarily consumed (RACC) and per labeled serving, than the reference food that it resembles and for which it substitutes as specified in § 381.413 (j)(1)(i) (ii) and (iii); and

(ii) As required in § 381.413(j) for relative claims, the percent (or fraction) that the calories were reduced; the identity of the reference food; and clear and concise quantitative information comparing the level of the calories in the product per labeled serving with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., "This Italian turkey sausage contains 25 percent fewer calories than our regular Italian turkey sausage. Calorie content has been lowered from 200 to 150 calories per serving.").

(c) *Use of terms such as "sugars free", "no sugars", or "zero sugars".* (1) Consumers may reasonably be expected to regard terms that represent that the product contains no sugars or sweeteners, e.g., "sugars free" or "no sugars", as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a product may not be labeled with such terms unless:

(i) The product contains less than 0.5 grams of sugars, as defined in 21 CFR 101.9(c)(6)(ii)(A) per reference amount customarily consumed (RACC) and per labeled serving;

(ii) The product contains no added ingredients that are sugars; and

(iii) (A) It is labeled "low calorie" or "reduced calorie" or bears a comparative claim of special dietary usefulness labeled in compliance with paragraph (b) (2), (3), or (4) of this section, or

(B) Such term is immediately accompanied, each time it is used, by the statement "Not a reduced calorie food", "Not a low calorie food", or "Not for weight control."

(2) The terms "no added sugars", "without added sugars", or "no sugars added" may be used, provided:

(i) No amount of sugars as defined in 21 CFR 101.9(c)(6)(ii)(A) is added during processing or packaging;

(ii) The product does not contain ingredients containing added sugars such as jam, jelly, and concentrated fruit juice;

(iii) The sugars or content has not been increased above the amount naturally present in the ingredient(s) by some means such as the use of enzymes;

(iv) The product that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement indicating that the product is not low calorie or calorie reduced (unless the product meets the requirements for a low or reduced calorie product) and directing consumers' attention to the nutrition panel for further information on sugars and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a product is unsweetened or contains no added sweeteners in the case of a product that contains apparent substantial inherent sugar content, e.g., juices.

§ 381.461 Nutrient content claims for sodium content.

(a) *General requirements.* The following nutrient content claims about the sodium content of a product may be used on the label and in labeling, provided that:

(1) The product is labeled in compliance with § 381.409; and

(2) The nutrient content claims comply with § 381.413.

(b) *Sodium content claims.* (1) The terms "sodium free", "free of sodium", "no sodium", or "zero sodium" may be used on the label or in labeling of a product that usually contains or substitutes as specified in § 381.423(e)(1) for a product that usually contains sodium, provided that:

(i) The product contains less than 5 milligrams of sodium per reference amount customarily consumed (RACC) and per labeled serving; and

(ii) The product contains no ingredient that is salt (sodium chloride); and

(iii) If a product meets this condition without the benefit of special processing, alteration, formulation or reformulation to lower the sodium content, it is labeled to disclose that sodium is not usually present in the product, e.g., "_____, a sodium free food."

(2) The terms "very low sodium", "very low in sodium", and "a very low sodium food" may be used on the label or in labeling of products (except meal-type products as described in § 381.413(l)), provided that:

(i) The product does not provide more than 35 milligrams of sodium per reference amount customarily consumed (RACC) and per labeled serving, and

(ii) The product does not provide more than 35 milligrams of sodium per 100 grams.

(iii) If a product meets these conditions without the benefit of special processing, alteration, formulation or reformulation to vary the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches (e.g., "_____, a very low sodium food").

(3) The term "very low sodium", "very low in sodium", or "very low sodium meal" may be used on the label or in labeling of meal-type products as defined in § 381.413(l), provided that the meal contains 35 milligrams or less of sodium per 100 grams of product and meets the requirement of paragraph (b)(2)(iii) of this section.

(4) The terms "low sodium", "low in sodium", or "a low sodium food" may be used on the label or in labeling of products (except meal-type products as defined in § 381.413(l)), provided that:

(i) The product does not provide more than 140 milligrams of sodium per reference amount customarily consumed (RACC) and per labeled serving; and

(ii) The product does not provide more than 140 milligrams of sodium per 100 grams.

(iii) If a product meets these conditions without the benefit of special processing, alteration, formulation or reformulation to vary the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches (e.g., "_____, a low sodium food").

(5) The term "low sodium", "low in sodium", or "low sodium meal" may be used on the label or in labeling of meal-type products as described in § 381.413(l), provided that the meal contains 140 milligrams or less sodium per 100 grams of product and meets the requirement of paragraph (b)(4)(iii) of this section.

(6) The term "reduced sodium", "reduced in sodium", or "sodium reduced" may be used to describe a product (except meal-type products as defined in § 381.413(l)), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its sodium content by 50 percent or more with a minimum of more than 140 milligrams per reference amount customarily consumed (RACC) and per labeled serving from the reference food that it resembles and for which it substitutes as specified in § 381.413(j)(1) (i) and (ii); and

(ii) As required in § 381.413(j) for relative claims, the percent (or fraction) that the sodium was reduced; the identity of the reference food; and clear and concise quantitative information comparing the level of the sodium in the product per labeled serving with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium—50 percent less sodium that regular _____. Sodium content has been reduced from 300 to 150 milligrams of sodium per serving.").

(7) A comparative claim using the term "less" may be used on the label or in labeling of a product including meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less sodium with a minimum reduction of more than 140 milligrams per reference amount customarily consumed (RACC) and per labeled serving than the reference food that it resembles and for which it substitutes as specified in § 381.413(j)(l) (i), (ii), and (iii); and

(ii) As required in § 381.413(j) for relative claims, the percent (or fraction) that the sodium was reduced; the identity of the reference food; and clear and concise quantitative information comparing the level in the sodium in the product per labeled serving with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., "This chicken noodle soup contains 25% less sodium than our regular chicken noodle soup. Sodium content has been lowered from 300 to 325 milligrams per serving.").

(c) The term "salt" is not synonymous with "sodium." Salt refers to sodium chloride. However, references to salt content such as "unsalted", "no salt", and "no salt added" are potentially misleading.

(1) The term "salt free" may be used on the label or in labeling of products only if the product is "sodium free" as defined in paragraph (b)(1) of this section.

(2) The terms "unsalted", "without added salt", and "no salt added" may be used on the label or in labeling of products, provided:

(i) No salt is added during processing;

(ii) The product that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the product is not sodium free, such claims are immediately accompanied each time they are used, by the statement, "Not a sodium free food" or "Not for control of sodium in the diet."

§ 381.462 Nutrient content claims for fat, fatty acids, and cholesterol content of poultry products.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a poultry product may only be made on the label and in the labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The poultry product for which the claim is made is labeled in accordance with § 381.409.

(b) *Fat content claims.* (1) The terms "fat free", "free of fat", "no fat", "zero fat", or "nonfat" may be used on the label or in labeling of a poultry product, provided that:

(i) The product contains less than 0.5 gram of fat per reference amount customarily consumed and per labeled serving size;

(ii) The product contains no added ingredient that is a fat or oil; and

(iii) As required in § 381.413(e)(2), if the poultry product meets these conditions without the benefit of special processing, alteration, formulation or reformulation to lower fat content, it is labeled to disclose that fat is not usually present in the product.

(2) The terms "low fat" or "low in fat" may be used on the label or in labeling of poultry products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains 3 grams or less of fat per reference amount customarily consumed, per labeled serving size, and per 100 grams of product; and

(ii) If the poultry product meets these conditions without the benefit of special processing, alteration, formulation or reformulation to lower fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms "low fat" or "low in fat" may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 3 grams or less of fat per 100 grams; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation or reformulation to lower fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms "reduced fat", "reduced in fat", or "fat reduced" may be used on the label or in labeling of a product, except meal-type products as defined in § 381.413(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its fat content by 50 percent or more, with a minimum reduction of more than 3 grams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 381.413(j)(1) (i) and (ii); and

(ii) As required in § 381.413(j)(2) for relative claims, the percent (or fraction) that the fat has been reduced, the identity of the reference food, and quantitative information comparing the level of fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 381.413(j)(2)(ii) (e.g., "Reduced fat—50 percent less fat than our regular ground turkey. Fat content has been reduced from 28 grams to 14 grams per serving.").

(5) A comparative claim using the term "less" may be used on the label or in labeling of a poultry product, including meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less fat, with a minimum reduction of more than 3 grams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 381.413(j)(2) (i), (ii), and (iii); and

(ii) As required in § 381.413(j)(2) for relative claims, the percent (or fraction) that the fat has been reduced, the identity of the reference food, and the quantitative information comparing the level of fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 381.413(j)(2)(ii) (e.g., "This _____ contains 40 percent less fat than _____. Fat content has been lowered from 9 grams to 5.5 grams per serving.").

(6) The term "_____ percent fat free" may be used on the label or in labeling of a poultry product, provided that:

(i) The product meets the criteria for "low fat" in paragraph (b) (2) or (3) of this section.

(ii) The label or labeling discloses the amount of total fat per serving (as declared on the label) of the poultry product expressed in grams to the nearest one-half gram. When the total fat content is less than 0.5 grams per serving, the amount may be declared as "0." Such disclosure shall appear in immediate proximity to the most prominent such claim as defined in § 381.413(j)(2)(ii) and in type size that shall be no less than one-half the size of the type used for such claim.

(iii) The percent of reduction and the words "fat free" are in uniform type size.

(iv) A claim for "100 percent fat free" meets all criteria for "fat free" in paragraph (b)(1) of this section.

(c) *Fatty acid content claims.* The label or labeling of poultry products that bear claims with respect to the level of saturated fat shall disclose the level of total fat and cholesterol in the product in immediate proximity to such claim each time the claim is made and in type that shall be no less than one-half the size of the type used for the claim with respect to the level of saturated fat. Declaration of cholesterol content may be omitted when the product contains less than 2 milligrams of cholesterol per labeled serving size.

(1) The terms "low in saturated fat" or "low saturated fat" may be used on the label or in labeling of a poultry product, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains 1 gram or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and not more than 15 percent of calories from saturated fatty acids; and

(ii) If a product meets these conditions without benefit of special processing, alteration, formulation or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(2) The terms "low in saturated fat" or "low saturated fat" may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 1 gram or less of saturated fatty acids per 100 grams of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to

the particular brand to which the label attaches.

(3) The terms "reduced saturated fat", "reduced in saturated fat", or "saturated fat reduced" may be used on the label or in labeling of a poultry product, except meal-type products as defined in § 381.413(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its saturated fatty acid content by 50 percent or more, with a minimum reduction of more than 1 gram per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 381.413(j)(1) (i) and (ii); and

(ii) As required in § 381.413(j)(2) for relative claims, the percent (or fraction) that the saturated fat was reduced, the identity of the reference food, and the quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 381.413(j)(2)(ii) (e.g., "Reduced saturated fat. Contains 50 percent less saturated fat than the national average for _____. Saturated fat reduced from 14 grams to 7 grams per serving").

(4) A comparative claim using the term "less" may be used on the label or in labeling of a poultry product, including meal-type products as defined in § 381.413(l), provided that:

(i) The product contains 25 percent less saturated fat with a minimum reduction of more than 1 gram per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 381.413(j)(1) (i), (ii), (iii); and

(ii) As required in § 381.413(j)(2) for relative claims, the percent (or fraction) that the saturated fat was reduced, the identity of the reference food, and quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 381.413(j)(2)(ii) (e.g., "Brand Y _____ contains 40 percent less saturated fat than our regular Brand X _____. Brand Y contains 6 grams of saturated fat; Brand X contains 10 grams of saturated fat.").

(d) *Cholesterol content claims.* (1) The terms "cholesterol free", "free of cholesterol", "zero cholesterol", or "no cholesterol" may be used on the label or in labeling of a poultry product, provided that:

(i) For products that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams of product:

(A) The product contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size;

(B) The product contains 2 grams or less of saturated fat per reference amount customarily consumed and per labeled serving size;

(C) As required in § 381.413(e), if the product contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size without the benefit of special processing, alteration, formulation or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the product.

(ii) For products that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of product:

(A) The product contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size;

(B) The product contains 2 grams or less of saturated fat per reference amount customarily consumed and per labeled serving size; and

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the product. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 381.413(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim appears more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 381.413(e), if the poultry product contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the product, or

(E) If the product contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meet requirements of paragraph (d)(5)(i)(A) of this section) than the product for which it substitutes as specified in § 381.413(d) that has a significant (i.e., 5 percent or more) market share. As required in § 381.413(j)(2) for relative claims, the percent (or fraction) that the cholesterol was reduced, the identity of the reference food, and the quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 381.413(j)(2)(ii).

(2) The terms "low in cholesterol" or "low cholesterol" may be used on the label or in labeling of a poultry product, except meal-type products as defined in § 381.413(l), provided that:

(i) For products that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams of product:

(A) The product contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of product;

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size;

(C) As required in § 381.413(e), if the product contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of product without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of that type and not merely to the particular brand to which the label attaches.

(ii) For products that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of product:

(A) The product contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of product;

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the product. Such disclosure shall appear in immediate proximity to such claim

preceding the referral statement required in § 381.413(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 381.413(e)(2), the product contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of product without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of that type and not merely to the particular brand to which the label attaches, or

(E) If the product contains 20 milligrams or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(5)(i)(A) of this section) than the food for which it substitutes as specified in § 381.413(d) that has a significant (i.e., 5 percent or more) market share. As required in § 381.413(j)(2) for relative claims, the percent (or fraction) that the cholesterol has been reduced, the identity of the reference food, and the quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food are declared in immediate proximity to the most prominent such claim as defined in § 381.413(j)(2)(ii).

(3) The terms "low in cholesterol" or "low cholesterol" may be used on the label or in labeling of a meal-type product as defined in § 381.413(l) provided that the product meets the requirements of paragraph (d)(2) of this section except that the determination as to whether paragraph (d)(2)(i) or (ii) of this section applies to the product will be made only on the basis of whether the product contains 11.5 grams or less of fat per 100 grams of product, the requirement in paragraphs (d)(2) (i)(A) and (ii)(A) of this section shall be limited to 20 milligrams of cholesterol per 100 grams, and the requirement in paragraphs (d)(2) (i)(B) and (ii)(B) of this section shall be modified to require that the product contain 2 grams or less of saturated fat per 100 grams rather than per reference amount customarily consumed and per labeled serving size.

(4) The terms "reduced cholesterol", "reduced in cholesterol", or "cholesterol reduced" may be used on the label or in labeling of a poultry product or a product that substitutes for that food as specified in § 381.413(d), except meal-type products as defined in § 381.413(l), provided that:

(i) For products that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams:

(A) The product has been specifically formulated, altered, or processed to reduce its cholesterol content by 50 percent or more, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size from the reference food that it resembles and for which it substitutes as defined in § 381.413(j)(1)(i) and (ii);

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) As required in § 381.413(j)(2) for relative claims, the percent that the cholesterol has been reduced, the identity of the reference food, and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 381.413(j)(2)(ii). (ii) For products that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of product:

(A) The product has been specifically formulated, altered, or processed to reduce its cholesterol content by 50 percent or more, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food (as defined in § 381.413(j)(1) (i) and (ii)) that it resembles and for which it substitutes as specified in § 381.423(d) that has a significant (i.e., 5 percent or more) market share;

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the product. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 381.413(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 381.413(j)(2) for relative claims, the percent (or fraction) that the cholesterol has been reduced, the identity of the reference food, and the quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food it replaces are declared in immediate proximity to the most prominent such claim as defined in § 381.413(j)(2)(ii).

(5) A comparative claim using the term "less" may be used on the label or in labeling of a product or a product that substitutes for that product as specified in § 381.413(d), including meal-type products as defined in § 381.413(l), provided that:

(i) For products that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams:

(A) The product contains at least 25 percent less cholesterol, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 381.413(j)(1) (i), (ii), and (iii).

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) As required in § 381.413(j)(2) for relative claims, the percent that the cholesterol was reduced, the identity of the reference food, and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food are declared in immediate proximity to the most prominent such claim as defined in § 381.413(j)(2)(ii).

(ii) For products that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of product:

(A) The product contains at least 25 percent less cholesterol with a minimum reduction of 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food as defined in § 381.413(j)(1) (i), (ii), and (iii), that it resembles and for which it substitutes as specified in § 381.413(d) that has a significant market share (i.e., 5 percent or more);

(B) The product contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the product. Such disclosure shall appear each time the claim is made, in immediate proximity to such claim preceding the referral statement required in § 381.413(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and 248 ¶

(D) As required in § 381.413(j)(2) for relative claims, the percent (or fraction) that the cholesterol was reduced, the identity of the reference food, and the quantitative information comparing the level of cholesterol in the product per label serving size with that of the reference food it replaces are declared in immediate proximity to the most prominent such claim as defined in § 381.413(j)(2)(ii) (e.g., "This turkey omelette contains 30 percent less cholesterol than our regular omelette. Cholesterol lowered from 45 milligrams to 30 milligrams per serving. Contains I2 grams of fat per serving.").

(e) *Lean and Extra Lean Claims.* (1) The term "lean" may be used on the label or in labeling of a poultry product, provided that the product contains less than 10.5 grams of fat, less than 3.5 grams of saturated fat, and less than 94.5 milligrams of cholesterol per 100 grams.

(2) The term "extra lean" may be used on the label or in labeling of a poultry product, provided that the product contains less than 4.9 grams of fat, less than 1.8 grams of saturated fat, and less than 94.5 milligrams of cholesterol per 100 grams.

§§ 381.463-381.468 [Reserved]

§ 381.469 Petitions for nutrient content claims.

(a) This section pertains to petitions for claims, expressed or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Petitions included in this section are (1) petitions for a new (heretofore unauthorized) nutrient content claim, (2) petitions for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and (3) petitions for the use of an implied claim in a brand name.

(c) Petitions to be filed under this section shall be submitted in quadruplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address.

(d) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies are included in a petition, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter I, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations are included, the petition shall include statements regarding each such clinical investigation relied upon in the petition that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter I, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter I, title 21.

(g) The availability for public disclosure of petitions submitted to the agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application from the petitioner, the present petition must provide the data.

(i) The petition must be signed by the petitioner or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The petition shall include a statement signed by the person responsible for the petition, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the petition.

(k) (1) Petitions for a new nutrient content claim shall include the following data and be submitted in the following form.

(Date)

Name of petitioner _____

Post-office address _____

Subject of the petition _____

FSIS Hearing Clerk, Regulations Development Unit, Policy Office, Food Safety and Inspection Service,

U.S. Department of Agriculture, Washington DC 20250.

Dear Sirs: The undersigned, _____ submits this petition pursuant to 9 CFR 381.469 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the descriptive term and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement should address why the use of the term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

B. A detailed explanation supported by any necessary data, of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose. The petition should also include data and information, e.g., surveys to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

C. Analytical data that demonstrates the amount of the nutrient that is the subject of the claim, that is present in the products for which the claim is intended. The assays should be performed on representative samples using the Association of Official Analytical Chemists (AOAC) methods where available. If no AOAC method is available, the petitioner shall submit the assay method

used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data should include a statistical analysis of the analytical and product variability.

D. A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The latter item should specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis should specifically address the dietary practices of such group, and should include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner _____
By _____
(Indicate authority)

(2) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner (i) that the petition is undergoing Agency review and the petitioner will subsequently be notified of the Agency's decision to file or deny the petition; or (ii) that the petition is incomplete, e.g., one that lacks any of the data required by this section, one that states such data in a manner that is not readily understood, or one that has not been submitted in quadruplicate, in which case the petition will be denied and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 100 days of the date of receipt of the petition, the Administrator will notify the petitioner by letter that the petition has either been filed or denied. If denied, the notification shall state the reasons therefor. If filed, the date of the notification letter becomes the date of filing. A petition that has been denied shall not be made available to the public. A filed petition shall be available to the public as provided under paragraph (e) of this section.

(4) Within 90 days of the date of filing, the Administrator will, by letter of notification to the petitioner, (i) deny the petition, or (ii) inform the petitioner that a proposed regulation to provide for the requested use of the new term will be published in the **Federal Register**. The Administrator will publish the proposal to amend the regulations to provide for the requested use of the nutrient content claim in the **Federal Register** within 90 days of the date of filing. The proposal will also announce the availability of the petition for public disclosure.

(l)(1) Petitions for a synonymous term shall include the following data and be submitted in the following form.

_____
(Date)
Name of petitioner _____
Post-office address _____
Subject of the petition _____
FSIS Hearing Clerk, Regulations Development Unit, Policy Office, Food Safety and Inspection Service,
U.S. Department of Agriculture, Washington, DC 20250.

Dear Sirs: The undersigned, _____ submits this petition pursuant to 9 CFR 381.469 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart Y of this part).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the synonymous descriptive term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement should address why the use of the synonymous term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

B. A detailed explanation supported by any necessary data, of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This item shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing term defined by regulation. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose. This item shall also include data and information, e.g., surveys, to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

C. A detailed analysis of the potential effect of the use of the proposed claim on food consumption and any corresponding changes in nutrient intake. The latter item should specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis should specifically address the dietary practices of such group, and should include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner _____
By _____
(Indicate authority)

(2) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner (i) that the petition is undergoing Agency review and the petitioner will subsequently be notified of the Agency's decision to grant the petitioner permission to use the proposed term or to deny the petition; or (ii) that the petition is incomplete, e.g., one that lacks any of the data required by this part, one that states such data in a manner that is not readily understood, or one that has not been submitted in quadruplicate, in which case the petition will be denied and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 90 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and subsequently denied), the Administrator will notify the petitioner by letter of the Agency's decision to grant the petitioner permission to use the proposed term, with any conditions or limitations on such use specified, or to deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition.

(4) As soon as practicable following the granting of a petition, the Administrator will publish a notice in the **Federal Register** informing the public of his or her decision. If the petition is granted, the approved synonymous term will be included in the regulations listing terms permitted for use in nutrient content claims.

(m)(1) Petitions for the use of an implied nutrient content claim in a brand name shall include the following data and be submitted in the following form.

_____
(Date)
Name of petitioner _____
Post-office address _____
Subject of the petition _____
FSIS Hearing Clerk, Regulations Development Unit, Policy Office, Food Safety and Inspection Service,
U.S. Department of Agriculture, Washington DC 20250.

Dear Sirs: The undersigned, _____ submits this petition pursuant to 9 CFR 317.369 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement should

address why the use of the brand-name as proposed will not be misleading. The statement should provide examples of the types of products on which the brand name will appear. It should also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient should meet the requirements stated under petition format item C in paragraph (k)(1) of this section.

B. A detailed explanation supported by any necessary data, of why use of the proposed brand name is requested. This item shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose.

C. A detailed analysis of the potential effect of the use of the proposed brand name on food consumption, and any corresponding changes in nutrient intake. The latter item should specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet. If the branded product is intended for a specific group within the population, the analysis should specifically address the dietary practices of such group, and should include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner _____
By _____

(2) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner (i) that the petition is undergoing Agency review or (ii) that the petition is incomplete, i.e., one that lacks any of the data required by this part, one that states such data in a manner that is not readily understood, or one that has not been submitted in quadruplicate, in which case the petition will be denied and the petitioner will be notified as to what respect the petition is incomplete.

(3) The Administrator will publish a notice of the petition in the **Federal Register** announcing its availability to the public and seeking comment on the petition. The petition shall be available to the public to the extent provided under paragraph (e) of this section. The notice shall allow 30 days for comments.

(4) Within 100 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and subsequently denied), the Administrator will (i) notify the petitioner by letter of the Agency's decision to grant the petitioner permission to use the proposed brand name if such use is not misleading, with any conditions or limitations on such use specified, or (ii) deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition. Should the Administrator not notify the petitioner of his or her decision on the petition within 100 days, the petition shall be considered to be granted.

(5) As soon as practicable following the granting of a petition, the Administrator will publish a notice in the **Federal Register** informing the public of such fact.

§§ 381.470–381.479 [Reserved]

§ 381.480 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 381.409 Of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener, e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A product purporting to be "low calorie" must comply with the criteria set forth for such foods in § 381.460(b) (2) and (3).

(d) *"Reduced calorie" foods and other comparative claims.* A product purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 381.460(b) (4) and (5).

§§ 381.481–381.499 [Reserved]

§ 381.500 Exemption from nutrition labeling.

Poultry products used for further processing shall be exempt from nutrition labeling, provided that the labels for these products bear no nutrition claims or nutrition information.

Done at Washington, DC, on October 31, 1991.

Ronald J. Prucha,

Acting Administrator, Food Safety and Inspection Service.

Note: Appendix A to the Preamble will not be codified in the Code of Federal Regulations.

Appendix A to the Preamble

U.S. Department of Agriculture

Food Safety and Inspection Service

Preliminary Regulatory Impact Analysis of Proposed Regulations for Nutrition Labeling of Meat and Poultry Products

I. Introduction

A. Purpose

This analysis is a Preliminary Regulatory Impact Analysis (PRIA) prepared in compliance with the provisions of Executive Order 12291 and the analysis requirement of the Regulatory Flexibility Act (Pub. L. 96–354) dealing with impacts of regulation on small entities. The analysis also includes a Takings Analysis as required by Executive Order 12630. The analysis examines costs, benefits and economic impacts associated with proposed rules for nutrition labeling of meat and poultry products.

As this preliminary analysis will show, the Agency believes that the potential health benefits are substantial and justify the costs that will be incurred. Because of the preliminary nature of this analysis and the magnitude of the costs and benefits involved, FSIS requests that all interested parties, including meat and poultry processors, food retailers, trade associations, health professionals, consumers, etc., submit any additional information regarding the validity of the cost or benefit estimates included in this analysis. FSIS plans to publish a supplement to this PRIA for public comment within 60 days of this proposal. The Agency is particularly interested in receiving early comments on this original PRIA and on the alternatives considered to facilitate formulation of the supplement to the PRIA. FSIS is especially interested in the following questions:

1. What would be the expected percent of meat and poultry products with nutrition labeling under the voluntary section of the various labeling alternatives?

2. What evidence is there that consumers who do not read labels consume less nutritious food because they can no longer

use the mere existence of a label as a convenient and efficient signal of nutritional quality? What health benefits would consumers gain under the various voluntary labeling alternatives?

3. What changes would be expected in the formulation of foods under a mandatory program? That is, to what extent would producers be expected to reformulate products to make them more attractive (from a nutrition standpoint) under a mandatory program?

4. How would market share of currently unlabeled and labeled foods change under a mandatory program?

5. What shifts in consumption patterns would occur between food groups under a mandatory nutrition labeling program?

6. What costs are associated with the prior label approval process? Specifically, does data exist on the length of time it takes to bring a product to market relative to a system where prior approval is not required?

The final RIA will incorporate all comments received on the relative costs and benefits of the proposed rule. FSIS will then consider the conclusions of the final RIA in developing any subsequent final rules based on this proposal.

B. Description of the Proposed Action

The proposed action would permit voluntary nutrition labeling on single-ingredient, raw meat and poultry products and require nutrition labeling for all other meat and poultry products, with the exception of products used for further processing. Under the mandatory nutrition labeling program, small packages and products packaged in other than consumer size packages would have the option of providing nutrition labeling information either on the package or by alternate means. This proposed action applies to products prepared and packaged under Federal or State-inspection programs and products imported into the United States.

As this analysis is being published in its entirety as an appendix to the proposal, a detailed description of the proposed action has not been included herein. The analysis uses the term "processed products" to refer to meat and poultry products that have undergone some manufacturing process such that they are no longer single-ingredient, raw meat and poultry products. The term "fresh" product is used interchangeably with "single-ingredient, raw" product.

C. Need for Federal Regulatory Intervention

As part of the 1990–1991 Regulatory Program, OMB has provided guidance on preparing regulatory impact analyses.[1] That guidance stresses the need to identify the market failure that establishes the potential need for the proposal. One type of market failure is inadequate information. The Regulatory Program provides the following guidance on addressing market failures due to inadequate information.

- Where market failure due to inadequate information is the rationale for government intervention, a regulatory action to improve the availability of information will ordinarily be the preferred alternative.
- Because the current state of knowledge about the economics of information is not highly developed, regulatory intervention to address an information problem should only be undertaken where there is substantial reason to believe that private incentives to provide information are seriously inadequate and that the specific regulatory intervention proposed will provide net benefits for society.

Based on the OMB guidance, FSIS identified four points that need to be addressed in an analysis of a market failure due to inadequate information. These are:

- Identify Market Failure.
- Identity Reason to Believe Private Incentives Inadequate.
- Select Action to Improve Availability of Information.
- Show That Proposed Action Provides Net Benefits.

1. Identification of Market Failure

For this regulatory action the market refers to the supply and demand for nutrition information on the labels of meat and poultry products. Consumer research shows a high and growing demand for nutrition information. For example, in the recent Health and Diet Survey, 74 percent of respondents answered "yes" when asked if they pay attention to nutrition information on labels.[2] Yet, only an estimated 35 to 50 percent of processed meat and poultry products have any nutrition labeling. The Department has concluded that the demand for nutrition labeling exceeds the availability, clearly indicating a market failure.

The market for nutrition information is not a market where consumers can determine the existence of a desired characteristic by inspection of the product before purchase or by use of the product after purchase. It is not a market where consumers can send clear signals to manufacturers through their purchase decisions. Factors such as price and taste obscure the message. The following anecdotal evidence illustrates the current inefficiency in the market for nutrition labeling information:

A large processor that has consistently provided nutrition labeling distributed a new product line without a nutrition panel. Based on the volume of consumer letters and phone calls, they modified their labeling to include a nutrition panel. The costs of modifying the labeling and the costs associated with consumer letters and calls are all costs that can be attributed to the inefficiency in the market for nutrition information.

In economic terms, the costs described above provide evidence of a market with high transaction costs. If transaction costs were zero, consumers would simply identify the level of nutrition information desired and food manufacturers would provide it. Thus, high transaction costs are characteristic of markets where clear communication is difficult. An obvious question to ask is: What will the Nutrition Labeling and Education Act (NFEA) of 1990 do to the transaction costs in the market for nutrition information?

The Department has concluded that there must be harmonization of nutrition labeling between USDA and the Food and Drug Administration (FDA). Different policies will decrease consumer understanding and add to the transaction costs that are already high. This position is supported by public comments responding to the Department's Advance Notice of Proposed Rulemaking (ANPR) on nutrition labeling. For example, a large association stated that harmony with FDA requirements "would prevent unnecessary confusion for the consumer and simultaneously, would minimize the burden of compliance with two different sets of requirements for the food processor. It would further enhance consumer education efforts, * * *" While the exact number of companies that manufacture both USDA and FDA-regulated foods is unknown, it is probably well over a thousand just based on the number of companies that produced items such as soup, frozen pizza, entrees or complete meals. With respect to the comment on consumer education efforts, the Department believes that harmonization is very important for efficient nutrition education programs.

2. Reason Private Incentives Are Inadequate

As identified above, an estimated 35 to 50 percent of processed meat and poultry products have some nutrition labeling. There is reason to believe that private incentives have gone as far as they will go. There is some evidence that voluntary nutrition labeling may have reached a plateau. As the OMB guidance referred to earlier points out, "Sellers are least likely to supply adequate information about a particular characteristic of their product where the characteristic is negatively valued by consumers * * *".

The recent survey of 1,600 products by Public Voice for Food and Health Policy [3] showed that for many product categories, the lower fat and lower caloric products showed higher levels of nutrition labeling. One could argue that there is less nutrition labeling on the products where it is needed most. The Department is not implying that this is a uniform practice, because there are companies that have made the corporate decision to provide nutrition labeling on all products, regardless of nutrient content. The point is that the voluntary program has lower participation for products that have higher levels of the more negatively valued characteristics and there is minimal private incentive for this to change.

3. Action to Improve Availability of Information

The proposed action will require that nutrition information appear on the packages (except very small packages) of processed meat and poultry products that are packaged in consumer-sized packages for sale in retail stores directly to household consumers. This action will provide nutrition information for an estimated 50 to 65 percent of such

[1] Regulatory Program of the United States Government—1990–91, Office of Management and Budget, Appendix V, Regulatory Impact Analysis Guidance.

[2] Results of 1988 Health and Diet Survey, Food Labels and Consumer Food Safety Sources, USDA, FSIS, August 1991.

[3] LEAN ON LABELS: A Survey of Meat and Poultry Products in Today's Marketplace, Public Voice for Food and Health Policy, March 1991.

products that currently are not nutrition labeled. The proposed action will also require that nutrition information be provided with products packaged in bulk for the HRI (hotels, restaurants, and institutions) trade.

4. Show That the Action Provides Net Benefits

Based on the analysis presented in this PRIA, FSIS estimates that the 20-year benefits for the proposed rule are at least $2.0 billion. For the same time period the costs will be $1.3 billion or less, depending on the time allowed for companies to comply with the rule and the availability of data bases to reduce analytical testing costs.

II. Regulatory Options/Summary of Costs and Benefits

A. Introduction

This chapter describes alternatives for providing nutrition information on product labels and provides an overview of the general costs and benefits associated with each alternative.

The alternatives identified focus on improving the availability of information, as opposed to more traditional "command-and-control" forms of regulation. An example of a "command-and-control" option to address the market failure for nutrition information would be standards setting limits for fat, saturated fat, cholesterol, etc., for different categories of meat and poultry products. Requiring nutrition labeling does not restrict product innovation, preserves freedom of choice, does not require any reformulation, and, therefore, should be a less costly regulatory approach than setting of standards.

Research initiated by the former U.S. Regulatory Council [4] cited three advantages of a market oriented approach such as information disclosure:

- Preserves freedom of choice for firms and consumers;
- Is likely to be a less costly remedy to the regulatory problem;
- Impinges less on competition and Innovation.

B. Further Issues

Several further issues could be considered in conjunction with all of the options and will be included in the amended RIA during the comment period. The costs of transition included the loss of label inventories and the development of new labels beyond those already considered in this analysis. These costs could be reduced by grandfathering existing labels, although such an action would increase consumer confusion.

A second issue for further consideration is the possibility of allowing some variation in label formats. As in the case of grandfathering, variations would reduce compliance costs, but possibly increase consumer confusion and reduce health benefits.

A third issue is the possibility of dropping or revising prior label approval, now required by FSIS. With the increase in the number of labels expected under mandatory labeling for processed products, prior approval would either increase administrative costs or, if FSIS resources were not increased, result in delays in approving new labels.

C. Options

Five options were considered for the Preliminary Regulatory Impact Analysis.

- Current Program/Status Quo
- Voluntary Program Consistent with FDA
- Voluntary Program with Incentives
- Mandatory/Voluntary Approach
- Mandatory Nutrition Labeling for all Products

Discussions of each option follow.

1. Current Program/Status Quo

This option is provided to serve as a baseline for considering the other options. The "status quo" option implies no regulatory action. Under this alternative, nutrition labeling would continue to be regulated as it is currently: nutrition labeling is voluntary unless the product label makes a specific nutrition claim, in which case nutrition labeling becomes necessary. The information to be provided on the labels would remain the same as under the current program, and labels would be approved using the same criteria currently in use.

Under the current program, firms may choose between two types of nutrition labels. A detailed label, containmg nutrition information, in the format and style provided by the existing FDA regulations, or an abbreviated format that includes only calories, protein, carbohydrates, and fat per serving of the product. Labels are approved in conjunction with a Nutrition Labeling Verification (NLV) program. FSIS estimates that between 35 and 50 percent of the existing processed meat and poultry products carry nutrition labeling at the present time. (This chapter will use a point estimate of 40 percent to simplify the presentation.)

FDA is in the process of modifying its existing regulations, in accordance with the NLEA. FSIS will have to revise existing policies that make references to FDA regulations.

Although costs and benefits are not usually associated with a "status quo" option, in this case, a number of costs become apparent. The presence of two labeling schemes, three counting the abbreviated format, could confuse consumers and would complicate both the market for nutrition information and existing nutrition education programs. In fact, consumer confusion might even offset some of the health benefits associated with the new nutrition labeling efforts by FDA. In addition, although the status quo option imposes no direct costs on the meat and poultry industry, there are associated administrative costs for firms that produce both FDA-regulated and USDA-regulated products. These firms would have to maintain two different label schemes, with different formats and different nutrient requirements. For some firms, these may be important costs, and may lead some firms to drop out of the voluntary nutrition labeling program for USDA-regulated products. A final cost—and one which would be difficult to quantify—would be loss of confidence by the public in USDA's ability or interest in providing nutrition education.

PRO

- The current program is voluntary, so the benefits to participants can be presumed to exceed their costs.

CON

- Under a voluntary program, products containing large amounts of fat, saturated fat, cholesterol, or sodium are less likely to be labeled. Consumers will make choices they would not make under mandatory labeling.
- Firms which now produce and label USDA-regulated and FDA-regulated products would bear administrative costs associated with maintaining two labeling schemes. For some firms, this might lead to the decision to abandon voluntary nutrition labeling for USDA-regulated products.
- Different labeling schemes would confuse consumers and complicate the market for nutrition information.
- Consumers could lose confidence in USDA's ability or interest in providing nutrition information.

2. Voluntary Labeling, Consistent With FDA

Second option is a voluntary program consistent with the regulations that FDA will publish to implement the NLEA. FSIS would issue rules requiring that all firms that wish to voluntarily provide nutrition information on labels of either fresh or processed meat and poultry products, do so in the manner prescribed by FDA to implement the NLEA.

This option avoids the confusion and multiple labeling schemes that would result from maintaining the status quo. Complying with the new label requirements would increase costs to firms and is likely to reduce the percent of products labeled below the estimated 40 percent currently. The situation is summarized in Table 1.

[4] Information Disclosure, A Practical Guide to the Use of Information Disclosure as a Regulatory Alternative, Project on Alternative Regulatory Approaches, Administrative Conference of the United States, September 1981.

TABLE 1.—BENEFITS AND COSTS OF ALTERNATIVE OPTIONS (RELATIVE TO STATUS QUO) [1]

	Voluntary labeling of all meat and poultry products, consistent with FDA		Voluntary labeling for raw products, mandatory for processed, consistent with FDA	
	6 Months [2]	24 Months [2]	6 Months [2]	24 Months [2]
Manufacturers' Costs (billion dollars)	≤.52	≤.39	1.28	0.97
Health Benefits (billion dollars)	Small	Small	2.0	1.8
Percent of Processed Products Labeled on Final Implementation Date	≤40	≤40	100	100
Benefit/Cost	Uncertain	Uncertain	1.5	1.9

[1] This table contains tentative estimates to be refined in the supplemental PRIA discussed at the beginning of this PRIA.
[2] Time to comply.

A first estimate of compliance costs for voluntary labeling, consistent with FDA is $390 to $520 million depending on whether the time for compliance is lengthened from 6 to 24 months. (This estimated range is based on the estimated costs of $968 million and $1.28 billion for a voluntary/mandatory program with a compliance period of 24 and 6 months, respectively. These cost estimates are developed in detail in the remainder of this impact analysis. The costs presented here are 40 percent of the estimates for the voluntary/mandatory program.) However, taking into account the probable reduction in labeled products, the cost would be expected to be less.

The cost would be less for a second reason also. Because companies already test the voluntary-labeled products for some nutrients and food components, the costs would most likely be less than 40 percent of the total cost of mandatory nutrition labeling for all processed products.

Under the proposed rule, most processed meat and poultry products opting for nutrition labeling would be required to disclose the following: Total calories, Calories from fat, Protein, Saturated fat, Iron, Total fat, Total carbohydrates, Sodium, Cholesterol, Calcium.

Presumably many voluntary-labeled meat and poultry products are not analyzed for the nutrients or food components not currently included on the labels. This option would, therefore, impose substantial analytical costs on firms that would choose to continue using nutrition labeling on a voluntary basis.

Benefits of a totally voluntary program are a result of two counteracting forces, the increase in health benefits from more complete labeling of some products consistent with FDA and the increase in health costs from consumers' unknowing consumption of nutrients they would have avoided if there were no reduction in the number of labeled products. Thus, the benefits become uncertain under voluntary program. Although Table 1 shows the benefit/cost ratio to be uncertain, the counteracting forces may keep benefits below the costs.

PRO

- Products with nutrition labels whether FDA- or USDA-regulated, would be consistent; thereby reinforcing information received by consumers.
- More nutrition information would be available to consumer on those products that continue to be labeled.

CON

- Under a voluntary program, products containing large amounts of fat, cholesterol, and sodium would continue to be less likely to be labeled, as under the current program, thus leading consumers to make choices they would not make under mandatory labeling. Even if consumers assumed that unlabeled products contained more of nutrients whose consumption they wished to reduce, they would not know which nutrient(s) was (were) present in large amounts in an unlabeled product.

Furthermore, it is not clear that consumers equate lack of labeling with nutrients whose consumption they wish to reduce. Research focusing on educated women, assuming education is a proxy for acquisition of available nutrition knowledge, found that as nutrition information became more prevalent the women reduced red meat consumption to avoid fat. However, they substituted other high-fat foods, such as cheese and salad oils, apparently unaware of the fat content of mixtures, such as salads, which contained the high-fat foods. Their total fat intake remained unchanged.[5]

- The increased costs of compliance compared to the current situation could reduce the percent of products labeled below the current estimate of 40 percent. The reduction in labeled products could have negative health benefits, as consumers made choices they would not make if fully informed.
- Positive health benefits associated with increased information on labels might be offset by higher health costs from these uninformed choices due to reduced availability of labeled products.

3. Voluntary Program consistent with FDA, with Compliance Incentives

This option modifies the voluntary program, which requires labeling, if voluntarily chosen, to be consistent with the FDA format. The option would attempt to ameliorate the disadvantage of those options by offering technical assistance, free or subsidized product analysis to small businesses, possibly centrally printed standardized forms, or other positive incentives. The costs of these incentives and the projected industry response will be included in an amendment to the RIA during the comment period.

PRO

- Reduction in compliance costs would limit the reduction in labeled products expected under the voluntary program without incentives
- Centrally monitored and/or implemented activities might be more efficient and reduce duplication, compared with costs incurred by numerous small and/or medium-sized companies under both voluntary labeling without incentives and mandatory labeling.

CON

- Compared with the option for mandatory labeling for processed products, this option would not likely result in all processed meat and poultry products being labeled.
- Compared with mandatory labeling, the fewer labeled products would still result in uninformed consumer choices, probably continued excess consumption of nutrients associated with cancer and heart disease, and therefore, more early deaths.

4. Voluntary Labeling for Raw Products, Mandatory Labeling for Processed Products

This option is the tentative position outlined by FSIS in the Advance Notice of Proposed Rulemaking (ANPR) published on April 2, 1991. That option consists of a mandatory nutrition labeling program for processed meat and poultry products and a voluntary approach for single-ingredient, raw meat and poultry products. Processed products shipped to other establishments for use as ingredients would not be covered by the mandatory program. Raw products using nutrition labeling on a voluntary basis would have to comply with all applicable requirements. The program would apply to the products packaged in federally or State inspected establishments or imported already packaged and labeled for retail sale.

The benefits, discussed in detail in chapter III, are estimated at $2.0 billion over a 20-year period. Benefits are based on an estimate of how consumers will change their food consumption when provided with additional nutrition label information. Changes in dietary intake were used to estimate public health benefits in terms of reduced cancer and coronary heart disease. The model used to estimate benefits did not account for benefits that could result from decreased rates of osteoporosis, obesity, hypertension, etc. As consumers are given more informative labeling in a better format, uncertainty over

[5] Daniel Putler and Elizabeth Frazao, "Diet/Health Concerns About Fat Intake," *Food Review*, Economic Research Service, USDA, January-March, 1991.

the ingredient and nutrient content of the foods they now eat will decrease, and some consumers will select more nutritious, healthier foods.

The main advantages of this program would be widespread, consistent and uniform information provided to consumers on labels and the resulting health benefits from improved diets. The program would, of course, cost manufacturers more than a voluntary program.

PRO

- Consumers face uniform labels on all labeled food products.
- Widespread, uniform labels would allow consumers to reduce excess consumption of nutrients associated with coronary heart disease, breast cancer, prostate cancer, and colon/rectum cancer and consequently avoid early deaths from those diseases.
- Health benefits are estimated to be $1.8 to $2.0 billion and exceed compliance costs by $700 to $800 million depending upon whether the time for compliance is lengthened from 6 months to 2 years.
- Mandatory labeling would probably lead to product reformulation, with additional health benefits even among consumers who might not read labels.

CON

- Manufacturers would pay higher costs or analyzing and labeling additional products.
- The large number of labels required under this option would make prior label approval severely restraining, unless it were significantly streamlined.

5. Mandatory Labeling of All Meat and Poultry Products

This option raises the question of development of nutrition data for raw commodities by individual firms versus that development by single program supported jointly by USDA and the commodity industry. Preparation of materials in a single location is more efficient. Furthermore, FSIS wants it regulatory option to encourage centrally supported nutrition research on the agricultural commodities such as beef, pork, chicken, and turkey. Therefore, it does not favor this option.

Currently, there are central programs to provide point-of-purchase nutrition information for fresh meat and poultry products using USDA Handbook No. 8 data.

This meat Nutri-Facts program was developed as a cooperative effort of the American Meat Institute, the Food Marketing Institute, and the National Livestock and Meat Board. The program was developed to provide consumers, retailers, and industry with information about red meat and nutrition. A key component of the program is the Meat Nutri-Facts manual, which, among other information, provides camera-ready copy of a variety of in-store nutrition information materials. These materials all use data from USDA Handbook No. 8. The cost of the project was approximately $300 to $350 thousand for market research, artwork and preparation of camera ready copy. In using these point-of-purchase materials, each store would be responsible for printing costs. FDA has estimated that there are 99,000 retail stores that fall under the compliance guidelines of the NLEA. If printing costs averaged $500 for all these stores, then the cost of voluntary nutrition labeling of fresh meat products would be approximately $50 million each time the materials had to be replaced.

A similar program for poultry, Poultry Nutri-Facts, was developed by the Food Marketing Institute, the National Broiler Council, and the National Turkey Federation. Both the meat and poultry manuals also provide nutrition information for a variety of recipes using fresh cuts as ingredients. It is the Department's understanding that these manuals will be updated to harmonize with the FDA regulations issued to implement the NLEA

Given the fact that FSIS expects most nutrition data for fresh products to come from Handbook No. 8, it would be far more efficient for one source to develop the materials than for processors who packages fresh product to develop their own artwork and labeling materials. This is, centrally-developed, point-of-purchase materials should cost far less than individually developed labels.

Probably the largest cost saving initiative is the ongoing research to determine the physical and chemical composition of frequently retailed fresh cuts. Because much of Handbook No. 8 is outdated, USDA encourages and cooperates with private sector studies to update data on the composition of fresh cuts. For example, a recent study on the composition and marketing of pork products at retail [6] was supported, in part, by the National Pork Board through the Pork Industry Group of the National Livestock and Meat Board, and in cooperation with the Agricultural Research Service and the Human Nutrition Information Service of USDA.

A similar study related to beef [7] was supported by the Agricultural Research Service, USDA, the Cattlemen's Beef Promotion and Research Board, the National Cattlemen's Association, and the Beef Industry Council of the National Livestock and Meat Board.

PRO

- All labels for fresh and processed meat and poultry products would provide nutrition information.
- Health benefits would be higher than under voluntary programs.

CON

- Costs of having individual firms develop their own nutrition labeling for fresh commodities would be higher than if labeling materials were prepared in a central location.
- Higher compliance costs could be passed on to consumers.

[6] A Nationwide Survey of the Composition and Marketing of Pork Products at Retail, D.R. Buege and others, Department of Meat and Animal Science, Meat Science and Muscle Biology Laboratory, University of Wisconsin-Madison.

[7] National Beef Market Basket Survey, J.W. Savell and others, Texas Agricultural Experiment Station, Texas A&M University, 1991.

III. Health Benefits

A. Overview

In examining the public comments on the ANPR and other sources of information that discuss the potential benefits of nutrition labeling, FSIS found that benefits have been articulated in varying ways, frequently in terms of the confusion that will occur if the Department of Agriculture does not adopt rules consistent with those that will be promulgated by FDA to implement the NLEA. The following are typical of comments that are directed at identifying the benefits of the proposed rule.

- Nutrition labeling provides consumers with information to make more informed choices when purchasing food products.
- Additional nutrition labels will decrease consumer uncertainty about the nutrient content of foods, allowing consumers to make more informed food purchase decisions.
- If meat products do not have nutrition labels, consumers will mistakenly avoid an important source of iron in their diet.
- If all foods are not nutrition labeled, consumers will make purchases that will negate the benefits from selectively purchasing foods with nutrition labels.
- If labeling is not consistent, the added confusion will detract from the potential benefits.
- If nutrient content information was available on all food, there would be less of the good food-bad food rhetoric that adds to confusion.

All of the above statements relate directly or indirectly to the issue of how nutrient information on labels will affect purchase and consumption behavior. They all relate to the usefulness or effectiveness of nutrition labeling, where effectiveness would be measured in terms of how purchase decisions change. Thus, for the most part, the general benefit statements eventually relate to dietary change which should be quantifiable in health benefits.

It could be argued that some consumers would place a value or benefit directly on improved information even if they chose not to change behavior. In other words, there may be some willingness-to-pay for improved nutrition labeling for more informed choices even if consumers don't plan to use the information to change their diet. However, for the purposes of this analysis, the benefits of the proposed rule are viewed as the public health benefits that result when consumers change eating patterns as a result of having additional nutrition information.

The discussion of separate benefits for USDA-regulated and FDA-regulated foods tends to imply that benefits can be related to the proportion of food labeled with nutrition information. However, there is strong support for a viewpoint that there really is a single benefit analysis and that the potential benefits are not linearly related to the coverage of food, but will be greatly enhanced by the consistent labeling of all food.

For the purpose of estimating public health benefits, this PRIA draws heavily on the work [8] conducted by the Center for

[8] Estimating the Benefits of Nutrition Label Changes, Research Triangle Institute, April 1991.

Economics Research, Research Triangle Institute (RTI) for the Food and Drug Administration. A key analytical tool utilized by RTI was the Browner health effects model. The Browner model is a computer simulation model developed for the Department of Health and Human Services by Dr. Warren Browner and associates at the Institute for Health Policy Studies, University of California at San Francisco. The model estimates the impact of changes in dietary intake of total fat, saturated fat, and cholesterol on the incidence and mortality of four diseases—coronary heart disease (CHD), breast cancer, prostate cancer, and colon/rectum cancer.

The Department has not conducted an independent evaluation of the analysis performed by RTI. Their final report presented to FDA discusses the important assumptions and limitations of the work. The Department believes that everyone involved in the FDA/RTI study should be commended for their efforts in advancing the methodology available for estimating public health benefits of nutrition label changes. The fact that the study was done will make an important contribution to the national debate on the cost and benefits of nutrition label changes.

B. Scenarios Analyzed

The inputs for the Browner model are changes in nutrient intakes. To develop alternative inputs, the FDA/RTI study developed different scenarios that describe how consumers might change their diet in response to changes in the availability of nutrient content information. The starting point or baseline data for the scenarios is an estimate of the excess fat, saturated fat and cholesterol in the diet of U.S. consumers. The estimated excess was developed comparing data from the 1987–1988 Nationwide Food Consumption Survey (NFCS) and the daily reference values (DRVs) for fat, saturated fat and cholesterol. The DRVs are recommended dietary levels being proposed by FDA for fat, fatty acids, cholesterol, carbohydrate, fiber, sodium and potassium. Table 2 shows the estimated average dietary change necessary for consumers to meet the DRVs.

TABLE 2.—PERCENTAGE REDUCTION REQUIRED IN NUTRIENT INTAKE NECESSARY TO MEET DRVS

Food component	Men	Women
Fat	20.1	18.5
Saturated Fat	25.1	24.0
Cholesterol	13.5	None*

*Women's average daily intake of cholesterol was below the daily reference value.

The first scenario assumed that all consumers are willing and able to achieve the DRVs for fat, saturated fat and cholesterol, i.e., the average consumer would reduce fat and cholesterol intake by the percentages shown in Table 2. This response to mandatory nutrition labeling provides an upper bound for the public health benefits. The FDA analysis refers to this as the "perfect diet" scenario. A second scenario reduced the Table 2 values by the percentage of total dietary fat and cholesterol attributable to meat and poultry products (Table 3).

TABLE 3.—PERCENTAGE OF DIETARY FAT AND CHOLESTEROL ATTRIBUTABLE TO MEAT AND POULTRY PRODUCTS

Food component	Men	Women
Fat	33.1 (32.4)	29.7 (30.1)
Saturated Fat	33.1 (32.1)	29.2 (29.5)
Cholesterol	38.0 (40.7)	37.1 (39.7)

*The percentages not in parentheses are from the FDA/RTI Study. The values in parentheses are from data provided to FSIS by HNIS for men and women 19 and older.

Thus, in the second scenario men would reduce their total fat intake by 13.5 percent which is the level of 20.1 percent from Table 2 reduced by 33.1 percent from Table 3. The second scenario assumed that consumers would reduce fat and cholesterol intake from FDA-regulated foods by Table 1 percentages, but consumption of meat and poultry products would remain unchanged because the NLEA covered only FDA-regulated products.

It is important to distinguish between the NFCS category of meat and poultry and the category of all USDA-regulated meat and poultry products. The NFCS category for meat and poultry does not include products such as soup or pizza where the primary ingredient is not meat or poultry. The conclusion is that USDA-regulated products probably account for a substantially greater percentage of fat and cholesterol than indicated by the data in Table 3.

FSIS is aware that there has been considerable criticism of the 1987–1988 NFCS, primarily focused on the response rate of 35 percent. This is not a concern in using the data for a general estimate on sources of fat. Data from 1985 show similar findings, i.e., meat and poultry accounted for 30.6 percent of total fat and 38.8 percent of saturated fat in the U.S. Food Supply.[9]

Because the effectiveness of nutrition labeling has been related to percentage of food covered, it may be important to consider the proportion of fat and cholesterol that is consumed through products covered by the proposed rule, i.e. retail sales of processed products in consumer-sized packages. FSIS examined available data on source of total fat from meat and poultry broken down by the categories of fresh product versus processed product and retail purchases (consumed at home) versus eating out.

This preliminary analysis found more data available on the issue of retail sales versus HRI sales than on the source of fat. A recent report by ERS [10] showed that retail sales represented 55 percent of total food sales in 1989. Total retail food sales were $276 billion (55 percent) while food service sales were $223 billion (45 percent). In 1982, food consumed away from home accounted for 37 percent of all dollars spent on food, up from 33 percent in 1970.[11] These data show a clear trend for increased consumption away from home.

The National Broiler Council conducts a biannual survey of broiler industry marketing practices. Their report [12] on 1989 data estimated that 60.3 percent of product for the domestic food market was distributed to retail grocery stores and 39.7 percent to public eating places, institutions, or government procurement programs, etc. While their study addresses primarily fresh products it also includes some further processed products such as nuggets and patties. Similar data from their 1981 survey showed that 68.5 percent of product was distributed to retail stores, indicating that the proportion of poultry consumed outside the home is increasing.

The analysis did not find any data that could address the question concerning the specific amount of dietary fat from USDA-regulated products covered by the proposed rule. HNIS provided data from the NFCS survey showing that meat and poultry products contribute a higher percentage of fat and cholesterol for food eaten at home than for food eaten away from home. This suggests that meat and poultry products account for a higher proportion of fat in retail sales. After examining the data on sources of fat from meat and poultry products, FSIS concluded that the second scenario from the FDA/RTI study would have to be modified to reflect retail sales of processed products if the second scenario was selected to estimate public health benefits.

A third scenarioo in the FDA/RTI study reduced health benefits by an additional 55 percent, based on an estimate that only 45 percent of consumers are (1) aware of the diet-health relationship, (2) read and understand labels and (3) will use nutrition labels to change their nutrient intakes after new mandatory labeling regulations are implemented

The last scenario developed by RTI was an estimate of consumer response based on fundings from a program conducted by FDA in conjunction with Giant Food, Incorporated. That study, referred to as the "Special Dietary Alert" (SDA), used special shelf labels to call consumers' attention to various nutrient descriptors of food. For example, a flag may have called attention to a product that qualified under FDA guidelines as being "low cholesterol." In addition, a guidebook was offered either free or at nominal charge. Using the SDA data, RTI extrapolated the findings to develop an estimate of dietary change for the population. That estimate is shown in Table 4.

[9] The Market for Fat Substitute by Rosanna Morrison, National Food Review, USDA, ERS, April–June 1990.

[10] The Food Marketing System in 1989, USDA, ERS, Agriculture Information Bulletin Number 603, Anthony E. Galo, May 1990.

[11] Report on the U.S. Red Meat Industry, Prepared for: The American Meat Institute, Temple, Barker and Sloane, Inc., July 4, 1984.

[12] Broiler Industry Marketing Practices Calendar Year 1989, National Broiler Council, Washington, D.C., 1990.

TABLE 4.—ESTIMATED PERCENTAGE REDUCTION IN NUTRIENT INTAKE BASED ON SPECIAL DIET ALERT

Food component	Men	Women
Fat	1.4	1.1
Saturated Fat	1.3	0.7
Cholesterol	0.1	0.1

C. Estimates of Health Benefits

The scenarios developed by RTI to estimate changes in nutrient intakes from FDA-regulated foods also provide a framework for discussing the potential benefits from changing nutrient intakes from meat and poultry products. The first FDA/RTI scenario assumed that all consumers would reduce their intake of fat and cholesterol from all food groups by the percentages shown in Table 2. That is, consumers would have nutrition information available for both FDA-regulated and USDA-regulated foods and would modify their diet in order to meet the DRVs for fat and cholesterol. (The changes in fat and cholesterol intake are assumed to start one year after the promulgation of regulations and to last indefinitely.) The resulting estimated benefits are shown below in Table 5.

Table 5.—Maximum Health Benefits From Diet Improvement Over 20 Years

Cases of CHD and Cancer Avoided	725,155
Deaths Avoided	308,366
Life-Years Gained	2,280,549

Table 5 shows the maximum possible benefits from dietary changes of all foods U.S. consumers eat. In this "perfect diet" scenario, the benefits attributable to meat and poultry products are shown in Table 6 below.

Table 6.—Maximum Health Benefits From Diet Changes Meat and Poultry Products—20 Years

Cases of Cancer and CHD Avoided	221,707
Deaths Avoided	95,770
Life-Years Gained	715,199

Attributing the Table 6 benefits to meat and poultry assumes a proportional reduction in fat and cholesterol across all food categories. As shown in Table 3 above, meat and poultry represent 33 percent of total fat intake for men and 30 percent for women, and this consumption is assumed to remain unchanged. Thus, in the "perfect diet" scenario, 33 percent of the dietary fat reduction for men and 30 percent of the dietary fat reduction for women will result from changes in meat and poultry consumption.

To correspond to the third scenario of the FDA/RTI study, the benefits in the above table for meat and poultry were reduced by 55 percent based on the estimate that 45 percent of consumers are aware of labels, read labels and understand the information provided. The resulting benefits are shown in Table 7.

Table 7.—Health Benefits from Diet Improvement Over 20 Years—45 Percent Response

Cases of CHD and Cancer Avoided	99,768
Deaths Avoided	43,097
Life-Years Gained	321,840

Using the scenario based on estimates derived from the Special Dietary Alert program the estimated benefits attributable to meat and poultry products are shown in Table 7.

Table 8.—Health Benefits from Diet Improvement Over 20 Years

Cases of CHD and Cancer Avoided	17,260
Deaths Avoided	5,818
Life-Years Gained	37,012

The Table 8 benefits represent the best available estimate for the benefits of the proposed rule. These estimates are derived from a study that measured actual consumer response to new nutrition information. In using the analogous estimate of benefits for FDA-regulated foods, the FDA regulatory analysis [13] identifies several factors that would lead one to conclude that the estimates are high but also several factors that would lead one to conclude that the estimates are low. Obviously, the actual change in consumer behavior due to the additional nutrient labeling is a key variable. The estimate based on the SDA is used because it is an extrapolation from some limited but actual consumer response data.

In order to facilitate the comparison of costs and benefits, the health benefits, e.g., life-years gained will be valued in dollars. Recognizing that there are different methodologies for assigning dollar values to diseases avoided and life-years gained, this analysis has chosen to use the methodology selected by RTI in their work for FDA. Using the RTI methodology, the medical care cost savings (discounted at 5 percent) [14] are estimated at $258 million. Avoided medical care costs undervalue the true benefits of a health care regulation because they do not include productivity losses or pain and suffering losses. On the other hand, the figures presented here overstate the true reduction in such costs as the costs of competing illnesses are not subtracted. That is, even though cancer or CHD may be avoided another disease may occur such that only net savings should be reported.

In their study, RTI used an estimated value of life of $1,500,000 derived from wage premium data. This is a relatively conservative value based on willingness-to-pay studies. Using the expected discounted life years remaining from age 40, and a discount value of 5 percent, a value of $89,074 per life year saved was derived. Combining this figure with the discounted number of life years saved produces a benefits estimate of $1.63 billion. As discussed earlier, there is reason to believe the fat contribution from USDA-regulated products is substantially higher than available estimates for fat from "meat and poultry." Under an assumption that USDA-regulated products account for half of dieting fat and cholesterol, the projected benefits based on the SDA data would be $2.6 billion rather than $1.63 billion. The best estimate for USDA regulated products is probably somewhere in between. Based on the SDA data and the extent of USDA-regulated foods, FSIS will use $2.0 billion as the best available estimate of benefits. FDA presented other methods of valuing benefits that would increase the estimated benefits by a factor of more than five. For example, an alternative approach is to apply a mean value to all early deaths, regardless of age. A value of $30 million per early death would result in a benefit estimate of $9.57 billion ($3.0 million × 5,818 deaths avoided discounted to 3,189).

In its regulatory analysis for nutrition labeling, FDA took the position that they believe that the estimate of the health gains derived from the SDA study is probably an underestimate. The two primary reasons for this belief identified by FDA are the fact that no reformulation took place during the SDA study and the quantification of early death benefits left out quality of life gains from fewer cases of CHD and cancer. Each case of cancer and CHD that does not result in early death still tremendously reduces the quality of life for both the afflicted and those around them.

There are also reasons to discount estimates of major changes in consumer purchasing patterns. A recent report [15] published by the National Livestock and Meat Board noted that the absence of additional change in the second 2-year period for SDA supports the idea that there is a limited pool of nutrition-concerned shoppers, and sales of items with positive nutritional attributes could be expected to level off after a certain time period. The paper also noted that sales of the SDA nutrition booklet were relatively low when priced at $.50.

[13] Draft Regulatory Impact Analysis of the Proposed Rules to Amend the Food Labeling Regulations, Economics Section, Center for Food Safety and Applied Nutrition, FDA, June 13, 1991.

[14] Discounting is used to put all costs and benefits in present value so they are comparable. Discounting takes account of the fact that resources in a given year are worth more than identical resources in a later year because of return on investment.

[15] In-Store Nutrition Information on Fresh Meat: Issues and Insights, Research Report No. 100-1, National Livestock and Meat Board, 1990.

FSIS views the SDA-based estimate of $2.0 billion as the best available estimate at the current time. The Agency is concerned that an important point can easily get lost in debating the methodology and that is the RTI finding that relatively small changes in nutrient intakes can generate large potential health benefits. While consumer awareness has increased since the SDA project, FSIS sees the potential for substantially higher benefits tied to the effectiveness of ongoing nutrition education programs. Nutrition labeling provides the information needed for the market to respond to changing demands generated by educational programs.

IV. Preliminary Compliance Cost Analysis

A. Scope, Purpose, and Overview of Methodology

1. Scope and Purpose of the Preliminary Compliance Cost Analysis

FSIS estimates that approximately 8,933 U.S. companies owning 9,503 meat and poultry manufacturing facilities would be affected by the proposed nutrition labeling rule. The number of facilities is based on actual counts as of September 30, 1990.[16] These companies and facilities would have to engage in activities to bring their current product labels into compliance, and subsequently incur costs.

The purpose of this chapter is to present preliminary estimates of the compliance costs that would be borne by affected U.S. companies to bring their current product labels into compliance. The preliminary estimates are primarily based on information collected by Research Triangle Institute (RTI) during personal interviews conducted in August and September, 1991, with nine processed meat and poultry companies, but also rely on information from selected analytical testing laboratories, the Bureau of the Census, FSIS, and miscellaneous other sources. The preliminary analysis also estimates annual recurring analytical costs to now-operating processed meat and poultry companies for current products, but does not address future costs as companies bring new products on-line under the proposed rule.

The preliminary cost estimates presented herein serve several purposes. The estimates can be compared to preliminary estimates of the benefits of the proposed rule, and they can be used to help determine industry impacts.

2. Overview of Methodology

Labeling decisions are normally made—and costs incurred—at the company-level rather than the facility-level. As most meat and poultry companies are single-plant companies, the "company" and "facility" are effectively synonymous in most instances. A significant number of companies own multiple establishments, however, and these companies tend to make labeling decisions for all of their affected facilities in a centralized manner. Indeed, some multi-plant companies manufacture identical products in more than one plant, and/or use identical labels in more than one plant.

Decisionmaking at the company level allows companies with multiple-facilities to take advantage of certain economies of scale.

In its study for the Food and Drug Administration (FDA) in January 1991,[17] RTI found that labeling costs vary by company. This appears to be true partly because larger companies tend to manufacture more products under more labels, and partly because companies of different sizes tend to incur different costs per label and per product.

Consistent with the methodology employed in that study, the processed meat and poultry industry has been segmented into three sizes of companies. Simply stated, the average cost of the proposed rule to each of three sizes of companies is estimated based on information collected during personal interviews with decisionmakers at nine meat and poultry companies and from several other sources. The average of the company cost estimates are then multiplied by the number of companies of each size in the population to derive total industry costs.

The methodology employed in this analysis consists of four fundamental steps. First is the collection of nutrition labeling cost information from nine companies and from several independent analytical laboratories. Second is the estimation of the average cost of the labeling rule for each of three sizes of companies using that information. Third is the estimation of the population of affected processed meat and poultry products companies in the U.S. in each of the three size ranges. Fourth is the extrapolation to the population of the compliance cost of the proposed rule.

RTI arranged and conducted nine personal interviews with owners, executives, and managers of nine potentially-affected companies. The companies were selected on the basis of type, size, location, and cooperation. Three small, three medium, and three large companies were interviewed. These companies are neither the largest nor the smallest in the industry, but rather were selected for their representativeness of large, medium, and small companies. Companies that produce a variety of processed meat and poultry products (beef, poultry, and pork; frozen, refrigerated, preserved and canned) were interviewed. Companies that sell only institutional products were excluded, because the objective of the analysis was to estimate the cost of providing nutrition labeling on processed retail products. Many of the companies interviewed do, however, produce both retail and institutional products. For the same reasons, companies that produce only fresh products were excluded, though again many of the companies interviewed produce both fresh and processed products. To make maximum use of project resources, three companies of each size were interviewed in each of three locations: North Carolina, Cincinnati, Ohio, and the vicinity of Dallas-Fort Worth, Texas. Lastly, since interviews lasted from 2 to 4 hours each, companies that were cooperative enough to dedicate that time were sought.

Interviews were conducted between August 13 and September 4, 1991. Without exception, the participating decisionmakers were prepared and generous with their time and information. Their identities are confidential as the information they provided was sometimes proprietary. Owners, executives, and managers were engaged in a series of inquiries related to the costs they would incur under the proposed mandatory nutrition labeling rule for processed meat and poultry products. Care was taken to limit the discussions to those products and labels that would actually be affected by the proposed FSIS rule.

Nutrition labeling cost extrapolation to the population using this methodology requires an estimate of the number of affected small, medium, and large meat and poultry companies. The estimate derived for and employed in this study is based on information provided by FSIS, information published in several trade journals, data from the 1987 Census of Manufactures, the 1987 Census of Wholesale Trade, and several simplifying assumptions. In brief, FSIS provided an estimate of the total number of affected meat and poultry facilities. An article in the June 1991 issue of *Meat Processing*[18] characterizing the sales and employment of the largest 200 companies in the meat and poultry industry helped with the estimate of the number of large companies. Estimates of the number of medium and small companies were then based on Census estimates of the size distribution of facilities.

The cost of the proposed rule to industry has been estimated by first multiplying the estimated average cost to each of three company sizes by the estimates of the number of small, medium, and large companies in the population, and then by summing across company sizes. Since it is very difficult to confidently estimate the compliance cost of such a rule with the available data, several estimates under varying assumptions are presented in a scenario framework.

The activities undertaken by companies to comply with a mandatory nutrition labeling requirement can be broken down into six categories: Administrative, analytical testing, marketing, printing transition, inventory transition, and equipment transition. Not all types of costs are necessarily incurred by all companies. The nine interviews suggest that while the majority of companies would incur administrative, analytical, printing transition, and label inventory transition costs, a significant number of companies might incur little if any costs for marketing and equipment transition.

Administrative Activities

The administrative activities potentially associated with the proposed nutrition labeling rule encompass a broad range of tasks. Administrative activities are usually the first reaction to a labeling rule and the

[16] Meat and Poultry Inspection, Report of the Secretary of Agriculture to the U.S. Congress, USDA, FSIS, March 1, 1991.

[17] Compliance Costs of Food Labeling Regulations, prepared for the Food and Drug Administration, Michael French et al., Center for Economics Research, Research Triangle Institute, January 1991.

[18] Meat Processing (1991). Top 200 Meatpackers, Processors, and Poultry Companies, June 1991, pp. 35–56.

last activities to complete the compliance process. After FSIS promulgates a labeling rule, companies will generally perform the following sequence of administrative events:

- Interpret the policy,
- Determine the applicability to their product labels,
- Establish a corporate position,
- Formulate a method for compliance, and
- Manage the compliance method.

It appears that, in general, administrative effort is related to

- The scope of the rule,
- The severity of the rule,
- The length of the compliance period, and
- The company size.

The 1991 study for FDA found that once a particular labeling rule is identified, personnel from up to eight different departments in large companies may become involved with interpreting the rule, determining its scope, and establishing a corporate position. They may continue the administrative process by forming a committee to develop a compliance method. Nutrition information for affected products must be determined by analytical methods or published data. If the committee agrees on a label change, signatures are required from representatives in each of the eight departments to authorize the change. Management then distributes a label change order to the appropriate departments, which begin the physical conversion to a new label.

The nine interviews with meat and poultry companies confirm that administrative activities may be as complex as those described in the FDA study for large companies It is also clear though that decisionmaking may involve one or only several individuals in medium and small firms.

Analytical Testing Activities

Analytical testing activities are conducted to determine the nutrition profiles of affected products. Analytical testing may be conducted in-house by some of the larger companies in the industry, but the majority of companies will rely on contract laboratories. Even the largest companies interviewed reported that they would contract-out nutrition analyses for certain nutrients and food components for lack of in-house capability.

Information was collected on the number of products each company has, the number of samples of each product they anticipate testing in response to the proposed rule, and their estimate of the cost per test. Companies were also asked whether they have analytical information in their files for certain formulations, and whether they would use this information or conduct repeat and supplemental analyses. Because only a subset of the interviewed companies had confidence in their estimates of analytical costs per product, price information was collected from several additional contract laboratories.

Market Testing Activities

FSIS acknowledges the possibility that some companies may reformulate some products in response to the rule. Rather than analytically test a particular product and redesign its label(s) with nutrition information, a company may, for example, reformulate it in an effort to reduce calories, fat, sodium, or other nutrients that it feels consumers may perceive as "too high" in the current formulation. Companies that do this might subject the new products to internal and/or external market tests.

It is also possible that some companies will conduct market tests of newly-designed labels. Subject to regulatory requirements, companies may market test various nutrition panels to see which one most appeals to consumers.

Label Conversion Activities

Label conversion is the most obvious activity performed during a mandated label change. When quantifying printing effort, it is important to differentiate between the normal activities of printing labels and the incremental activities attributable to rule-induced label changes.

Though none were identified in the nine interviews, some companies' labels for some products may already comply with the proposed rule, so there are no incremental printing costs for such labels. Other labels would be redesigned during the proposed rule's compliance period anyway, and so incremental printing costs would not be present. Depending on the frequency with which companies redesign labels at baseline and the allotted time for compliance, incremental printing activities may be nonexistent.

Consider the following scenario. A company redesigns labels every 12 months on average and is six months away from their next planned redesign when FSIS promulgates a nutrition labeling rule that allows one year for compliance. This company will likely combine mandated label changes with planned label changes for most of its products.

The 1991 study for FDA found that incremental printing effort is primarily conditional on the complexity of the label change, the printing process(es), and the length of the compliance period. The complexity of the label change determines the level of effort for artwork, stripping, and engraving. It also determines the number of plates or cylinders to modify or replace. The printing process also dictates what type of plate or cylinder to modify or replace. Finally, the length of the compliance period determines the opportunities available to coordinate planned film and printer plate or cylinder replacements with rule-induced replacements. For this reason, as the compliance period increases, incremental printing effort may decline. Because printing activities are specific to individual labels, computing incremental printing effort on a per-label basis is necessary.

Despite the similarity and relative simplicity of line copy changes, companies differ in incremental printing effort. If flexography or lithography printing is used, many companies engrave new lettering onto an existing printing plate to save time and resources. Other companies order new printing plates regardless of how minor the line copy change may be, for gravure printing, every label change will result in a new cylinder since modifying gravure cylinders is not possible.

Label Inventory Transition

The fifth activity category is label inventory transition from old to new labels. The probability of label inventory loss is positively related to the average label inventory and inversely related to the compliance period.

Equipment Transition

Equipment transition activities may involve costs for companies that have to scrap, sell, or modify equipment that they now own, and/or purchase new equipment. Two types of equipment are potentially involved, based on the nine interviews. One is labeling equipment that applies pre-printed labels to food packages. Some companies may own machines, for example, that can handle labels up to some maximum size, a size which may be inadequate for a nutrition panel. Other companies may have machines that can apply larger labels with nutrition panels to their packages, but only after some modification.

Another type of equipment that may be germane in the cost analysis is analytical equipment. This includes equipment that might be purchased to allow companies to do analytical testing in house, or at least to allow them to maintain better quality assurance on fat, moisture, and protein content so they can reduce the risk of having their products out of compliance in a less expensive manner than contracting out repeat analytical tests. Since companies might purchase analytical equipment in order to reduce costs, and since the cost estimates derived in this study are based on full, commercial analytical testing prices, equipment purchases may represent cost savings rather than incremental costs.

B. Compliance Cost Data From Company Interviews and other Sources

Most of the nine companies provided information that they consider proprietary. Examples include sales, employment, numbers of product formulations, numbers of labels, in-house analytical capabilities, estimates of compliance costs, etc. Partly to ensure confidentiality, and partly to ensure that the cost estimates of this preliminary analysis do not rely too heavily on the responses of any one company, the interview data have been averaged to compute compliance costs for representative small, medium, and large companies.

Based on the desire to extrapolate the interview cost results to the population of approximately 8,933 companies, and given the sales data for the companies interviewed, small companies have been defined as those with annual sales below $5 million, medium companies as those with annual sales between $5 million and $50 million, and large companies as those with annual sales above $50 million.

The average annual sales of processed meat and poultry products, average company employment, the average number of active labels for processed meat and poultry products, and the average number of processed meat and poultry products of the

small, medium-, and large companies interviewed by RTI for this project are presented in Table 9.

TABLE 9.—SALES, EMPLOYMENT, ACTIVE LABELS, AND PRODUCTS OF INTERVIEWED COMPANIES

	Small (<$5M)	Company size medium ($5M–$50M)	Large (>$50M)
Sales	$2.0M	$10.4M	$401.7M
Employment	23	73	3,133
Active Labels	43	56	772
Products	39	22	335

Note: Company sales, employment, active labels, and products are means of data reported by three small companies, three medium companies, and three large companies during interviews with RTI.

Note that the average sales of the small and medium companies are within the ranges established for these sizes. The average annual sales of the large companies, $402 million, can be placed in some context by noting that the mean and median sales of the 134 companies reported in *Meat Processing* (June 1991) with annual sales in excess of $50 million are $607 million and $160 million, respectively. Thus, the average interviewed large company's annual sales are below the mean and above the median.

The actual processed meat and poultry sales of the nine companies interviewed vary significantly around the mean. For example, one of the small companies has sales under $1 million per year, and another has sales approaching $5 million. Interviewed medium company sales vary from just over $5 million to just under $50 million. Interviewed large company sales vary from just over $50 million to nearly $1 billion. Also note that sales of several of the companies interviewed are somewhat higher when fresh products are included.

It is worth noting that the average number of active labels (for processed meat and poultry products) of medium companies is only somewhat higher than that for small companies, and that the average number of product formulations is actually higher for small companies than for medium companies. This is potentially significant, as it means that sales per product and sales per label are substantially lower for small companies than for medium, as they are lower for medium companies than for large. This in turn implies that compliance costs per dollar of firm sales may vary substantially by firm size.

Table 10 presents more information on these relationships. Note that the average annual sales per product for medium companies are nearly 10 times those of small companies, and that average annual sales per product for large companies are about 2.5 times those of medium companies. Though less pronounced, a similar relationship holds for sales per label.

TABLE 10.—ANNUAL SALES PER PRODUCT AND PER LABEL OF INTERVIEWED COMPANIES, BY COMPANY SIZE ($)

Size of company	Annual sales per product	Annual sales per label
Small Companies:		
Minimum	$17,333	$16,667
Means	50,128	45,308
Maximum	90,000	90,000
Medium Companies:		
Minimum	444,444	121,951
Mean	471,212	184,024
Maximum	500,000	244,595
Large Companies:		
Minimum	310,174	166,667
Mean	1,199,005	520,294
Maximum	5,000,000	2,391,304

The balance of this section presents estimated average costs of the proposed nutrition labeling rule to small, medium, and large companies interviewed. The cost estimates are primarily based on results from the nine company interviews, though price quotes obtained from several independent analytical laboratories are also employed. The average per-company costs of administrative activities, nutrition analysis activities, label printing transition activities, and inventory management activities are treated separately and then totaled.

In this analysis, product and label market testing activities are only discussed qualitatively. With data from a total of only nine companies, it is extremely speculative to quantify these two cost categories. Not a single medium-sized company indicated that it would do any market testing of new formulations or labels. Of the three small companies interviewed, two said they would not do any market testing, and one indicated they might, but probably wouldn't. Similarly, only one of the three large companies indicated they might market test reformulated products, and that company would test only a share of its formulations and then only if they reformulated. Since the data received suggest that market testing would be unusual, estimates of the costs are not presented here.

Analogously, it is extremely speculative to quantify costs of equipment transition. While one medium company and one large company indicated they would have to scrap or modify labeling machines, most companies indicated that they would neither scrap old equipment nor purchase new equipment. Several companies indicated that they might purchase analytical equipment, but it is not clear that these purchases would impose incremental costs over and above those estimated in this analysis. Consequently, equipment transition costs are not quantified in this analysis.

1. Administrative Costs of Nutrition Labeling

Preliminary estimates of the administrative costs that would be incurred by companies bringing current products and labels into compliance with the proposed rule are presented in Table 11. Whether and how administrative costs are related to company size in unclear. All companies except one reported administrative costs of between $2,000 and $20,000. A much higher estimate was reported by the largest company interviewed (sales approaching $1 billion). On a per-label basis, administrative costs average $214 for small companies, $81 for medium companies, and $112 for large companies.

TABLE 11.—ADMINISTRATIVE COSTS OF NUTRITION LABELING TO INTERVIEWED COMPANIES ($/COMPANY)

Size of company	Administrative cost
Small Companies:	
Minimum	$2,000
Mean	9,293
Maximum	19,200
Medium Companies:	
Minimum	2,000
Mean	4,554
Maximum	7,500
Large Companies:	
Minimum	9,600
Mean	86,333
Maximum	237,900

All of the estimates in Table 11 are based on responses by the interviewed companies under instructions to assume that they would have a one-year (12 month) period between promulgation of the nutrition labeling rule and enforcement. Essentially all companies maintained (acknowledged) that the administrative cost of bringing current labels into compliance would be higher (lower) if they had fewer (more) than twelve months to comply. One large company estimates that their administrative cost would be 50 percent higher under a 6-month compliance period and ⅓ lower under a 24-month compliance period, since there would be differences in overtime costs, opportunities for decisionmakers to discuss labeling issues during regularly-scheduled meetings, etc. However, since none of the other eight companies were able to quantify these same differences, we will not speculate on additional costs or savings to a representative company or industry of a shorter or longer compliance period.

2. Analytical Testing Costs of Nutrition Labeling

Analytical testing costs incurred by a given company depend on the number of products the company produces, the types of products the company produces, whether the decisionmakers elect to test for all components or only those components not already on file (incremental testing), and the number of tests per product the decisionmakers elect to conduct.

The range and means of numbers of products that would have to be analytically tested by the nine companies interviewed are reported in Table 12.

TABLE 12.—NUMBER OF PRODUCTS FORMULATIONS TO BE TESTED AT INTERVIEWED COMPANIES

Size of company	Number of products to be analytically tested
Small Companies:	
Minimum	22
Mean	39
Maximum	50
Medium Companies:	
Minimum	10
Mean	22
Maximum	38
Large Companies:	
Minimum	19
Mean	335
Maximum	806

Since the average number of products of small firms is greater than that of medium firms, analytical testing costs are higher for small firms than for medium firms. Testing costs are considerably higher though on average for large firms than for small or medium firms. Product types also influence analytical testing costs. Analytical profile costs essentially depend on the number of nutrients/components tested in a sample. The more components tested, the higher the cost of testing. Under the proposed rule, essentially all processed meat and poultry products would have to be tested for at least the following ten nutrients/components: Total calories, Total fat, Total carbohydrates, Protein, Sodium, Saturated fat, Cholesterol, Iron, Calcium, and Total calories from fat.

Some processed meat and poultry products (e.g. complete meals containing meat and poultry) would also have to be tested for one or more of the following: vitamin A, vitamin C, and dietary fiber. Since dietary fiber will be present in significant amounts less often than the other components, the costs of two additional analytical profiles have been estimated. One is the list of ten components plus vitamin A and vitamin C (the "expanded test"), and the other is the list of these twelve components plus dietary fiber (the "complete test").

For this preliminary analysis, a weighted-average analytical testing cost is computed and applied to all meat and poultry products. It is assumed that 50 percent of all products will be tested at the basic 10-component analytical testing cost, that 40 percent of products will be tested at the expanded twelve-component analytical testing cost, and that 10 percent of products will be tested at the complete thirteen-component analytical testing cost. Using the price estimates of seven analytical testing companies, the weighted-average estimate is $368, as presented in Table 13.

TABLE 13.—ANALYTICAL TESTING COSTS ($/SAMPLE)

	Range	Mean
Total calories		
Total fat		
Saturated fat		
Cholesterol		
Protein		
Carbohydrates		
Sodium		
Iron		
Calcium		
Calories from fat		
Subtotal	$206-378	$304
Vitamin A		
Vitamin C		
Subtotal	288-503	414
Dietary fiber		
Subtotal	350-610	506
Weighted-Average Cost [1]		368

[1] [$368=(0.5×$304)+(0.4×$414)+(0.1×$506)]
Note: Estimates based on informal price-quotes from seven companies.

Of the nine meat and poultry companies interviewed, five have essentially no analytical data on file for their formulations, while the other four have at least some nutrition information on file for at least some of their products. Of the four companies interviewed that have some nutrition information on file, three are large and one is medium. By definition, incremental nutrition testing—the testing of product samples only for nutrients/components not already known—is not an option for the five companies with no data on file. Of the four companies interviewed with some nutrition data on file for their products, two indicated that they would incrementally test if allowed to do so under the rule. The other two companies reported that as a matter of company policy, they would test new samples for all components rather than rely on incremental testing. For purposes of this preliminary analysis, the assumption is that no companies will conduct incremental testing of products. This assumption may tend to overestimate analytical testing costs.

A fourth and very influential analytical cost determinant is the number of samples of each product that would be tested by the company. The proposed rule does not specify the number of analytical tests that would be required for each product. Three of the companies interviewed (one large, one medium, and one small) indicated they planned to test one sample, or as few samples as allowed under the rule. One (small) company indicated they would test more than four samples of each product before nutrition labeling under the rule. The other five companies (two large, two medium, and one small) indicated they would test three or four samples (e.g. quarterly testing) of each product.

Because the number of tests performed per product is a very influential cost determinant, two scenarios are considered. One scenario assumes that all companies in the industry will test all of their products only once prior to label submittal. The single-test assumption may tend to underestimate analytical testing costs, somewhat balancing the earlier assumption of no incremental testing.

The other scenario assumes that companies will perform as many tests per product as they indicated during the interviews. This scenario is implemented by computing a product-weighted average number of tests per product for small, medium, and large companies. Based on the information provided, small companies would conduct an average of 4.3 tests per product, medium companies 3.4 tests per product, and large companies 2.7 tests per product.

Based on the company interviews, the number of tests that companies would conduct per product declines with increasing company size because smaller companies produce batches on a less continuous, more periodic basis and are more concerned about batch-to-batch consistency. All three of the small companies interviewed indicated that they produce many of their products on a weekly basis—or even a monthly basis—rather than on a continuous or daily basis. These same companies expressed concern about the consistency of the nutrition content of their products from batch-to-batch—especially those that are produced only weekly or less frequently. These concerns prompted the smaller companies to indicate that they would have to test products frequently.

Preliminary estimates of per-company analytical testing costs under both scenarios are presented in Table 14.

TABLE 14.—ANALYTICAL TESTING COSTS OF NUTRITION LABELING ($/COMPANY)

Size of company	Single-test scenario	Multi-test scenario
Small Companies:		
Minimum	$8,280	$35,604
Mean	14,413	61,977
Maximum	18,400	79,120
Medium Companies:		
Minimum	3,680	12,512
Mean	8,096	27,526
Maximum	13,984	47,546
Large Companies:		
Minimum	6,992	18,878
Mean	123,280	332,856
Maximum	296,608	800,842

*Assumes 4.3, 3.4, and 2.7 tests per product for small companies, medium companies, and large companies, respectively.

3. Printing Transition Costs

Printing costs incurred by any given company depend on the number of labels the company has to change, the types of labels the company has, and the period of compliance.

Label redesign (artwork) and printing plate modification or replacement is fairly label specific, though one company did indicate that there are some economies of scale in artwork—the more similar labels the company has to redesign, the lower the artwork cost per label other things being equal. Given any mix of label types and compliance period, the more labels a company has to bring into compliance with the rule, the greater the cost the company will incur. None of the approximately 2,600 labels for processed meat and poultry products manufactured by the nine companies interviewed during this study currently have nutrition panels that comply with the

proposed rule. While some of the larger companies have several labels with some nutrition information, none have information even on the basic-ten nutrients/food components. Generally, the more complex the label design and the greater the use of colors, the more expensive the artwork and plate change costs. Average costs per label increase with company size, apparently because larger companies use more complex and colorful labels on their products.

Average label redesign and plate changeover costs on a per-label basis are reported in Table 15.

TABLE 15.—LABEL REDESIGN AND PLATE CHANGE-OVER COSTS OF INTERVIEWED COMPANIES ($/LABEL)

Size of company	Average cost per label ($)
Small Companies:	
Minimum	$168
Mean	234
Maximum	275
Medium Companies:	
Minimum	200
Mean	1,457
Maximum	2,972
Large Companies:	
Minimum	1,053
Mean	2,251
Maximum	4,000

The period of compliance between promulgation of the nutrition labeling rule and enforcement will also influence printing costs. All companies change labels occasionally at baseline. Some companies change some labels every few months, while other companies have labels that have not been changed for several years. The greater the period of compliance, the better the opportunity for a company to coordinate a mandated nutrition label change with a change already planned at baseline.

Ranges and model company estimates of printing transition costs on a per-company basis under two compliance period scenarios are reported in Table 16.

TABLE 16.—NEW LABEL PRINTING COSTS OF NUTRITION LABELING ($/COMPANY)

Size of company	12-month period	24-month period
Small Companies:		
Minimum	$5,160	$0
Mean	7,148	4,632
Maximum	9,408	8,736
Medium Companies:		
Minimum	4,920	1,640
Mean	74,869	63,909
Maximum	160,488	160,488
Large Companies:		
Minimum	26,082	0
Mean	1,175,700	60,016
Maximum	3,000,000	167,006

Note: Estimates reflect the number of active labels per company, baseline label modification frequencies reported by companies, and average costs per label.

Each average (mean) estimate is based on the average number of label per model company, the average cost per label change, and the compliance period in relation to the baseline average label redesign period. Twelve-month per-company costs are approximately 10.5 times higher for medium companies than for small companies, and about 15.7 times higher for large companies than for medium companies. Remember that while larger companies may tend to change labels more frequently at baseline than smaller companies, larger companies have more labels to change and the per-label transition cost is higher.

4. Label Inventory Transition Costs

Label inventory transition costs will be incurred by companies that have to discard non-compliant labels at change-over and/or pay higher prices per label for smaller label orders during the transition period. Label inventory transition costs incurred by any given company will depend on the number of different labels the company has in inventory, their normal label inventory management practices, their label types (because more complex labels are more expensive), and the period of compliance. The average number of processed meat and poultry labels used by small, medium, and large companies interviewed by RTI are 43, 56, and 772, respectively. All nine companies indicated that they normally carry months—not years—of most of their labels in inventory. The simple mean label inventory time across all companies is 5.8 months. This perhaps explains why most of the nine companies interviewed indicated that the cost of inventory transition is not of major concern for them.

Most of the companies interviewed indicated that inventory losses would be minor or even nonexistent under either a 12-month or 24-month compliance period. In fact, the data they provided indicate that inventory costs are the smallest component of the cost of the nutrition labeling rule for eight of the nine companies, even assuming a 12-month compliance period. Estimated per-company label inventory transition costs under 6-month, 12-month and 24-month compliance period scenarios are reported in Table 17. Estimates for a 12-month compliance period range from $0 to $60,000 per-company, though averages are under $1,000 for small and medium companies. The 12-month cost estimates reported in Table 17 are those reported by companies during the RTI interviews.

TABLE 17.—LABEL INVENTORY TRANSITION COSTS OF NUTRITION LABELING ($/COMPANY)

Size of company	6-month	12-month	24-month
Small Companies:			
Minimum	$0	$0	$0
Mean	1,667	833	417
Maximum	4000	2,000	1,000
Medium Companies:			
Minimum	0	0	0
Mean	1,333	667	333
Maximum	4,000	2,000	1,000

TABLE 17.—LABEL INVENTORY TRANSITION COSTS OF NUTRITION LABELING ($/COMPANY)—Continued

Size of company	6-month	12-month	24-month
Large Companies:			
Minimum	0	0	0
Mean	66,667	33,333	16,667
Maximum	120,000	60,000	30,000

All companies reported that inventory transition costs would be substantially lower under a 24-month compliance period. The large company that estimated it would incur a $60,000 inventory transition cost under a 12-month compliance period also indicated that its cost would be "negligible" under a 24-month compliance period. Most companies found the difference more difficult to quantify. In this analysis it is assumed that inventory transition costs would be 50 percent lower under a 24-month compliance period than under a 12-month compliance period and 50 percent higher under a 6-month compliance period.

5. Total Compliance Costs

The total per-company compliance cost preliminary estimates are summarized in Table 18. The total cost is presented under six alternative scenarios: Combinations of three compliance periods (6-, 12-, and 24-month) and two analytical testing assumptions (single- and multi-test per product).

TABLE 18.—PRELIMINARY ESTIMATES OF COMPANY COMPLIANCE COSTS OF THE PROPOSED NUTRITION LABELING REGULATION ($/COMPANY)

Cost category	Small	Medium	Large
Administrative	$9,293	$4,554	$86,333
Analytical:			
Single-test	14,413	8,096	123,280
Multi-test	61,977	27,526	332,856
Printing:			
6-month	8,406	80,349	1,733,542
12-month	7,148	74,869	1,175,700
24-month	4,632	63,909	60,016
Inventory:			
6-month	1,667	1,333	66,667
12-month	833	667	33,333
24-month	417	333	16,667
Total:			
24-month/single	28,755	76,893	286,296
12-month/single	31,687	88,186	1,418,646
6-month/single	33,779	94,333	2,009,822
24-month/multi	76,319	96,322	495,872
12-month/multi	79,251	107,617	1,628,222
6-month/multi	81,343	113,763	2,219,398

C. Estimate of Population of Affected Companies

Preliminary estimates of the cost of the proposed nutrition labeling rule on a per-company basis have been presented, discussed, and qualified above. As explained in Section A.2, Overview of Methodology, an

estimate of the number of affected small, medium, and large processed meat and poultry companies is also required to estimate the industry cost. The methodology and results of a preliminary estimation of company counts is the topic of this section.

Based on the results of the nine company interviews, large companies are defined to be those with $50 million or more in annual sales; medium companies are those with annual sales between $5 million and $50 million; and small companies are those with annual sales under $5 million.

Using several data sources—FSIS's estimate of 9,503 meat and poultry establishments, Census data cross-tabulating sales and establishments with employment, and Meat Processing's list of the top 200 Meatpackers, Processors, and Poultry Companies—the number of small, medium, and large companies in the industry have been estimated.

Estimating the number of large companies is relatively straightforward. Meat Processing magazine publishes a list of the top 200 meat and poultry companies ranked by sales. According to this list there are 134 large companies—companies with $50 million or more in sales. The number of medium and small companies cannot be estimated from this list alone. FSIS data facilitates the calculation of the number of small and medium companies.

FSIS data shows there are approximately 9,503 federally- and state-regulated establishments. The top 200 list states that the 134 large companies (with annual sales in excess of $50 million) own 690 establishments. Subtracting these 690 establishments from the total of 9,503 leaves 8,813 as the total number of establishments owned by small and medium companies. The top 200 list also states that the 66 largest medium companies (the bottom 66 companies on the top 200 list) have a total of 80 establishments, or approximately 1.2 establishments per company. Assuming that the ratio of all other companies to establishments is 1 to 1, there are 8,733 (8,813−80) more medium and small companies besides the 66 previously mentioned medium companies. Thus, there are 134 large companies and 8,799 (66+8,733) medium and small companies.

It is now necessary to rely on another data source to estimate how many of these 8,799 companies are small and how many are medium. The 1987 Census of Manufacturers and Census of Wholesale Trade Industry Series provides data on the size distribution of facilities in the most important industries that produce processed meat and poultry products. By assuming that small facilities (those with under $5 million in annual sales) are owned by single-facility companies, the size distribution of small and medium facilities indicates the size distribution of small and medium companies.

Using the 1987 Census data for eight four-digit Standard Industrial Classification industries (Meat Packing, Sausages and Other Prepared Meats, Poultry Slaughtering and Processing, Canned Specialties, Frozen Specialties, Food Preparations not elsewhere classified, Poultry and Poultry Products Wholesale Trade and Meat and Meat Products Wholesale Trade), there are approximately 2.2 small facilities per medium facility.

Applying this ratio and combining the results with the previous estimates that there are 134 large and 66 medium companies with multiple establishments, there are an estimated 134 large companies, 2,933 medium companies, and 5,866 small companies that collectively own the estimated total of 9,503 meat and poultry establishments.

D. Preliminary Estimates of Compliance Costs

Preliminary estimates of the one-time compliance costs of the proposed nutrition labeling rule are derived by multiplying average small, medium and large company preliminary cost estimates (from Section B) by preliminary estimates of the total number of processed meat and poultry products companies of each size (from Section C).

The dependence of these estimates on the data collected from a small, non-random sample of meat and poultry products companies can not be overemphasized. Administrative, analytical, printing transition, and inventory transition costs of the rule are apparently highly dependent on the number of products and labels affected by the proposed rule. If the estimated numbers of affected products and labels for small, medium, and large companies are significantly greater or lesser than the actual numbers of products and labels at small, medium, and large companies in the industry, the preliminary cost estimates presented in this Chapter are biased accordingly.

Using the estimates of average numbers of labels per company given in Table 9, and the estimates given in Section C of the numbers of small, medium, and large companies in the industry, there are an estimated 519,934 affected labels. FSIS believes that this estimate is more likely to be high than low, primarily because the estimate is based on the assumption that all State plants have the same number of labels as the average of the three small firms that were interviewed. In the analysis, the 3,376 State plants account for 145,168 labels, an average of 43 per plant. The federally-inspected plants account for 374,766 labels.

Computing industry sales and products in an analogous manner, there are about 338,190 affected products. Assuming a total of 8,933 meat and poultry products companies, there is an average of 38 products per company. It is difficult to know whether this estimate is high or low based on the available data.

Preliminary estimates of the one-time industry cost of the proposed rule are presented in Table 19. Estimates range from $433 million (under the 24-month compliance period/single analytical test per product scenario) to $1,108 million (under the 6-month compliance period/multiple analytical test per product scenario).

TABLE 19.—PRELIMINARY ONE-TIME INDUSTRY COST ESTIMATES OF THE PROPOSED NUTRITION LABELING RULE ($ MILLION)

Cost scenario	
24-month, single test	$433M
12-month, single test	635M
6-month, single test	744M
24-month, multi-test	797M
12-month, multi-test	999M
6-month, multi-test	1,108M

Note: Cost estimates include administrative costs, analytical testing costs, label printing transition costs, and inventory transition costs. Cost estimates do not include costs of market testing reformulated products or re-designed labels, nor do they include costs of scrapping, modifying or purchasing equipment.

Printing and label inventory transition costs are assumed to be one-time expenses. While administrative costs of the rule may be incurred by affected companies into the future, analytical testing costs are assumed to be the major recurring expense.

Recurring analytical testing expenses that would be incurred by now-operating processed meat and poultry companies are estimated to be $535 million annually. This preliminary estimate assumes that 338,190 processed meat and poultry products will continue to be manufactured in the 20 years following enforcement of the proposed rule. FSIS anticipates that as time passes and companies gain confidence that their labels are within compliance tolerances, producers will test products, on average, once every two years. FSIS also estimates that approximately 40 percent of processed meat and poultry labels contain substantive nutrition information on their labels. The agency thus believes that while it is appropriate to assume that all products are subject to full tests during the compliance period, it is also reasonable to assume that the recurring 20-year analytical testing costs attributable to the proposed rule are only the incremental testing costs for those nutrients and food components that would not be analyzed at baseline.

Assuming that 50 percent of all products are un-tested each year, that 30 percent of all products are tested for all nutrients each year, and that 20 percent are incrementally tested each year for cholesterol, saturated fat, and calories from fat, the weighted-average analytical cost per product is $127.

The recurring analytical testing cost of the proposed rule is $43 million per year. The present value of 20 years of recurring analytical costs assuming a 5-percent discount rate is $535 million.

Preliminary estimates of the total present-value cost of the proposed rule are presented in Table 20.

TABLE 20.—PRELIMINARY PRESENT-VALUE INDUSTRY COST ESTIMATES OF THE PROPOSED NUTRITION LABELING RULE ($MILLION)

Cost scenario	
24-month, single test	$968M
12-month, single test	1,170M
6-month, single test	1,279M
24-month, multi-test	1,332M
12-month, multi-test	1,534M
6-month, multi-test	1,643M

Note: Includes both one-time compliance cost and five-percent discounted present-value of 20 years of recurring analytical testing costs.

Estimates range from $968 million to $1,643 million, depending on the scenario. The simple levelized annual cost over a 22-year period (assuming a 24-month compliance period) is between $44 million (assuming the single-test scenario) and $60.5 million (assuming the multi-test scenario). The simple levelized annual cost over a 21-year period (assuming a 12-month compliance period) is between $55.7 million and $73 million.

V. Impact of Costs

A. Methodology

The previous chapter developed a preliminary estimate for the cost of compliance, i.e., the costs incurred by meat and poultry firms to comply with the proposed rule over a 20-year period. Economic impact differs from cost of compliance in that the economic impact analysis attempts to answer questions like:

- Will meat and poultry processors be able to pass costs onto consumers in terms of higher prices?
- Will processors have to absorb some or all of the costs out of existing profits?
- Will the costs cause some firms to go out of business?
- Will small businesses bear a disproportionate amount of the cost burden?
- How many jobs could be lost because of businesses forced to close?

The following economic analysis examines impacts under two scenarios. The first is that all costs are passed on to consumers and the second is that all of the costs must be absorbed. These assumptions cover both extremes recognizing that the actual impact would be somewhere in between. Economic impact could also include demand reduction or shifts in consumer preference among products if cost increases are sufficiently large. This type of analysis is beyond the scope of this preliminary impact analysis.

B. Costs Assumed To Raise Prices

The cost analysis in Chapter IV includes several scenarios with different estimates of up-front, one-time costs and different recurring costs. This analysis uses the one-time cost of $635 million for the scenario that provides a 12-month compliance period and assumes that on the average each product will undergo a complete nutrition analysis at a cost of $368 per product. The nondiscounted recurring costs would be $43 million per year for laboratory analysis.

Based on the 1990 population census of 252.6 million, the one-time, nonrecurring cost of $635 million equates to approximately $2.50 per person or $6.90 per household. Subtracting out infants under 5 years and vegetarians, the cost per meat and poultry consumer is approximately $2.80.

The most recent data[19] on food expenditures show that the average urban household spent $1,335 per person on food in 1988. The average rural household spent $1,178 on food per person in 1988. The average number of individuals per household is 2.75 based on the 1990 Census. The total number of households was 91,947,410.[20] The per household cost of $6.90 represents approximately 0.19 percent of an average urban household food bill of $3,671 ($1,335 × 2.75) and 0.21 percent of an average rural household food bill of $3,240 per year.

The annual recurring analytical costs of $43 represent approximately $.50 per household. This amount is negligible (.01 percent) of an annual household food bill. None of the above calculations assume a wholesale or retail market because additional profits due to fixed markups are not costs of the proposed regulations.

C. Costs Absorbed By Companies

This section assumes that a one-time, nonrecurring cost of $635 million and an annual recurring cost of $43 million would be absorbed by the companies that manufacture and distribute to retail stores consumer-sized packages of processed meat and poultry products. To help place these aggregate costs in perspective, this section develops an average annual cost per pound of production for different sizes of companies. To develop the average annual cost, the one-time, nonrecurring costs are annualized over a 20-year period.

The analysis assumes that a maximum of 9,503 domestic establishments will be affected by the proposed rule. This figure is the sum of federally-inspected processing plants and State-inspected plants. As of September 30, 1990, FSIS had 6,127 establishments processing under Federal inspection. At the same time, there were 3,376 State-inspected plants. Most, but not all, of the total 9,503 establishments produce consumer-sized processed products for sale in retail stores. Without an estimate of the number of establishments producing only fresh product, or only product for further processing, the analysis assumes all 9,503 establishments would be affected. As described previously, the 9,503 establishments were converted into 8,933 small, medium, and large companies. The average one-time and average recurring costs by company size are shown in Table 21.

TABLE 21.—AVERAGE COST BY COMPANY SIZE

Annual sales processed products	Number of companies	Average one-time nonrecurring cost	Average annual recurring cost
Less than $5 Million	5,866	$31,687	$4,953
$5 to $50 Million	2,933	88,186	2,794
More than $50 Million	134	1,418,646	42,545

FSIS collects data on the total number of pounds of finished meat and poultry products prepared at each official establishment. This data includes both fresh and processed products. Assuming that all the small companies are single establishment companies, it was possible to develop annual costs per pound for the small companies as shown in Table 22. The nonrecurring costs are annualized over 20 years to correspond to the timeframe for benefits.

TABLE 22.—AVERAGE ANNUAL COST PER POUND OF PRODUCT

[Small companies]

	Average annual production of fresh and processed meat and poultry products	Average annual recurring cost per pound	Annualized average nonrecurring cost per pound [1]	Total annual average cost per pound
3,376 State Plants	24,000	$.21	$.16	$.37
Smallest 1,000 Federally-Inspected Plants	32,000	.16	.12	.28
Next 1,000 Larger Federally-Inspected Plants	174,000	.03	.02	.05

[19] Food Spending in American Households, 1980–88, David Smallwood and others, USDA. ERS, Statistical Bulletin Number 824, May 1991.

[20] Current Population Report Series P20, Number 447, March 1989–1990, Bureau of the Census, Department of Commerce.

TABLE 22.—AVERAGE ANNUAL COST PER POUMD OF PRODUCT—Continued

[Small companies]

	Average annual production of fresh and processed meat and poultry products	Average annual recurring cost per pound	Annualized average nonrecurring cost per pound [1]	Total annual average cost per pound
Next 500 Larger Federally-Inspected Plants	400,000	.01	.01	.02

[1] A 10 percent cost of capital was used, rather than the 5 percent discount rate because financing the up-front costs is a cost of capital. The social discount rate used to convert both costs and benefits to present value for comparison purposes would underestimate the annual costs.

The average annual costs shown in Table 22 are for nutrition labeling on processed products while the production includes both fresh and processed products. In this analysis, companies have been categorized as small based on their sales or production of processed products. The totals could include some large firms where only a small portion af their business applies here.

The annual costs per pound in Table 22 would indicate that many small companies would not be able to recover all cost increases immediately. One does not need a sophisticated model to conclude that many small firms would not be able to add either $.28 or $.37 per pound to the wholesale prices they receive for their products. Thus, many small companies will have to absorb some costs out of existing profits.

Average production of processed products was also estimated for large and medium companies. Average annual production for large companies was estimated at 80 million pounds, a figure heavily influenced by packing firms that ship large volumes of boxed beef. The average annual production for medium companies was estimated at 4 million pounds. The annual cost per pound for these companies is minimal.

Estimates of the number of companies that could potentially go out of business would require an analysis of costs, profits, and business alternatives including changes in products produced. A detailed analysis of the impact on profitability and estimates of the number of firms that could go out of business is beyond the scope of this preliminary analysis. In general, the food processing industry is characterized as being very competitive with relatively low profit margins. This would support a conclusion that many companies would not be able to recover cost increases immediately.

While low profit margins may be characteristic of food processing in general, the USDA-regulated meat and poultry industry is actually a group of industries with varying profit structures. From 1980 to 1985, the sausage and prepared meat industry reported an annual return on sales of from 2.0 to 2.7 percent.[21] A 1981 study [22] of the frozen pizza industry estimated profit before taxes at 16 percent. These findings would indicate that the short-term economic impact will vary greatly depending on both the size of company and the products produced. The impact will also be highly dependent on alternative data sources for nutrition information that could substantially lower analytical costs for many firms. Some firms have also indicated that they would simply eliminate low volume, marginal products to lower their costs.

This discussion of impact also recognizes that meat and poultry processing is a rapidly changing industry where many firms enter and leave the industry each year. Because FSIS issues a grant of inspection before an official establishment can operate, the Agency has an accurate count on the number of new plants and withdrawals. Table 23 shows the changes from FY 1988 to FY 1990.

TABLE 23.—GRANTS AND WITHDRAWALS

FY	Number of grants issued	Number of withdrawals	Withdrawal rate per 10,000
1988	370	635	919
1989	420	582	866
1990	335	500	769

Note: The figures in Table 22 apply to the 6,127 Federally-inspected establishments, not the 3,376 State plants.

The Agency does not collect data on the reason for withdrawal. The rates of withdrawal are significantly higher than the business failure rates shown in Table 24.

TABLE 24.—BUSINESS FAILURES FOR MEAT AND POULTRY INDUSTRIES

[Rate Per 10,000]

Year	SIC code 2011	SIC code 2013	SIC code 2015
1985	116	174	337
1986	158	86	305
1987	82	104	160
1988	112	115	59
1989	103	67	120
1990	90	123	105

Source: The Dun & Bradstreet Corporation, Economic Analysis Department, Code 2011: Meat Packing Plants, Code 2013: Sausages and Other Prepared Meats, Code 2015: Poultry Slaughtering and Processing.

D. Differential Impact On Small Companies

The costs for the proposed rule are not necessarily proportional for large and small companies. For the companies interviewed, the cost analysis found that the average number of active labels of medium companies is only somewhat higher than that for small companies, and that the average number of product formulations is actually higher for small companies than for medium companies. Thus, the resulting cost estimates will not be proportional to size. An earlier study by FSIS on the frozen pizza industry referred to above had observed similar finding. This is, small companies have more varieties and sizes of frozen pizza, on average, than large companies distributing national brands.

In determining the impact of the proposed rule, the important variable is the sales volume per product or average sales volume for each formulation. Higher sales per formulation will provide a broader sales base over which to spread the initial company costs. Thus, a small firm with larger sales of a few products may be less affected than a larger company with many product formulations.

E. Impact on Trade

In 1990, processed meat and poultry products represented approximately 17 percent of the 2.6 billion pounds of meat and poultry imports. Out of a total of 1,370 authorized plants, 243 plants in 24 countries exported processed products into the United States. Canada accounted for the largest number with 96 plants. FSIS estimates that less than 5 percent of imported processed products are currently nutrition labeled.

There are approximately 12,000 labels approved for imported products. Chapter IV (Table 19) estimated the nonrecurring costs of modifying 520,000 labels within 12 months at $635 million, or approximately $1,220 per label. Applying the average domestic cost to 12,000 labels results in an estimated cost of $14.6 million, an average of $60,000 per plant ($14.6 million divided by 243).

The annual recurring cost of $43 million represents approximately $127 per product or $83 per label. Applying the per label cost to 12,000 labels results in an annual non-discounted, recurring cost of approximately $1 million or approximately $4,100 for each plant exporting processed products into the United States.

[21] Industry Norms and Key Business Ratios, annual, reports, Dun & Bradstreet Credit Services.

[22] Economics Analysis of Using Cheese or Cheese-like Substances in Frozen Meat or Sausage Pizza, report to the Food Safety and Quality Service, USDA, Arthur D. Little, Inc., March 1981.

VI. Takings Analysis

A rule that requires companies to revise product labels has "takings implications" as defined under Executive Order 12630. Label inventories are private property. Inventories that are not exhausted by an effective date become non-compliant labels that would be essentially worthless and presumably discarded.

Executive Order 12630 requires that before taking private property for the protection of public health, the Department consider (1) the risk created by the property and (2) the potential cost to the government in the event that a court later determines that the action constituted a taking.

In this rulemaking, the relative public health risks and potential costs are both relatively small. The non-compliant labels represent a risk in that consumers would consume unknown levels of fat and cholesterol which could be higher than intended or perceived. Given the uncertainties concerning diet and health and the timeframes over which diet is expected to affect health, the unused inventories present a relatively small risk.

At the same time, the potential costs are relatively small. Based on Table 17 in Chapter IV, the label inventory transition costs for labels that would not be used before a 6-month compliance date would be $22.6 million. Similar costs for a 12-month compliance period would be $11.3 million.

Existing departmental guidance recommends considering feasible alternatives to the proposed action which would reduce the impact upon private property. The costs associated with unused label inventory could be reduced by allowing firms to either (1) use all existing label inventory that was procured prior to the proposal date, or (2) use existing inventory that includes some nutrition information.

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Wednesday
November 27, 1991

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101, et al.

Food Labeling; General Provisions; Nutrition Labeling; Nutrient Content Claims; Health Claims; Ingredient Labeling; State and Local Requirements; and Exemptions; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 90N-0134 and 90N-0135]

RIN 0905-AD08

Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this document to supplement, and to republish in modified form, its proposals entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (55 FR 29487, July 19, 1990) and "Food Labeling; Reference Daily Intakes and Daily Reference Values" (55 FR 29476, July 19, 1990). In those documents, the agency proposed to amend its food labeling regulations to require nutrition labeling on most foods that are meaningful sources of nutrients, to revise the list of required nutrients and food components and the conditions for declaring them in nutrition labeling, and to establish up-to-date reference standards for those nutrients and food components. FDA is now modifying those proposals and responding to the recent enactment of the Nutrition Labeling and Education Act of 1990 by proposing: (1) To add sugars and complex carbohydrates to the list of required nutrients in nutrition labeling; (2) to prescribe a simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling must be used; (3) to allow specified products to be exempt from nutrition labeling; and (4) to establish regulations for the nutrition labeling of vitamin and mineral supplements. The agency is also responding to a citizen petition regarding methodologies for determining protein quality.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Virginia L. Wilkening, Center for Food Safety and Applied Nutrition (HFF-204), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1561.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 19, 1990 (55 FR 29847), FDA published a proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter identified as the mandatory nutrition labeling proposal) to amend its food labeling regulations to require nutrition labeling on most food products that are meaningful sources of nutrients. FDA also proposed to revise the list of nutrients and food components that must be included in nutrition labeling by adding calories from fat, saturated fatty acids, cholesterol, and dietary fiber to that list. It proposed to make the listing of thiamin, riboflavin, and niacin optional rather than mandatory. In addition, FDA addressed the conditions under which other nutrients could be, or are required to be, included in nutrition labeling and proposed to allow manufacturers to voluntarily include a nutrition profile of selected food components in nutrition labeling.

In the same issue of the **Federal Register**, FDA published two technical supporting proposals. The first, entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (hereinafter identified as "the RDI/DRV proposal") (55 FR 29476), proposed: (1) To replace the current U.S. Recommended Daily Allowances (U.S. RDA's) with Reference Daily Intakes (RDI's); (2) to establish RDI's for protein and for 26 vitamins and minerals; (3) to establish RDI's for five groups: Adults and children 4 or more years of age, children less than 4 years of age, infants, pregnant women, and lactating women; and (4) to establish Daily Reference Values (DRV's) for adults and children 4 or more years of age for eight food components considered important to the maintenance of good health: Fat, saturated fatty acids, unsaturated fatty acids, cholesterol, carbohydrate, dietary fiber, sodium, and potassium. The second technical, supporting proposal, entitled "Food Labeling; Serving Sizes" (hereinafter identified as "the serving size proposal") (55 FR 29517), proposed: (1) To define serving and portion size on the basis of the amount of food commonly consumed per eating occasion by persons 4 years of age or older, by infants, or by children under 4 years of age (toddlers); (2) to require the use of both U.S. and metric measures to declare serving size; (3) to permit the declaration of serving (portion) size in familiar household measures; (4) to permit the optional declaration of nutrient content per 100 grams (g) (or 100 milliliters (mL)); (5) to define a "single serving container" as that which contains 150 percent or less of the standard serving size for the food product; and (6) to establish standard serving sizes for 159 food product categories to ensure reasonable and uniform serving sizes upon which consumers can make nutrition comparisons among food products. Interested persons were given until November 16, 1990, to submit comments to the agency on these three proposed rules.

On September 26, 1990, the National Academy of Sciences' (NAS) Institute of Medicine (IOM) issued a report entitled "Nutrition Labeling, Issues and Directions for the 1990s." (the IOM Report) (Ref. 1). The IOM report, written under contract to the Public Health Service, U.S. Department of Health and Human Services and the Food Safety and Inspection Service, U.S. Department of Agriculture (USDA), makes recommendations for changes in food labeling that will assist consumers in implementing the recommendations of the Surgeon General's Report on Nutrition and Health (Ref. 2) and the National Research Council report, "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 3). On October 5, 1990, FDA published in the **Federal Register** (55 FR 40944) a notice announcing the availability of the IOM report and requested interested persons to comment on the implications of the report for the agency's July 19, 1990, proposals and for the other proposals that the agency has issued or will issue on food labeling.

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535). The 1990 amendments make the most significant changes in food labeling law since the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (the act) and have a direct bearing on FDA's three July 19, 1990, proposals to revise nutrition labeling. The 1990 amendments add section 403(q) to the act which specifies, in part, that: (1) With certain exceptions, a food is to be considered misbranded unless its label or labeling bears nutrition labeling; (2) that certain nutrients and food components are to be included in nutrition labeling, although the Secretary can add or delete nutrients by regulation if he finds it necessary to assist consumers in maintaining healthy

dietary practices; (3) that nutrition labeling is to be provided for the most frequently consumed varieties of raw produce (fruits and vegetables) and raw fish according to voluntary guidelines or, if necessary, regulations; (4) that a simplified nutrition label is to be used when the food contains insignificant amounts of most nutrients; and (5) that FDA is to develop regulations governing labeling of foods to which section 411 of the act applies. The 1990 amendments also require FDA to develop and implement specific consumer education activities.

While the requirements of the 1990 amendments that pertain to nutrition labeling are similar in many respects to FDA's three proposals of July 19, 1990, differences do exist that require the agency to issue this supplementary proposal to amend the July 19, 1990, mandatory nutrition labeling proposal and to request further comment. Those aspects of the July 19, 1990, proposal that are not addressed in the preamble of this supplementary proposal remain unchanged from the mandatory nutrition labeling proposal or the RDI/DRV proposal. FDA is incorporating herein those portions of the July 19, 1990, preambles that relate to aspects of the mandatory nutrition labeling and RDI/DRV proposals that remain unchanged.

The agency is aware from a preliminary review of comments that some further changes to the mandatory nutrition labeling proposal may be necessary. For example, the agency has received comments requesting a change in the definition of saturated fatty acids. However, there has been insufficient time for the agency to thoroughly review all of the comments and make all appropriate changes before issuing this supplementary proposal. The agency is proposing below some changes as a result of its preliminary review of the comments where it believes that such changes will help to clarify the requirements of the mandatory nutrition labeling and RDI/DRV proposals. FDA is also responding to a petition on protein quality issues that it received before the enactment of the 1990 amendments.

Persons who have already submitted comments on issues raised by the mandatory nutrition labeling and RDI/DRV proposals that are not addressed in this preamble need not do so again unless they would like to amend their comments based on the changes made in this supplementary proposal or to submit comments on those changes. However, FDA is providing this opportunity for interested persons to submit comments on any issues addressed in the mandatory nutrition labeling proposal, the RDI/DRV proposal, or this supplementary proposal and on any and all aspects of these documents. FDA will consider and respond to all the comments that it receives on these documents in its final rule.

For clarity and completeness, the text of § 101.9 (21 CFR 101.9) set forth below includes the changes discussed in this supplementary proposal, the proposed provisions from the mandatory nutrition labeling proposal that have not been changed by this supplementary proposal, and the provisions of the current regulation to which the agency is either proposing no change or only minor nonsubstantive changes. To complete the section, the agency is also including the RDI and DRV values as proposed in the RDI/DRV proposal (55 FR 29476) (i.e., § 101.9 (c)(7)(iii), (c)(10)(iv), and (c)(11)(i), redesignated here as § 101.9 (c)(8)(iii), (c)(11)(iv), and (c)(12)(i)). There is nothing in the 1990 amendments that requires changes in the RDI/DRV proposal, and accordingly, the agency intends to analyze comments received on both the RDI/DRV proposal and this supplementary proposal and move toward a final regulation on these reference values with an effective date consistent with this rulemaking. Accordingly, the agency solicits any additional comments on the reference values and the groups for which RDI's are proposed.

Serving size, which is considered in proposed § 101.9(b), was addressed in the 1990 amendments but in a manner that is fully consistent with the agency's proposal (55 FR 29517). However, a preliminary review of the comments on the serving size proposal revealed significant disagreement. As a result, FDA is reconsidering its tentative position on serving size and intends to address this subject in a subsequent document. Therefore, FDA is not including proposed § 101.9(b) in the regulatory language at the end of this document.

Because the establishment and use of standard serving sizes is a new endeavor for the agency, FDA issued a notice on February 26, 1991 (56 FR 8084), announcing a public meeting to further discuss issues related to how serving size should be determined and presented as a part of nutrition labeling. The meeting was held on April 4, 1991, in Washington, DC. The agency was requested to hold an additional public meeting on the RDI/DRV proposal. However, FDA denied this request because it did not believe it could justify another public meeting given the resources and time constraints under which it is working to meet the requirements of the 1990 amendments (Ref. 3a). Unlike the serving size issue, the establishment of reference values for nutrition labeling has been a practice of the agency for almost 20 years and is based on well-recognized scientific and dietary guideline documents.

II. Mandatory Nutrition Labeling—Legal Authority

Before the passage of the 1990 amendments, the act did not specifically mention nutrition labeling. In the mandatory nutrition labeling proposal, however, FDA tentatively concluded that it had authority to require nutrition labeling on virtually all foods that are a meaningful source of nutrition. The agency found this authority in section 403(a)(1) of the act, which states that a food is misbranded if its label or labeling is false or misleading in any particular, section 201(n) of the act, which states that the labeling of a food is misleading if it fails to reveal facts material with respect to consequences that may result from use of the food, and section 701(a) of the act, which authorizes FDA to adopt regulations for the efficient enforcement of the act. In the mandatory nutrition labeling proposal (55 FR 29487 at 29492), the agency stated that:

> Given the history and use of nutrition labeling, the advances in nutrition science * * * and the public interest in healthful diets, FDA concludes that the nutritional content of a food is a material fact, and that a food label is misleading if it fails to bear nutrition information * * *.

The 1990 amendments confirmed the agency's authority to require nutrition labeling. Section 403(q) of the act states that a food shall be deemed to be misbranded if, with certain exceptions, it fails to bear nutrition labeling. Accordingly, FDA is proposing to revise § 101.9, as set forth below, to require nutrition labeling on all foods that are a meaningful source of nutrition under sections 201(n), 403(a)(1), 403(q), and 701(a) of the act.

III. Content of Nutrition Labeling

Section 403(q)(1) of the act, which was included in section 2(a) of the 1990 amendments, specifies that nutrition labeling shall include information on the total number of calories derived from any source; the number of calories derived from total fat; the amount of total fat, saturated fat (i.e., saturated fatty acids), cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, total protein, and any vitamin, mineral, or other nutrient

required to be placed on the label under the act before October 1, 1990, if the Secretary determines that information about the vitamin, mineral, or other nutrient will assist consumers in maintaining healthy dietary practices. Section 403(q)(2) of the act states that other nutrients may be required by regulation to be included in the nutrition label, or required nutrients may be removed, if the Secretary determines that their placement on the label would (or would not) assist consumers in maintaining healthy dietary practices.

In regard to section 403(q) of the act's reference to vitamins, minerals, and other nutrients that were required to be placed on the label before October 1, 1990 (section 403(q)(1)(E) of the act), FDA notes that this reference is somewhat confusing. No vitamins, minerals, or other nutrients were required to appear on the label and labeling of food before October 1, 1990. The apparent reference is to 21 CFR 101.9(c)(7)(iii), which provides that when nutrition labeling is required, it must include vitamin A, vitamin C, thiamin, riboflavin, niacin, calcium, and iron. FDA is proposing to require the inclusion of all of these nutrients in the nutrition label except for thiamin, riboflavin, and niacin, whose declaration the agency proposed to make voluntary in its mandatory nutrition labeling proposal (55 FR 29487). The agency tentatively concluded that "Public health concerns for deficient intakes of these nutrients (thiamin, riboflavin, and niacin) have lessened considerably in the last 20 years," and, accordingly, proposed to delete them as a mandatory part of nutrition labeling. The IOM report also stated that thiamin, riboflavin, and niacin are not current public health issues and did not recommend that the disclosure of their levels in food be required (Ref. 1). Thus, because the agency tentatively finds that inclusion of these three nutrients in the nutrition label is not necessary to assist consumers in maintaining healthy dietary practices, under section 403(q)(2)(B) of the act, FDA is proposing to delete them from the list of nutrients that are mandatory elements of nutrition labeling.

A. Sugars and Complex Carbohydrates

The principal change that the 1990 amendments would require in FDA's mandatory nutrition labeling proposal is the addition of sugars and complex carbohydrates to the list of nutrients and food components that must be declared in nutrition labeling. Accordingly, to comply with the 1990 amendments, FDA is modifying proposed § 101.9(c)(6)(i) and (c)(6)(ii)(A) of the mandatory nutrition labeling proposal to make the declaration of complex carbohydrates and sugars mandatory.

In the mandatory nutrition labeling proposal, the agency proposed to make the declaration of these two food components voluntary. FDA set out the factors that it considered in deciding whether a nutrient or food component should be mandatory or voluntary in nutrition labeling:

> The agency has proposed to make the declaration of a nutrient or food component mandatory in nutrition labeling when quantitative intake recommendations with respect to the nutrient or component are highlighted in the reports cited above (e.g., "Reduce total fat intake to 30% or less of calories." * * *), and the nutrient or component is of particular public health significance as defined in several recent consensus documents * * *. On the other hand, for those nutrients or food components for which quantitative intake recommendations are not highlighted but that do have some public health significance (e.g., "* * * increase intakes of starches * * *" * * *), or for which quantitative recommendations are available but that are not of pressing public health importance (e.g., the Recommended Dietary Allowances for several vitamins and minerals * * *), the agency is proposing to make declaration of the nutrient or component voluntary.
>
> (55 FR 29487 at 29493.)

Accordingly, while several recent dietary guidelines recommend that intakes of sugars and sugar-rich foods be limited (Refs. 2, 3, and 4), FDA did not propose to require the mandatory declaration of sugars content because specific quantitative recommendations have not been provided. Similarly, dietary guidelines have recommended increased consumption of complex carbohydrates but have not clearly defined the term "complex carbohydrates" and also have not highlighted quantitative consumption goals (Refs. 2, 3, and 4). Thus, FDA did not propose to require the mandatory declaration of complex carbohydrates in nutrition labeling. The IOM report also recommended that the declaration of sugars and complex carbohydrates be voluntary (Ref. 1).

As stated above, section 403(q)(2)(B) of the act allows the Secretary to determine whether information relating to nutrients specified in section 403(q)(1)(C), (q)(1)(D), (q)(1)(E), or (q)(2)(A) is necessary to assist consumers in maintaining healthy dietary practices and, if not, to delete such nutrients from the required list of nutrients in nutrition labeling. Accordingly, FDA has considered its option to continue to make the inclusion of sugars and complex carbohydrates optional rather than mandatory elements of nutrition labeling. However, a preliminary review of comments received by the agency on the mandatory nutrition labeling proposal shows consumer interest in having sugars and complex carbohydrates as a mandatory part of nutrition labeling. In addition, while current dietary guidance recommendations (Refs. 2, 3, and 4) have not specified quantitative amounts, the general directions of the recommended modifications in current intakes—i.e., increase complex carbohydrates and limit sugars—are specified. Based on these factors FDA has tentatively concluded that consumers would find the inclusion of these food components useful in maintaining healthy dietary practices. Therefore, in accordance with the 1990 amendments and consistent with consumer comments, FDA is proceeding to amend its mandatory nutrition labeling proposal by proposing in § 101.9(c)(6)(i) and (c)(6)(ii)(A) to include sugars and complex carbohydrates as mandatory elements of nutrition labeling.

However, the preliminary review of comments also shows support for voluntary, rather than mandatory declaration of sugars and complex carbohydrates. The agency acknowledges that the mandatory approach is potentially controversial for several reasons, and that there is some basis to question the appropriateness of this approach. First, the inclusion of complex carbohydrates and sugars within the mandatory nutrition label may be misleading to consumers because it may suggest that these food components have greater public health significance than has been established by existing diet and health studies. More specifically, the identification of a specific benefit for complex carbohydrates is confounded by the fact that diets high in complex carbohydrates are usually mixed diets that contain significant amounts of cereal grains, fruits, and vegetables which are high in fiber, vitamins, and minerals and low in fat (Ref. 2). Thus, it is unclear the extent to which complex carbohydrates impart health benefits separate from such factors as the presence of fiber, vitamins, minerals, and reduced levels of fat. For sugars, the major public health concern relates to the relationship between sugars and dental caries. However, other factors, such as the characteristics of the food that contains the sugars (e.g., stickiness), the frequency of consumption, and the sequence in a meal, appear to be as

important in the etiology of dental caries as the sugars themselves (Refs. 2 and 3).

Second, as noted above, the Surgeon General's report (Ref. 2) and NAS's Diet and Health report (Ref. 3) have not specified a recommended level of intake for either complex carbohydrates or sugars. FDA has tentatively concluded that without targeted recommendations from these major consensus reports, it would not be appropriate to establish reference values, i.e., DRV's, for these food components. Moreover, FDA is proposing DRV's for all the other food components required to be declared in nutrition labeling except for protein, vitamin A, vitamin C, calcium, and iron, for which RDI's are being established. The agency anticipates that the reference value DRV's and RDI's will be helpful for consumers in planning overall diets, and the agency does not know the extent to which the absence of DRV's for complex carbohydrates and sugars will be problematic or confusing for consumers.

Third, the terms "complex carbohydrates" and "sugars" have not been clearly or consistently defined. While it is most appropriate to chemically define these terms in a way that reflects the physiological effects and health benefits associated with food substances, available consensus reports have not attempted to do so (Refs. 1 through 4). In its mandatory nutrition labeling proposal in which sugars and complex carbohydrates were proposed as voluntary, FDA proposed to define sugars as the sum of all free mono- and oligosaccharides and (and their derivatives) that contain four or fewer saccharide units (55 FR 29487 at 29513). This definition includes tri- and tetrasaccharides primarily to avoid underdeclaration of the sugars content of foods rich in corn syrups. It also includes sugar alcohols because they have sweetening, nutritional, and metabolic effects similar to sugars. This definition differs from that used by Canada (Ref. 5), the Codex Alimentarius Commission (Ref. 6), and the European Community (Ref. 7), all of which limit the definition of sugars to mono- and disaccharides.

FDA defined complex carbohydrates in the mandatory nutrition labeling proposal as the sum of dextrins and starches, i.e., those carbohydrate components that contain 10 or more saccharide units exclusive of dietary fiber (55 FR 29487 at 29497). However, the inclusion of dextrins (saccharide units of 10 or more) within the definition of complex carbohydrates may inappropriately classify the relatively low molecular weight carbohydrates in some nutritive sweeteners as complex carbohydrates. This definition may result in some foods, such as coffee whiteners and ice cream, that contain large amounts of low conversion (i.e., low dextrose equivalent) corn sweeteners being classified as sources of complex carbohydrates. These low molecular weight carbohydrates may have nutritional or metabolic effects different from those of commonly recognized complex carbohydrates. Thus, it may be misleading to consumers if these foods are labeled as containing complex carbohydrate.

FDA specifically requested comments on these suggested definitions and solicited alternative suggestions in the mandatory nutrition labeling proposal. FDA has not yet reviewed the comments that were submitted. Therefore, the agency has not modified the definition of sugars, although it has added a more precise definition of dextrins, as "saccharide units of 10 or more," to the definition of complex carbohydrates in § 101.9 (c)(6)(i).

Finally, from a compliance perspective, the proposed approach of including complex carbohydrates and sugars as mandatory elements of nutrition labeling poses certain analytical problems. Specifically, available and widely used laboratory methods provide for the analysis of carbohydrate in foods in a manner that may not be sufficiently specific for regulatory purposes. For example, available analytical procedures now measure carbohydrate as either more than 4 saccharide units or as single saccharide units up to 4 units. Suitable analytical procedures would be needed if complex carbohydrates were to be defined as those carbohydrates that contain a specified number of saccharide units that exceeds 4 (e.g., 10 units).

Therefore, because of all of these concerns and because this approach constitutes a change from the mandatory nutrition labeling proposal, FDA requests specific comments on its proposal to include complex carbohydrate and sugars as mandatory elements of nutrition labeling. The agency solicits comments concerning the utility and appropriateness, as well as the feasibility, of requiring declaration of complex carbohydrate and sugars content particularly as such declarations relate to and are supported by public health goals. If the mandatory declaration of these food components is considered necessary to assist consumers in maintaining healthy dietary practices, the agency further requests comments on the physiological effect of carbohydrate fractions, on appropriate chemical definitions and analytical methodologies for these substances, and on the impact, if any, of the absence of a DRV for these food components. Based on such comments and the other information that it has received, the agency will decide, under section 403(q)(2) of the act, whether to include complex carbohydrate and sugars in the required list of nutrients in nutrition labeling.

B. Protein Quality

While not directed to do so by the 1990 amendments, the agency is including in this supplementary proposal a modification of the mandatory nutrition labeling proposal regarding the determination of protein quality. This action is in response to a citizen petition submitted by Protein Technologies International, Inc. (Docket No. 90P-0052), requesting that the agency accept an amino acid scoring method that is corrected for protein digestibility in addition to the presently accepted procedure, the Protein Efficiency Ratio (PER) method. The agency has decided that the petition has merit, and that the agency's response to it should be integrated into this rulemaking because protein quality is an important part of nutrition labeling. Therefore, the agency is incorporating into this proposal most of the concepts from the petition and providing that any final rule based on this proposal will be a final disposition of the subject petition.

In the mandatory nutrition labeling proposal, FDA indicated that a more flexible approach to determining protein quality was desirable. The preamble stated:

> As new methodologies and new information on amino acid requirements of various age groups become available, the agency believes it must become more flexible in regard to permitted protein quality methodologies. Therefore, while the PER method described in the Official Methods of Analysis of the Association of Official Analytical Chemists may continue to be used as one of the methods for assessing the protein quality of foods, alternative acceptable validated procedures may be used as they become available.
>
> (55 FR 29487 at 29499).

Dietary protein serves as a source of essential and nonessential amino acids, the building blocks of body protein, and also as a source of energy. Because excess amino acids are not stored in the body, humans need a constant supply of good quality dietary protein to support growth and maintenance of body protein. Primarily, assessment of protein quality is a measure of the content,

proportion, and availability of essential amino acids in food protein. Accurate methods for determining protein quality are necessary because different food protein sources are not equivalent in their ability to support growth and body protein maintenance. When nutrition labeling regulations were promulgated in 1973, FDA used the PER method for measuring protein quality of foods and made a gross separation of protein types into high and low quality proteins with a separate U.S. RDA for each category (38 FR 2128, January 19, 1973). This method continues to be used in current regulations (§ 101.9(c)(7)(ii)).

The need for improved methods of assessing protein quality has been recognized for over a decade, but suitable alternative methods were not available. The PER method measures the ability of a protein source to support growth in young, rapidly growing rats. It is an expensive and time-consuming biological assay that compares weight gain in rats fed a test protein to the gain in rats fed a protein standard, casein. Moreover, as indicated in the agency's proposal on common or usual names for vegetable protein products (43 FR 30472, July 14, 1978), there has been increasing scientific data to demonstrate that the PER method for evaluating protein is not very precise for measuring protein quality for human needs. In brief, PER overestimates the value of some animal proteins for human growth and underestimates the value of some vegetable proteins because rapidly growing rats have a higher need for certain essential amino acids (Ref. 8, p. 4). The continued use of the PER method to assess comparative protein quality for food labeling purposes was discussed in a recent review article published in the *Journal of Nutrition* (Ref. 9).

Following publication of the mandatory nutrition labeling proposal, the Codex Alimentarius Commission accepted a method for assessing protein quality that uses a protein digestibility-corrected amino acid score (PDCAAS) (Ref. 9a, p. 80). This method had been recommended in a report from a joint expert consultative group of the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO) (Ref. 8). The standard used for assessing protein quality in the PDCAAS method is the amino acid scoring pattern established by FAO/WHO/United Nations University (UNU) in 1985 for preschool children 2 to 5 years of age (Ref. 10). To calculate PDCAAS, the test food is analyzed for protein and amino acid composition and the digestibility of the protein is determined with a standardized rat balance method. Overall, the most limiting essential amino acid (that is, the amino acid that is present at the lowest level in the test food compared to the standard) is identified in the test food by comparing the levels of individual amino acids in the test food with the FAO/WHO pattern of the essential amino acids established as a standard for children 2 to 5 years of age. The value of the most limiting amino acid (the ratio of the amino acid in the test food over the amino acid value from the pattern) is multiplied by the percent of digestibility of the protein. This resulting number is the PDCAAS.

The FAO/WHO/UNU report proposed separate amino acid scoring patterns for infants, preschool children 2 to 5 years of age, school-aged children 6 to 12 years of age, and adults, implying that protein quality varies with the age of the individual. The report stated that protein and diets containing essential amino acids that met the greater needs of young children were also adequate for older children and adults, whereas the reverse may not be true (Ref. 10). Five years later, the FAO/WHO consultative group evaluated the FAO/WHO/UNU report and concluded that there is no adequate basis to use different scoring patterns for different age groups with the exception of infants who have much greater needs for essential amino acids (Ref. 8). They recommended that the FAO/WHO/UNU amino acid scoring pattern for preschool children should be used to evaluate protein quality for all age groups, except infants. They also concluded that the protein digestibility-corrected amino acid score is the most suitable regulatory method for evaluating protein quality of foods, stating that "Since this method is based on human amino acid requirements, it is inherently more appropriate than animal assays used for predicting protein quality of foods and the Consultation therefore recommends that the procedure be adopted as the preferred method of measuring protein values in reference to human nutrition" (Ref. 8).

The agency has reviewed the FAO/WHO report and tentatively accepts its conclusion that the protein digestibility-corrected amino acid score method is more appropriate for assessing protein quality of foods than animal assays and is preferable for regulatory purposes. Therefore, the agency is proposing in § 101.9(c)(8)(ii) to require the use of the PDCAAS method as the method for determining protein quality for food intended for children over 1 year of age and adults. While this method is recommended for all children above 1 year of age, it is not recommended for infants, and therefore FDA proposes in § 101.9(c)(8)(ii) to retain the PER method for assessing protein quality and to retain casein as the standard in expressing the percentage of the RDI for protein in foods represented and purported to be for use by infants. FDA notes that there is an inconsistency between the FAO/WHO report cited above (Ref. 8) and a report of the meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) which was held in February 1991 (Ref. 10a). While the CCNFSDU endorsed the use of the PDCAAS method, it adopted a higher standard for protein quality for children 1 to 3 years of age. The CCNFSDU report requires that "The amino acid score * * * should not be less than 70 percent of that of casein." The agency invites comments on the difference between the two reports especially with regard to issues of safety and public health of children between the ages of 1 and 3 years of age.

C. Terminology

1. Food Components

To be consistent with terminology used in the 1990 amendments, FDA is modifying the listing of "fat" to "total fat," "carbohydrates" to "total carbohydrates," "fiber" to "dietary fiber," and "saturated fatty acid" to "saturated fat." The agency had used the abbreviated terms "fat," "carbohydrate," and "fiber" to minimize space requirements for nutrition labeling. However, both the comments on the mandatory nutrition labeling proposal and research that the agency conducted in the fall of 1990 have shown that these abbreviated terms cause some consumer confusion (Ref. 11). FDA's research showed that many consumers did not realize that the "saturated fat" content was a part of the "fat" content, as listed (Ref. 11). The agency learned that many consumers think that it is necessary to add the grams of fat and the grams of saturated fat to get a total fat value (Ref. 11). While nutrition education programs are needed to address this issue, FDA believes that consumer confusion will be reduced by the use of the more explicit term "total fat."

Likewise, now that the agency is proposing to make complex carbohydrates and sugars mandatory elements of nutrition labeling, the use of the term "total carbohydrates" will help make clear that the term includes the two subelements listed beneath it. These

changes in terminology are supported by the IOM report which used the term "total fat" and recommends use of the term "total carbohydrate" when carbohydrate components are listed on the nutrition information panel, with the subgroups indented (Ref. 1).

In contrast to the listings for fat and carbohydrates, the agency does not believe there is a need to add the term "total" in front of "protein" because there are no other protein terms that are permitted to be listed. In addition, it may be helpful to minimize space requirements by the declaration of protein content since the percent RDI may be included on the same line (proposed § 101.9(c)(7)(i), redesignated as § 101.9(c)(8)(i) in this document). In regard to fiber, comments have stated that the use of the more precise term "dietary fiber" would help clarify the type of fiber being declared. FDA agrees with these comments and, as stated above, is using the suggested term in this supplementary proposal.

FDA is also proposing to require the use of the abbreviated terms "saturated fat," "unsaturated fat," "polyunsaturated fat," and "monounsaturated fat" in nutrition labeling in place of the more scientifically correct terms that include "fatty acid." The abbreviated terminology is used in the 1990 amendments and was recommended in the IOM report (Ref. 1). It also is consistent with terminology used in the dietary recommendations given in the Surgeon General's report (Ref. 2) and the Dietary Guidelines for Americans (Ref. 4). The agency has tentatively concluded that use of the abbreviated terms will help to reduce consumer confusion, as well as help to minimize space requirements within nutrition labeling.

2. Reference Values

In its mandatory nutrition labeling proposal (55 FR 29487), FDA acknowledged that the replacement of the U.S. RDA's with two sets of reference values, RDI's and DRV's, could potentially be confusing to consumers if both of the new terms were used on the food label. Although it is necessary to distinguish between RDI's and DRV's for regulatory purposes, FDA does not consider the distinction to be important to a consumer's understanding of the nutrition information presented on the food label. Therefore, FDA asked for comments on the possibility of listing the reference values on the label under a single new term.

On its own, FDA has arrived at "Daily Value" as a possibility for use as this single term. FDA believes that this term would be appropriate for two reasons. First, it is consistent with section 2(b)(1)(A) of the 1990 amendments, which directs the Secretary to require that information on the nutrition label be presented in a manner that enables consumers to understand the significance of the information presented in the context of a total daily diet. This term makes clear that the reference value is a daily intake level. Second, FDA has conducted consumer research that included discussions of the term "Daily Value" and, in general, the term was correctly interpreted by consumers (Ref. 11). However, consumers did suggest that the use of the word "value" was confusing. They commented that the word implied price or cost, rather than a reference standard.

The agency has received additional comments that also indicate that the term "Daily Value" may not be appropriate and has the potential to cause confusion. Alternative suggestions made to the agency include: Daily allowance, daily level, balanced daily allowance, recommended daily amount (or standard), daily limit, daily need, daily requirements, daily intake, and total daily value.

The agency is not proposing alternative terms that use words such as "recommended," "requirement," or "need" because such terms could be misleading to consumers and complicate nutrition education efforts. For example, some reference values are intended to guide consumers relative to maximum intakes (e.g., total fat), while others are intended to serve as a basis for planning general diets to meet nutrient requirements (e.g., vitamin C) or as minimum intakes (e.g., potassium). It would be incorrect to imply that FDA "recommends" that consumers consume the maximum intake level for total fats, or that such levels are "required."

FDA is, therefore, specifically reiterating its request for comment on, and suggestions for, appropriate terminology to be used to refer to both RDI's and DRV's when used as reference values on the food label, particularly as to the most meaningful and appropriate term to convey to consumers the purpose and intent of the reference values.

D. Fatty Acids

In its mandatory nutrition labeling proposal, FDA requested comments concerning the definitions of, and content declarations for, the different types of fatty acids (55 FR 29487). FDA stated that the available evidence does not support a cholesterol-raising effect for *trans* isomers when they are substituted for saturated fatty acids in the diet. New research and commentary have been published (Refs. 12 and 13), however, concerning the effect of *trans* isomers of fatty acids on the serum cholesterol levels. In view of these publications, the agency is requesting comments on the significance of the new findings for nutrition labeling and further requests that persons who submitted comments concerning *trans* isomers in response to the mandatory nutrition labeling proposal reevaluate their comments relative to the newest data and, if appropriate, submit additional or revised comments.

The agency also notes the increased use of fats containing long and very long chain fatty acids (e.g., components of partially hydrogenated menhaden oil) in the food supply and the potential for the marketing of novel compounds in which fatty acids are linked to carbon structures in a manner that will reduce their digestibility. As a result, these compounds will have the technical effects of fat without the calories. The agency is requesting comment concerning the appropriateness of current fat related definitions and analytical procedures for the declaration of these compounds with respect to mandatory nutrition labeling. FDA also requests the submission of the results of any research finding that will assist the agency in arriving at appropriate definitions for fatty acid groups.

In addition, definitions for "saturated" fatty acids and "unsaturated" fatty acids proposed by FDA are at variance with those of Canada (Ref. 5), the Codex Alimentarius Commission (Ref. 6), and the European Community (Ref. 7). Differing definitions among these organizations, Canada, and the United States could result in added analytical expenses for nutrition labeling and to support nutrition claims for internationally marketed products. The agency therefore requests comment on the need for internationally uniform fat definitions for purposes of labeling.

E. Additional Information

Section 2(b)(1)(C) of the 1990 amendments stipulates that regulations shall "permit the label or labeling of food to include nutrition information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section * * *." In its mandatory nutrition labeling proposal, FDA proposed to allow the voluntary declaration of several food components (e.g., unsaturated fat and soluble fiber) and any naturally occurring vitamins and

minerals for which RDI's have been proposed in § 101.9(c)(10)(iv), which is redesignated as § 101.9(c)(11)(iv) in this document. However, the agency requested comment on the merits of allowing a voluntary listing of nutrients and food components beyond those required in nutrition labeling. The agency raised questions about how the presence of these additional nutrients and food components on the label would be interpreted by consumers, and whether the listing of some voluntary nutrients and food components would actually be misleading (55 FR 29493). Through the inclusion of section 2(b)(1)(C) in the 1990 amendments, Congress would appear to have settled this issue, and, accordingly, the proposed regulations will continue to allow specified nutrients and food components, like unsaturated fat and soluble fiber, to be included voluntarily in nutrition labeling. However, the House Report on the 1990 amendments (Ref. 16) states that the regulations that FDA adopts should assure that the information that is included voluntarily does not interfere with the consumer's understanding of the information that is required to be included in the nutrition label. Therefore, FDA requests comment on whether it is necessary to include limits on the voluntary information that may be provided.

IV. Nutrition Label Format

As stated above, section 2(b)(1)(A) of the 1990 amendments states that implementing regulations shall "require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet." FDA interprets this provision as supporting the proposed DRV's and as a mandate for the agency to continue the effort that it began as part of Secretary Sullivan's food labeling initiative of conducting consumer research to determine the most useful and appropriate format for nutrition labeling.

FDA began its research by testing consumer reactions to alternative label formats in five consumer focus groups (Ref. 11). A focus group session is a qualitative information-gathering technique in which a group of 8 to 10 persons is guided through a discussion of a specific topic by a trained moderator. A session usually lasts about 1 to 2 hours. While the outcomes of these sessions are generally not quantifiable, they can help in guiding the design and interpretation of structured research projects and can provide useful insights into consumer behavior.

The agency's preliminary consumer focus group sessions were designed to provide qualitative information on four types of nutrition label formats, specifically bar graphs, pie charts, adjectival descriptors, and tabular numeric formats (Ref. 11). In designing the focus group sessions, FDA included specific comparison tasks or discussion issues that targeted the participants' ability to use and interpret the format. In this way, the discussions were structured to explore issues beyond stated preference and initial visual appeal. However, the extent to which familiarity with the current label influenced participants' responses could not be determined.

The outcome of the focus group discussions suggested that participants had difficulty using pie charts and bar graphs. In addition, formats based on adjectival descriptors, such as the use of the word "high" to designate the level of a nutrient in a food, did not increase participants' ability to compare levels of nutrients between foods. The tabular numeric format, which was similar to the current label, was readily used and most often appropriately interpreted by participants. Some participants suggested that this type of format required "less work" to interpret than bar graphs or pie charts. Virtually all participants favored some type of label standard or reference value for macronutrients and food components associated with chronic disease conditions (Ref. 11).

The agency also has conducted a large scale quantitative study to evaluate the communication effectiveness of five alternative label formats. The study employed a representative national sample of 1,000 adult primary food shoppers and a separate sample of 500 undereducated shoppers (Ref. 14). The criteria on which labels were evaluated included: Accuracy with which consumers distinguished between nutritionally dissimilar foods, time required to make distinctions, confidence in using formats, and rated helpfulness of formats for food selection and meal planning. Study respondents provided comments about the most helpful and least helpful features of the formats.

On May 20, 1991 (56 FR 23072), FDA published a notice in the **Federal Register** that announced the availability of a report of the results of this study. The notice also asked for comments on the study and on proposed additional format research.

Should FDA ultimately decide, based on comments and the results of the studies, that changes in the format of nutrition labeling appear to be necessary, it intends to propose those changes in time to include any such changes in the final nutrition labeling regulations that must be published by November 8, 1992.

The proposed DRV's were used in several formats studied in the focus group sessions as well as in some of those investigated in the quantitative study (Refs. 11 and 14). In these and other studies (Ref. 15), consumers indicated a desire to have reference values, such as the proposed DRV's, on food labels. A preliminary review of comments received on the mandatory nutrition labeling and RDI/DRV proposals also indicates great consumer interest in having these reference values become a part of nutrition labeling. The DRV's appear to help fulfill the requirements of section 2(b)(1)(A) of the 1990 amendments in that they enable consumers to "comprehend such information (i.e. nutrition labeling) and to understand its relative significance in the context of a total daily diet."

In light of these responses, the agency is of the opinion that use of the DRV's will help meet the objectives of the 1990 amendments and is therefore proposing to make them mandatory in some form. How they will be expressed within nutrition labeling and in what form is the subject of further format research. However, at this time FDA wishes to advise that it intends to require inclusion of DRV's in nutrition labeling, and it therefore requests further comments on how they might be expressed.

There are certain additional aspects of the current format that are directly affected by the 1990 amendments (i.e., highlighting, use of ranges, and a simplified format). A discussion of these matters follows.

A. Highlighting

Section 403(q)(1) of the act provides that "The Secretary may by regulation require any information required to be placed on the label * * * to be highlighted * * * by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices."

FDA's current regulations do not address this issue. While many examples of highlighting of nutrients in nutrition labeling can be found in the marketplace, the agency has viewed the practice as a marketing activity rather than as a tool for educating or assisting consumers in planning a healthy diet. Highlighting is widely practiced by designers of print communications.

including food package designers, as a means of enhancing the readability of print materials. However, FDA has not conducted any research to determine the effectiveness of highlighting in directing consumer attention to specific nutritional information or in helping consumers to retain the highlighted information.

Comments are requested on the usefulness of highlighted information to consumers. For example, the agency asks for comments on what information, if any, should be highlighted; how, when, or where highlighting should be used; the circumstances in which it may be misleading (e.g., highlighting the cholesterol, but not the fat content of a food); and what costs are involved. Research findings would be particularly useful.

B. Ranges for Nutrients

Section 2(b)(1)(D) of the 1990 amendments directs FDA to permit the quantitative information on nutrition labeling to remain the same (i.e., to be stated as a single value) or to be stated as a range:

> * * * even though (i) there are minor variations in the nutritional value of the food which occur in the normal course of the production or processing of the food, or (ii) the food is comprised of an assortment of similar foods which have variations in nutritional value.

FDA, since 1973, has provided guidelines for deriving nutrition label values that are representative of the range of nutrients in a food. Under the guidelines, the label values are established by statistical analyses of data gathered to account for seasonal effects, growing/harvesting regions, storage, and other variables that affect nutrient content. This procedure, together with FDA's compliance standards in § 101.9(e)(4)(ii) and (e)(5) (renumbered as § 101.9(g)(4)(ii) and (g)(5) in this proposal), which allow up to a 20 percent deviation for naturally occurring nutrients, permits most foods to be represented by a single label value for each nutrient, even those that are quite variable.

The agency believes that single values calculated using this procedure are more informative, and are less confusing, for consumers than are ranges of values, especially where the ranges are large. It is true that requiring a single value may result in underdeclaration of some nutrients (e.g., vitamin C) and overdeclaration of others (e.g., sodium) when variability is high. However, the single value will fairly represent the nutrient levels that the consumer can depend upon receiving from the product over time. A single value also permits manufacturers to avoid frequent product analyses and label changes, and it requires that FDA take compliance action only if a label significantly misrepresents the nutrient content of a food.

The statistical procedures used by FDA are discussed in a guide, "Compliance Procedures for Nutrition Labeling," as noted in the mandatory nutrition labeling proposal (55 FR 29487 at 29507). This guide may be obtained from the Division of Nutrition, Center for Food Safety and Applied Nutrition (address above). A revised guide, to be entitled "FDA Nutrition Labeling Manual—A Guide for Using Data Bases," will be available by the time a final rule in this proceeding is issued. The revised guide will provide a more comprehensive discussion of procedures for using a data base to develop a nutrition label. It will also discuss some suggested alternatives to current procedures. In the revised guide, the agency will provide for the use of a mean value derived from a satisfactory data base for use in nutrition labeling in conformance with § 101.9(g)(4)(ii). In order to ensure that the data base is adequate for this purpose, a maximum coefficient of variation will be incorporated in the revised guide in addition to other requirements. The coefficient of variation is the standard of deviation (a measure of variability) expressed as a percentage of the mean. The mean value that may be used should be derived from an acceptable data base that meets the criteria given in detail in the booklet and summarized below:

Number of samples	Maximum coefficient of variation
5	17
10	25
20	31
30	34
40	36
50	37

Thus, if the sampling plan is acceptable to the agency, and the above number of samples are assayed, then, if the coefficient of variation is equal to or less than the maximum coefficient of variation applicable to the number of samples as specified above, the mean value may be used for labeling purposes instead of the calculated value using the agency formula.

The booklet detailing the requirements of an acceptable data base will have a more complete discussion of the use of mean values and calculated values and when each may be used for reasonable nutrient label values. The agency intends to publish a notice in the Federal Register when the revised guide is completed to provide an opportunity for public review.

FDA tentatively concludes that the agency's current compliance policy with respect to labeling in the face of nutrient variability, satisfies the requirements of the 1990 amendments. While the legislative history (Ref. 16) states that section 2(b)(1)(D) is to give the Secretary flexibility to permit nutrient values to be declared as a range, the agency does not believe that doing so will assist consumers in maintaining healthy dietary practices and, therefore, is not proposing any changes in its regulations in response to this section. However, the agency solicits specific comment on the use or display of ranges on nutrition labels.

C. Simplified Format

In an effort to keep the space requirements for the nutrition label to a minimum, FDA proposed in the mandatory nutrition labeling proposal that certain nutrients and food components (i.e., calories from fat, saturated fatty acids, cholesterol, fiber, vitamins, and minerals) could be omitted from the tabular listing if they are not present in the food or are present in very small amounts. When these nutrients and food components are omitted from the tabular listing, FDA proposed to require that the statement "Not a significant source of _____." with the blank filled in with the missing items, be included within the nutrition labeling (55 FR 29487 at 29502).

Section 403(q)(5)(C) of the act, takes a somewhat different approach. It states that:

> * * * If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.

In discussing label format issues, the IOM report (Ref. 1, p. 299) states that "There is an obvious tension between the goal of label uniformity, which will facilitate consumer use of nutrition labeling, and the possible need for modification for specific foods or markets." While the benefits of consistency in the presentation of nutrition information are stressed, the report also states that "It may be appropriate to allow foods that contain very few of the mandatory components of nutrition labeling to use an

abbreviated version of the standards format * * *."

Research conducted in conjunction with selection of the current nutrition label format showed that consumers of all educational backgrounds were consistently more accurate in identifying individual nutrient differences between foods, as well as in making overall comparative judgments about nutrition quality, when nutrients not present at significant levels were omitted from the nutrition label (Ref. 17). These results need to be weighed against other research that showed strong consumer preference for having all nutrients reported on the label rather than only those nutrients that are actually present in the food (Ref. 15).

To reflect the part of section 403(q)(5)(C) that states "* * * If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food * * *," FDA is proposing in § 101.9(f)(1) to consider all 15 nutrients and food components that would be mandatory under this proposal as "required nutrients." The 15 food components and nutrients to be included are: calories, calories from fat, total fat, saturated fat, cholesterol, total carbohydrate, complex carbohydrate, sugars, dietary fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron. While the agency generally refers in this document to calories as a measure of energy; to fat, fatty acids, cholesterol, carbohydrates, fiber, protein, and sodium as food components; and to vitamins and minerals as nutrients, it is clear in section 403(q)(2)(B) of the 1990 amendments that all of these categories are included under the general term "nutrients." Accordingly, FDA is proposing to use all of them in calculating "* * * one-half the nutrients required * * *." Therefore, FDA interprets the language in section 403(q)(5)(C) quoted above as meaning that if a food contains insignificant amounts of 8 or more required nutrients, it is subject to the simplified format. To ensure that the determination as to when this format is required is not unnecessarily complicated, FDA is proposing not to count nutrients other than the 15 listed above as required nutrients, even if the nutrients are added to a standardized enriched food and therefore would have to be declared in nutrition labeling (§ 101.9(f)(1) and (3)(iii).

For purposes of determining when a food must bear the simplified format, section 403(q)(5)(C) of the act also directs the Secretary to determine when a food contains "insignificant amounts" of these required nutrients. For this purpose, FDA is proposing in § 101.9(f)(2) to define "insignificant amount" as that amount that may be rounded to zero in nutrition labeling.

To clarify the point at which very low levels of nutrients or food components may be rounded to zero, the agency is proposing additions in proposed § 101.9 to indicate precisely what analytical amounts may be rounded down to zero: § 101.9(c)(3), calories; § 101.9(c)(3)(i), calories from total fat; § 101.9(c)(3)(ii), calories from saturated fatty acids, unsaturated fatty acids, carbohydrates, and protein; § 101.9(c)(4), total fat; § 101.9(c)(4)(i), saturated fatty acids; § 101.9(c)(4)(ii), unsaturated fatty acids; § 101.9(c)(4)(ii)(A), polyunsaturated fatty acids; § 101.9(c)(4)(ii)(B), monounsaturated fatty acids; § 101.9(c)(6), total carbohydrate; § 101.9(c)(6)(i), complex carbohydrate; § 101.9(c)(6)(ii)(A), sugars; § 101.9(c)(6)(ii)(B), sugar alcohol; § 101.9(c)(7), dietary fiber; § 101.9(c)(7)(i)(A), soluble fiber; § 101.9(c)(7)(i)(B), insoluble fiber; and § 101.9(c)(8), protein. In the case of calories, which are proposed to be declared to the nearest 5-calorie increment in nutrition labeling (up to 50 calories), the amount specified that would be expressed as zero is "less than 5 calories." For total fat, total carbohydrate, complex carbohydrates, sugars, sugar alcohol, dietary fiber, soluble fiber, insoluble fiber, and protein, FDA is proposing less than 0.5 g as the amount that can be expressed as zero. For saturated fatty acids, unsaturated fatty acids, polyunsaturated fatty acids, and monounsaturated fatty acids, FDA is proposing less than 0.25 g as the amount that can be expressed as zero.

Current regulations (§ 101.9(c)(7)(i)) provide that vitamin and mineral values of less than 2 percent of the U.S. RDA are to be declared as zero. This provision was carried forward in the mandatory nutrition labeling proposal as proposed § 101.9(c)(10)(iii), now redesignated as § 101.9(c)(11)(iii). Consequently, FDA is proposing that a value of less than 2 percent of the RDI (set forth in proposed § 101.9(c)(10)(iv), redesignated in this document as § 101.9(c)(11)(iv)) be considered insignificant. This cutoff is supported by the imitation food regulation (§ 101.3(e)(4)(ii)) which identifies 2 percent or more of the RDI as a measurable amount of a nutrient. Anything less than a measurable amount could be considered "insignificant."

Current regulations (§ 101.9(c)(8)(i)) require that sodium content be declared as zero when less than 5 mg are present per serving (portion). This value is consistent with the definition of "sodium free." This requirement for zero declaration was carried forward in the mandatory nutrition labeling proposal in § 101.9(c)(8), which is redesignated as § 101.9(c)(9) in this proposal.

In the case of cholesterol, the agency proposed in § 101.9(c)(5) of its mandatory nutrition labeling proposal that a zero declaration of cholesterol be allowed when the cholesterol content of a food is less than 2 mg per serving (portion). This level is consistent with the definition of "cholesterol free" (55 FR 29456) that FDA has proposed.

Currently no single food composition data base has all of the information needed to determine what, or how many, foods would be required to bear the simplified format using the above criteria. Available data bases lack information particularly on sugars, complex carbohydrates, and dietary fiber. FDA utilized several available data bases to create a file that contains information on all required nutrients (Ref. 18). This file makes it possible to obtain some information on the types and number of traditional foods that would be required to bear the simplified format. Using this file, it appears that the proposed rules would require that the following types of foods bear the simplified format: beverages such as sweetened coffee and tea, soft drinks, and fruit and fruit-flavored drinks; fats and oils including some salad dressings; all types of sugar; sweets such as syrups, gelatin desserts, jams, jellies, and some candies; pickles; some condiments and sauces; salt and seasoning salts; and a limited number of grain products, fruits, and vegetables.

FDA is proposing in § 101.9(f)(3)(i) to prescribe a simplified format that resembles the minimum label requirements as described in the mandatory nutrition labeling proposal (55 FR 29487 at 29502) in that total calories, total fat, total carbohydrate, protein, and sodium would be declared as a minimum (i.e., as a core requirement). In addition, FDA is proposing in § 101.9(f)(3)(ii) that any other nutrients or food components that are required components of the full nutrition label and identified in § 101.9(f)(1) be declared in the simplified format if they are present in more than insignificant amounts.

The minimum label requirements stated in the mandatory nutrition labeling proposal allowed nutrients and food components (other than the core

requirements—that is, total calories, total fat, total carbohydrate, protein, and sodium) to be omitted from the tabular listing if a statement was added within the nutrition label stating "Not a significant source of _____," with the blank filled in by the missing nutrients or food components. The primary difference between that format and the simplified format being proposed here is that, as long as no additional nutrients (e.g., potassium) are declared, the nutrients or food components (other than the core requirements) that are required parts of the full nutrition label but that are present in insignificant amounts would not be identified on the simplified label. In these circumstances, manufacturers would not have to include the statement "Not a significant source of _____" on their label.

However, under proposed § 101.9(f)(4), if manufacturers voluntarily choose to declare additional nutrients or food components that are not among the 15 required nutrients (e.g., potassium), as allowed by section 2(b)(1)(C) of the 1990 amendments, they will then be required to use the statement "Not a significant source of _____," with the blank filled in with the name of any required nutrients or food components that are missing or present in insignificant amounts. The agency is also proposing in § 101.9(f)(4) that if the product is voluntarily enriched or fortified with added vitamins or minerals, any such nutrients must be declared within the simplified format and followed by the above statement. Such a voluntary addition of nutrients is viewed by the agency as an effort to market the food as a significant source of nutrients. The agency believes such action would be misleading under section 201(n) of the act unless consumers are advised about the full nutritional profile of the food.

However, as an exception, under proposed § 101.9(f)(3)(iii), standardized enriched foods that qualify for use of the simplified format may use this format without the added statement even though they include nutrients that are required by the standard to be added (e.g., thiamin, riboflavin, and niacin in enriched flour) but that are not among the 15 required nutrients.

This exception is being proposed because, in many cases, these standardized foods have been enriched because of the food standard and not at the choice of the manufacturer.

A nutrition label for a soft drink that uses the simplified format would state:

NUTRITION INFORMATION PER SERVING

Serving size	12 fl oz (360 mL)
Servings per container	1
Calories	145
Total fat	0 g
Total carbohydrate	36 g
Sugars	36 g
Protein	0 g
Sodium	20 mg

fl oz=fluid ounces
mg=milligram

However, a nutrition label using the simplified format for a vegetable oil that voluntarily declares polyunsaturated and monounsaturated fats would state:

NUTRITION INFORMATION PER SERVING

Serving size	1 tbsp (14 g)
Servings per container	64
Calories	130
Calories from total fat	130
Total fat	14 g
Saturated fat	2 g
Polyunsaturated fat	4 g
Monounsaturated fat	8 g
Total carbohydrate	0 g
Protein	0 g
Sodium	0 mg

Not a significant source of cholesterol, complex carbohydrate, sugars, dietary fiber, vitamin A, vitamin C, calcium, or iron.

To save space and to allow greater flexibility in presentation, FDA is proposing in § 101.9(f)(5) that nutrition information for the simplified format may be presented in vertical columns (as above) or in lines. Under the proposal, when a line presentation is used, any nutrients or food components that are subelements that would otherwise be indented under a principal element (e.g., saturated fat as a subelement of total fat) must be put in parentheses in the proper order. Examples of a line presentation for the two products listed above are as follows:

Nutrition Information

Serving size: 12 fl oz (360 mL)
Servings per container: 1
Per serving: 145 calories, 0 g total fat, 36 g total carbohydrate (36 g sugars), 0 g protein, 20 mg sodium.

Nutrition Information

Serving size: 1 tbsp (14 g)
Servings per container: 64
Per serving: 130 calories (130 calories from total fat), 14 g total fat (2 g saturated fat, 4 g polyunsaturated fat, and 8 g monounsaturated fat), 0 g total carbohydrate, 0 g protein, 0 mg sodium. Not a significant source of cholesterol, complex carbohydrate, sugars, dietary fiber, vitamin A, vitamin C, calcium, or iron.

To attract the consumer's attention to the smaller nutrition label, to clarify the information in the simplified format to the consumer, and in recognition of section 403(q)(1) of the act and of section 2(b)(1)(A) of the 1990 amendments, the agency is also considering the usefulness of requiring that the headings "NUTRITION INFORMATION" and "PER SERVING" be highlighted by larger type, bold type, or contrasting color. Comments are requested on this possible use of highlighting.

V. Exemptions

The 1990 amendments specifically exempt certain foods from the requirements of section 403(q) of the act. Some of these exemptions are the same as those included in FDA's mandatory nutrition labeling proposal. A discussion of the authority for these exemptions and, where differences exist, of the revised exemptions follows.

A. No Nutritional Significance

Section 403(q)(5)(C) of the act states:

> If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. * * *

In accordance with this provision of the statute, FDA is revising proposed § 101.9(a). As set out in the mandatory nutrition labeling proposal, this section would have required that nutrition labeling be provided on all foods that are a meaningful source of calories or nutrients. The agency proposed that a food be classified as a "meaningful" source of calories or nutrients if it contained:

(1) Two percent or more of the RDI for protein, vitamin A, vitamin C, iron, or calcium per serving (portion);

(2) More than 40 calories per serving (portion) or more than 0.4 calories per g; or

(3) More than 35 mg of sodium per serving (portion).

FDA is compelled by the statute to revise proposed § 101.9(a) to exempt from nutrition labeling only those foods that contain insignificant amounts of all of the nutrients and food components required within nutrition labeling. Thus, consistent with the preceding discussion on the simplified format, the agency is proposing to define "insignificant" in

§ 101.9(a) as that amount that allows a declaration of zero in nutrition labeling.

FDA is also compelled by the statute to make this exemption available only when there are no nutrition claims in the label, labeling, or advertising for the food. FDA therefore has modified proposed § 101.9(a) to restrict the exemption for foods with insignificant amounts of nutrients to such situations. The proposed provisions point out that nutrition claims or information set forth in any context, and in any form of expression, implicit as well as explicit, will bar a food from an exemption from nutrition labeling under the "no nutritional significance" provisions.

B. Small Business

Section 403(q)(5)(D) of the act establishes a small business exemption by providing that:

> If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than $50,000, the requirements of subparagraphs (1), (2), (3), and (4) (of section 403(q)) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim.

This section of the statute requires a modification of the relevant provision that FDA included in the mandatory nutrition labeling proposal. That provision, § 101.9(h)(1), would have provided an exemption for foods offered for retail sale by firms that have an annual amount of food sales of not more than $500,000.

Under section 403(q)(5)(D) of the act, however, a food product is exempt from nutrition labeling if it is offered for sale by a person who has annual gross sales made, or business done in sales, of food and other merchandise to consumers of not more than $500,000 or annual gross sales made, or business done in sales, of food alone of not more than $50,000. Accordingly, the food products sold by a company would be exempt if the company had annual gross sales, made, or business done in sales, to consumers of more than $500,000 but less than $50,000 worth of sales made, or business done in sales, of food to consumers, or if it had annual gross sales, or business done in sales, to consumers of less than $500,000 even though it had more than $50,000 worth of sales made, or business done in sales, of food to consumers. Only businesses having more than $500,000 in gross sales made, or business done in sales, to consumers and more than $50,000 in sales, or business done in sales, of food alone to consumers would not be exempt. Proposed § 101.9(h)(1), redesignated in this proposal as § 101.9(j)(1), has been revised accordingly.

For the purposes of this regulation, FDA is proposing in § 101.9(j)(1)(ii) that a person who offers food for sale, or who has business done in sales, to consumers is any person who manufactures, packs, or distributes food for ultimate sale to consumers at the retail level, as well as any person directly involved in the retail sale of foods to consumers. This proposed provision clarifies the coverage of the small business exemption.

As discussed in the June 13, 1990, report of the Committee on Energy and Commerce, House of Representatives (Ref. 16), wholesale business, that is, sales not involving consumers, is not included in calculations of gross sales. Sales from all stores or other outlets owned by a particular corporation or other business, however, must be added together in determining whether the business qualifies for the exemption (Ref. 16).

In proposed § 101.9(j)(1)(iii), FDA is carrying forward from the mandatory nutrition labeling proposal its position that the calculation of the amount of sales should be based on the most recent two year average of business sales, and that, where firms have been in business less than two years and wish to claim the small business exemption, reasonable estimates of sales must indicate that annual sales will not exceed the dollar amounts specified. The agency recognizes that foreign firms may also be entitled to the small business exemption. In order to provide comparable treatment to such firms, FDA is proposing in § 101.9(j)(1)(iii) that the total sales of a foreign firm in the United States would be the level of business activity used in determining whether the firm has less than $500,000 sales to consumers or less than $50,000 in food sales to consumers.

C. Restaurant Food

Sections 403(q)(5)(A)(i) and (ii) of the act exempt from the nutrition labeling requirements foods that are served in restaurants or similar food service establishments, that are principally processed and prepared in a retail establishment, that are ready for consumption although not necessarily for consumption at the place of sale, and that are not offered for sale outside the establishment. FDA tentatively concludes that proposed § 101.9(h)(2) and (h)(3), which are redesignated as § 101.9(j)(2) and (j)(3) in this document, appropriately reflect these provisions of the legislation. Therefore, FDA is not modifying § 101.9(j)(3). However, to reflect the exemption contained in section 403(q)(5)(F) of the act, FDA is modifying § 101.9(j)(2) to exempt foods sold by a distributor who sells principally to restaurants and other food service establishments from the nutrition labeling requirements. Manufacturers, packers, or distributors of foods for restaurant use should nutrition label their food products if there is a reasonable possibility that the food will be purchased directly by consumers (Ref. 25).

D. Small Packages

Section 403(q)(5)(B) of the act provides an exemption from nutrition labeling on labels of foods that are in packages that are so small that it is impracticable to comply with the statutory requirements and that do not contain any nutrition information. According to the House Committee Report (Ref. 16):

> * * * In order to qualify for the exemption, the Secretary must find that the information on the label would be difficult to read, while leaving a reasonable amount of room for the name of the product and other information that is required by law to be on the label. * * *

FDA had attempted to exempt very small packages by proposing an exemption in § 101.9(h)(11) for small individually packaged "bite-size" pieces of food. The agency has been made aware of the confusion over the term "bite size" through the number of requests it has received to define it. Therefore, in response to the 1990 amendments and to the requests for clarification that it has received, FDA is revising proposed § 101.9(h)(11), which is redesignated as § 101.9(j)(11) in this document, to specify a standard for a package that is sufficiently small to be exempt from nutrition labeling. To promote consistency within its food labeling regulations, the package size that the agency is proposing as its standard is the same package size that it uses as the standard in § 101.2(c)(3)(i) for exempting small packages of foods from type size requirements, namely that the "package is designed such that it has a total surface area available to bear labeling of less than 12 square inches." Thus, under this proposal, foods sold in packages of this size or smaller will not be required to bear nutrition labeling on their label unless, as provided in section 403(q)(5)(B) of the act, nutrition information (e.g., nutrition claims) is presented on the label.

By focusing on the size of the label, FDA is complying with the direction from the House Committee on Energy

and Commerce (Ref. 16, p. 16) that the agency not permit manufacturers to avoid section 403(q) of the act by increasing the size of the name and other legally required information so that insufficient space is left for nutrition information. Because the size of the label is the deciding factor in determining eligibility for the exemption, the manufacturer is left with the responsibility for determining how the required information is to be fit into the available label space if that space is of the requisite size.

FDA believes, however, that nutrition information about the food in very small packages can still be provided to consumers through alternative means. Section 403(q)(5)(B) of the act states only that the nutrition labeling requirements shall not apply to the label of the food. It says nothing about the labeling. The absence of clear statutory direction for labeling exemptions for these packages gives the agency discretion to decide whether labeling should also be exempted. Under these circumstances, FDA believes that it should only provide an exemption for this labeling if compliance with nutrition labeling requirements is impracticable. FDA knows of no reason why firms could not provide nutrition information on placards or through display of the label for the container in which the small packages are shipped (e.g., the label of a box containing "penny candy"). Therefore, the agency is proposing in § 101.9(j)(11) to require that nutrition information that would otherwise be required on the label be displayed clearly at the point of purchase according to § 101.9(a)(2) for food not in packaged form.

The agency believes that relatively few food packages will qualify as "small" under the proposed exemption. FDA has reviewed information from the agency's 1982 Food Labeling and Packaging Survey (FLAPS) and found that, for the foods in the survey, the proposed exemption for packages with less than 12 square inches of total surface area available for labels would primarily exempt candy rolls, breath sweeteners, and a few very small individual-serving size canned foods (Ref. 19). However, because FLAPS did not consider every brand of food in the marketplace, additional foods may be included.

E. Medical Foods

Section 403(q)(5)(A)(iv) of the act exempts medical foods from the nutrition labeling requirements. This section defines a "medical food" by incorporating by reference the definition in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). Medical foods are currently exempted from the nutrition labeling regulations in § 101.9(h)(4), which was redesignated as § 101.9(h)(7) in the mandatory nutrition labeling proposal.

FDA is amending proposed § 101.9(h)(7) (and redesignating it as § 101.9(j)(7)) to reflect the wording of the explicit exemption of medical foods in the act and to incorporate the statutory definition of "medical food" into the nutrition labeling regulations. That definition is:

> The term *medical food* means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

The agency advises that it considers the statutory definition of medical foods to narrowly constrain the types of products that can be considered to fall within this exemption.

For the efficient enforcement of the act, under section 701(a), FDA is proposing to clarify this definition by providing criteria in § 101.9(j)(7) for use in identifying a medical food. These criteria are based on the agency's expertise on medical foods and on a survey of the literature on this subject.

Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims (e.g., fiber in relation to cancer) by the requirement that medical foods be used under medical supervision. In general, to be considered a medical food, a product must, at a minimum, meet the following criteria: The product must be a food for oral or tube feeding; the product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be intended to be used under medical supervision (Ref. 20).

The term "medical foods" does not pertain to all foods fed to sick patients. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in its natural state) for the patient who is seriously ill or who requires the product as a major treatment modality. Typical medical foods are enteral nutrition products. Enteral nutrition is defined as nutrition provided through the gastrointestinal tract, taken by mouth, or provided through a tube or catheter that delivers nutrients beyond the oral cavity (i.e., directly to the stomach) (Ref. 21). Medical foods may require special quality control procedures, adequate and appropriate directions for use, and substantiation of labeling claims (Ref. 22). They are generally not available on the retail shelf.

Medical foods are intended for the partial or exclusive dietary management of patients under medical supervision who, because of specific therapeutic or chronic medical needs, have limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who have other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone (Ref. 22). Medical foods are intended for the dietary management of such patients by providing nutrition specifically modified to include as many nutrients as necessary while minimizing adverse signs and symptoms that might result from the provision of other nutrients that are not ingested, digested, absorbed, or metabolized normally by the patient (Ref. 22).

The statute requires that a medical food be consumed or administered enterally under the supervision of a physician. *Under the supervision of a physician* means that the intended use of a medical food is for the dietary management of a patient receiving active and ongoing medical supervision (e.g., in a health care facility or as an outpatient). The physician determines that the medical food is necessary to the patient's overall medical care. The patient sees the physician on a recurring basis for, among other things, instructions on the use of the medical food.

Medical foods are not foods that are simply recommended by a physician or other health care professional as part of an overall diet designed to reduce the risk of a disease or medical condition or as weight loss products. Moreover, medical foods are not dietary supplements for the general population that can be openly purchased from retail shelves or by mail order, although it is true that dietary supplements may be recommended by a physician for a specific condition or disease. The intended use and degree of medical oversight for these latter products is not sufficient to qualify them as medical foods, and such products will continue to be regulated as foods for special dietary use.

Single ingredient nutrient products that are promoted for the treatment of specific disease states will continue to be regulated under existing drug law

(e.g., zinc sulfate for the treatment of acrodermatitis enteropathica), as will all injectable nutrient formulations (Ref. 20). Parenteral nutrients also are drugs and not medical foods. By definition, medical foods are consumed or administered enterally (21 U.S.C. 360ee(b)(3)).

FDA's traditional policy has been to regulate medical foods as foods for special dietary use. However, in light of the existing definition of foods for special dietary use and the definition of medical food that has been enacted by Congress (see 21 U.S.C. 350(c) and 360ee(b)(3)), FDA is reevaluating its policy. FDA intends to address the issue of medical foods at length in a future **Federal Register** document.

Section 101.9(h)(7), as proposed in the mandatory nutrition labeling proposal, contained the phrase, "* * * except that such products shall be labeled in compliance with part 105 of this chapter" (55 FR 29487 at 29516). FDA recognizes that there are currently no regulations in 21 CFR part 105 or elsewhere in the CFR that specify labeling requirements for medical foods. To avoid confusion to readers of this proposal, the agency is deleting this phrase until at least such time as labeling regulations are developed for these foods. However, FDA believes that the proper labeling of the nutrient content and purported uses of medical foods, perhaps in a different manner or in more detail than is required for other, more traditional foods, and adequate and appropriate directions for use, as well as assurances of the quality of medical food products, are all of vital public health interest. Therefore, the agency intends to develop regulations covering these aspects of medical foods in the near future.

F. Infant Formula

Section 403(q)(5)(A)(iii) of the act specifically exempts infant formula from the nutrition labeling requirements. In its mandatory nutrition labeling proposal (55 FR at 29505), the agency proposed to exempt infant formula from nutrition labeling because it is already subject to special labeling requirements which are set out in 21 CFR part 107. (See proposed § 101.9(h)(4).)

FDA is now proposing § 101.9(j)(6) to incorporate the statutory exemption for infant formula into its regulations. Further, the agency is proposing to add the phrase, "except that such foods shall be labeled in compliance with part 107 of this chapter," to direct the reader to the location of the appropriate regulations for the labeling of infant formula

G. Foods Represented for Use as the Sole Item of the Diet

Foods represented for use as the sole item of the diet currently are exempted from the nutrition labeling regulation by § 101.9(h)(3) (redesignated in the mandatory nutrition labeling proposal as § 101.9(h)(6)) with the proviso that "such foods shall be labeled in compliance with part 105 of title 21, Chapter 1, Code of Federal Regulations." Section 403(q)(5) of the act does not provide a specific exemption for foods represented for use as the sole item of the diet. Further, the agency recognizes that there are no regulations in 21 CFR part 105 at this time that explicitly deal with the labeling of such foods. Therefore, FDA has reconsidered the proposed exemption.

The agency is not aware of any reason why foods that are neither medical foods nor infant formula, but that are represented as the sole item of the diet (e.g., formulated weight loss products), should not be labeled with at least the amount of nutrition-related information that is now being proposed for traditional foods in the general food supply. Accordingly, FDA is deleting the exemption for foods represented for use as the sole item of the diet from its proposed regulations. After the current round of rulemaking to implement the 1990 amendments to the act, FDA will consider whether there should be additional or different requirements for the nutrition labeling of these products. The exemption can then be established if regulations are developed to deal specifically with these foods.

H. Foods Shipped in Bulk Form

Section 403(q)(5)(A)(v) of the act exempts food described in section 405(2) of the act from nutrition labeling. Section 405(2) of the act exempts from any labeling requirement food that is to be processed, labeled, or repacked at a site other than that where it was originally processed or packed. Such food is currently exempted by § 101.9(h)(8), redesignated in this supplementary proposal as § 101.9(j)(8). The redesignated § 101.9(j)(8) has been revised to more closely reflect the statutory language of section 405(2) of the act.

I. Raw Agricultural Commodities and Raw Fish

Section 403(q)(4) of the act provides for the dissemination of nutrition information for raw fruit, vegetables, and fish to consumers at retail locations. The act provides that by November 8, 1991, FDA is to issue:

(1) Voluntary guidelines that advise food retailers on how to provide the nutrition information specified in the statute to consumers;

(2) Regulations that identify the 20 varieties of most frequently consumed raw vegetables, fruit, and fish to which the guidelines will apply; and

(3) Regulations that define the circumstances that constitute substantial compliance by retailers with the guidelines.

After issuing these guidelines and regulations, the agency is to survey retailers of raw produce and fish, and by May 8, 1993, it is to issue a report on actions taken by food retailers to provide consumers with nutrition information under the voluntary guidelines. If the agency finds that food retailers are in substantial compliance with the guidelines, it need not take any further action for 2 years, at which time, it is to conduct a new survey. This cycle will repeat every 2 years. If, however, the agency finds that there is not substantial compliance with the guidelines, it is directed to issue proposed regulations that mandate nutrition labeling on the top 20 varieties of raw fruit, vegetables, and fish.

FDA is taking steps to implement this section of the 1990 amendments. First, the agency is withdrawing the exemption that it proposed (§ 101.9(h)(10) (55 FR 29516)) for fresh fruit and vegetables in containers of not more than 1 dry quart. FDA proposed to exempt these containers because of the statutory exemption for fresh produce in small containers in section 405(1) of the act. The 1990 amendments, however, provide that this exemption does not apply to nutrition labeling and health claims (section 5 of the 1990 amendments).

Secondly, consistent with section 403(q)(4)(A) of the act, FDA is proposing in § 101.9(j)(10) to exempt raw fruits and vegetables and raw fish from the nutrition labeling regulations. FDA will propose to remove this exemption if, and when, the agency finds that there is not substantial compliance with the voluntary guidelines. In exempting raw fish, FDA interprets the exemption of the 1990 amendments to apply to unpackaged raw fish and to fish packaged by the retailer for immediate sale, not to products such as frozen fish fillets or canned oysters that are packaged by the manufacturer or packer for direct sale to the consumer. Because these products have been processed in some way and not simply iced, they cannot be considered to be raw for purposes of section 403(q)(4)(B)(i)(II) of the act. Fish products such as frozen

fillets and canned oysters are required to bear nutrition labeling under the act.

Thirdly, FDA published in the **Federal Register** (56 FR 30468, July 2, 1991) proposed voluntary guidelines for labeling raw produce and fish; a proposed regulation that defines the applicability of the guidelines by listing the 20 most frequently consumed varieties of raw fruits, vegetables, and fish; and a proposed regulation that defines "substantial compliance" with the voluntary guidelines. This action is being followed by publication elsewhere in this issue of the **Federal Register** of the guidelines and final regulations. In addition, FDA is planning for the biennial survey of food retailers.

J. Foods Sold From Bulk Containers

Section 403(q)(3) of the 1990 amendments states: "For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subparagraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale." Congress intended that this section cover foods received in, and sold from, bulk containers where the consumer selects and packages the food (Ref. 16).

In its mandatory nutrition labeling proposal, the agency stated its intention that foods sold from bulk containers be nutritionally labeled:

> * * * Many foods, such as candies, cookies, and pasta, are offered for sale from large containers such as barrels or bins. FDA has traditionally required that these foods be labeled in accordance with section 403(i)(2) of the act through the use of a counter sign or card on the labeling of the bulk container (21 CFR 101.100(a)(2)). The agency believes that nutrition labeling can be provided in a similar manner. Therefore, the agency proposes to require nutrition information for such foods. (55 FR 29505)

The agency continues to believe that nutrition labeling can, and should, be presented on the labeling of the bulk container or on a counter card, sign, or other appropriate device as identified in § 101.100(a)(2) for ingredient labeling of bulk foods. This position is supported by the legislative history (Ref. 16) that points to the impracticality of requiring nutrition labeling to be printed on the bags that the consumer would put the food into for purchase.

To prevent any confusion or misunderstanding on this issue, FDA is proposing to add an exemption, § 101.9(j)(14), for foods sold from bulk containers at a retail establishment provided that the nutrition labeling be displayed prominently and conspicuously at the point of purchase.

VI. Other Nutrition Labeling Provisions

A. Corrections

The agency is proposing to make a few nonsubstantive changes to its mandatory nutrition labeling proposal to make the following corrections:

(1) In its mandatory nutrition labeling proposal, the agency inadvertently omitted a sentence in proposed § 101.9(c)(4)(ii) that specifies how the amount of unsaturated fat is to be expressed on the nutrition label. FDA has corrected this omission by adding a sentence that states that unsaturated fat is to be declared in grams, to the nearest gram, with exceptions noted if the amount present is less than 1 g.

(2) In proposed § 101.9(c)(6), the agency redefined carbohydrate to exclude dietary fiber. The result of this proposed change is that the definition of a carbohydrate would no longer include those components that were traditionally considered part of carbohydrates but that are not digested and, therefore, do not contribute calories to the diet. However, the agency overlooked that a parallel change was needed in § 101.9(c)(3) to delete the direction to subtract dietary fiber from carbohydrate when determining the number of calories by the general Atwater factors of 4, 4, and 9 calories per gram for protein, carbohydrate, and fat, respectively. To correct this oversight, FDA is proposing to amend § 101.9(c)(3) to no longer require the subtraction of dietary fiber from carbohydrate since this correction has already been made in defining carbohydrate content. The agency also is proposing in § 101.9(c)(6) to add a more complete description of the method to be used in calculating total carbohydrate by subtracting the sum of crude protein, total fat, dietary fiber, moisture, and ash from the total weight of the product.

(3) In the mandatory nutrition labeling proposal, the paragraphs pertaining to dietary fiber (§ 101.9(c)(6)(iii) through (c)(6)(iii)(B)) were placed within the larger section pertaining to carbohydrates (§ 101.9(c)(6)). Because FDA is defining total carbohydrate to exclude dietary fiber, the agency believes that there will be less confusion if the paragraphs relating to dietary fiber are redesignated as § 101.9(c)(7). Therefore, the agency is proposing this redesignation and, consequently, the redesignation of the remaining paragraphs within § 101.9(c).

(4) The last sentence in proposed § 101.9(c)(10)(ii) in the mandatory nutrition labeling proposal is repeated in the last sentence in proposed § 101.9(c)(10)(iii). FDA is proposing to eliminate this unnecessary repetition by deleting the sentence from the paragraph now redesignated as § 101.9(c)(11)(iii).

(5) In § 101.9(c)(11)(i) which was published as part of the RDI/DRV proposal, the agency referred to the reference caloric intake of 2,350 calories as the "* * * population-adjusted mean of the recommended caloric intake (i.e., 2,350 calories)." While this statement correctly refers to the NAS's recommended caloric intakes (Ref. 24), some persons were confused, interpreting the statement to mean that FDA was recommending a caloric intake of 2,350 calories. To prevent this erroneous interpretation, FDA is proposing to amend § 101.9(c)(11)(i), now redesignated as § 101.9(c)(12)(i), to state "* * * a reference caloric intake of 2,350 calories * * *."

(6) To be consistent with the manner in which percent RDI's are reported in nutrition labeling, the agency is proposing to include a requirement in § 101.9(c)(12) that when a nutrition profile is given, the percent DRV's be expressed in 2-percent increments up to and including the 10-percent level, 5-percent increments above 10 percent and up to and including the 50-percent level, and 10-percent increments above the 50-percent level. The mandatory nutrition labeling proposal did not specify this manner of declaring amounts.

(7) In the RDI/DRV proposal, the agency proposed DRV's for total fat (75 g) and carbohydrates (325 g) based on a reference caloric intake of 2,350 calories. The agency did not propose a DRV for protein, but it did propose an RDI value of 50 g for protein for adults and children 4 or more years of age. The agency recognizes that clarification may be necessary concerning these values because the caloric value of the DRV's for total fat (675 calories) and total carbohydrates (1,300 calories) when coupled with the caloric value of the RDI for protein (200 calories) do not sum to the reference caloric intake of 2,350 calories.

The dietary recommendations that serve as the basis for the DRV's for total fat and carbohydrate (i.e., 30 percent and 55 percent of calories, respectively (Ref. 3)) result in the assumption that protein intake will furnish the remaining calorie requirements, i.e., protein will comprise approximately 15 percent of calories. The assumption is made by persons developing dietary guidance materials that protein will be used not only to meet protein requirements but also to meet some of the caloric needs. This level of protein intake (15 percent

of calories) is consistent with current U.S. dietary consumption patterns and is not considered to be a level of intake inconsistent with good health (Ref. 3). The RDI for protein, on the other hand, is based on the human requirement for protein and reflects the levels of high quality protein needed to maintain body stores and to support growth and development. Therefore, the RDI for protein does not provide the same level of caloric value as the level of protein intake that is incorporated into dietary pattern recommendations. To clarify this issue, FDA is proposing to add a note to the DRV listing in § 101.9(c)(11)(i), redesignated as § 101.9(c)(12)(i) in this proposal, to state that the caloric contribution of protein is assumed to be approximately 15 percent.

(8) FDA is proposing to amend the regulations by removing current § 101.9(c)(7)(v) (proposed § 101.9(c)(11)(iv) (55 FR 29515)). This section allowed for general claims of significance and nutritional superiority. However, the 1990 amendments suggest a somewhat different approach. Section 403(r)(2)(A)(i) of the act only allows such claims if they use terms defined in regulations, and under section 3(b)(1)(A)(iii) (V) and (VI) of the 1990 amendments, "less" and "high" are among the terms that FDA must define. In light of these facts, FDA will define and provide for the proper use of such terms in a separate **Federal Register** document on nutrient content claims.

(9) FDA proposed changes in current § 101.9 (e)(5) and (e)(6) in its mandatory nutrition labeling proposal to specify the food components that it expects will vary by less than 20 percent from the labeled value, and to specify where reasonable excesses or deficiencies would be allowed in nutrition labeling. To complete this activity, the agency should also have proposed changes in current § 101.9(e)(4) so that the nutrients and food components specified in that paragraph are the same as those for which reasonable excesses are allowed in § 101.9(e)(6). Paragraphs (e)(4) through (e)(6) would then identify the upper and lower boundaries for all nutrients and food components declared in nutrition labeling. Accordingly, FDA is proposing to add total carbohydrate, complex carbohydrate, unsaturated fat, and potassium to § 101.9(e)(4), (e)(4)(i), and (e)(4)(ii), which are redesignated as § 101.9(g)(4), (g)(4)(i), and (g)(4)(ii) in this proposal, to specify the amount of variability allowed. Likewise, total carbohydrate was inadvertently left out of § 101.9(e)(6), and the agency is now proposing to insert it in that paragraph, redesignated as § 101.9(g)(6) in this proposal.

(10) The agency failed to explain its rationale in the mandatory nutrition labeling proposal for rearranging the order of some food components within the nutrition label and to specifically request comment on that order. The rationale was based on comments that FDA had received over time that many consumers were finding it difficult to pick out information on fats in the current nutrition label. The agency determined that there was a potential benefit in ordering the information, at least in part, according to its public health significance. To accomplish this goal, FDA proposed in its mandatory nutrition labeling proposal to rearrange the order of the three sources of energy (i.e., fat, carbohydrate, and protein) in § 101.9(c) to state fat first, followed by carbohydrates and protein. This ordering was selected to support the position of the Department of Health and Human Services, as stated in the forward to the Surgeon General's Report on Nutrition and Health, that "Of highest priority among the (dietary) changes (that can improve the health prospects of many Americans) is to reduce intake of foods high in fats and to increase intake of foods high in complex carbohydrates and fiber" (Ref. 2, p. v.). Subelements of fat and carbohydrates are proposed to be listed immediately under the declaration of each element. Comments are requested on this proposed arrangement.

B. Increments

In addition to the above corrections, FDA is proposing to change the increments for declaring fats and fatty acids. The agency is proposing in § 101.9(c)(4), (c)(4)(i), (c)(4)(ii), (c)(4)(ii)(A), and (c)(4)(ii)(B) to require declaration of total fat, saturated fat, unsaturated fat, polyunsaturated fat, and monounsaturated fat, respectively, in ½ g increments. The agency is proposing this change to increase the consistency between the probable quantitative declaration of a food component and its level of significance. For example, sodium, which has a DRV of 2,400 mg, may be reported to the nearest 10-mg increment when the serving contains more than 140 mg of sodium. This reporting represents a ratio of the increment to the DRV of 10/2400, which is equivalent to 0.4 percent (hereafter the ratio will be reported parenthetically following the percent equivalent). This ratio is similar to that for carbohydrates, which are to be declared to the nearest g and for which the ratio of the increment to the DRV of 325 g is 0.3 percent (1/325). These values differ significantly from the comparable ratios for total fat and fatty acids, which are to be reported to the nearest g. The ratio for total fat with a DRV of 75 g is 1 percent (1/75); for saturated fat with a DRV of 25 g, 4 percent (1/25); and for unsaturated fat with a DRV of 50 g, 2 percent (1/50). DRV s were not proposed for polyunsaturates or monounsaturates, therefore similar calculations cannot be made for them. The ratio of the increment to the DRV for cholesterol (300 mg) is 2 percent (5/300) and of the increment to the RDI for protein (50 g for adults and children over 4 years of age) is 2 percent (1/50).

In reviewing all of these ratios, the ratio for saturated fat is clearly the highest. Requiring ½ g increments for all fatty acids lowers the ratio to 2 percent for saturated fat (0.5/25) and to 1 percent for unsaturated fat (0.5/50). A similar change for total fat that would allow all fat entries to be rounded to the same increment lowers the ratio to 0.7 percent (0.5/75). These ratios are more comparable to those for sodium, carbohydrate, cholesterol, and protein.

The agency believes the proposed change to allow declaration of fat and fatty acids in ½ g increments will provide consumers with more precise information and a greater ability to discriminate among products. It will also make calculation of the number of calories from fat more consistent with the declared amount of fat, because calories are to be reported to the nearest 5-calorie increment up to and including 50 calories. The disadvantages are that, because of natural variability in fat content in some foods, the 0.5 g increment will convey to the consumer a degree of precision that may not be supported by the analytical measurements and thus the degree of reliability of the value for some foods may be decreased. Moreover, where the food matrix complicates fat extraction, the cost of analysis will be higher. The agency therefore requests comment on this proposed change, and whether it would be preferable to maintain 1 g increments for declaring fat and fatty acids.

A similar argument can be made for requiring that dietary fiber (with a ratio of the increment to the DRV of 25 g of 4 percent (1/25)) be declared to the nearest 1/2 g. However, the precision of the analytical methodology for determining quantitative amounts of fiber does not allow for that degree of accuracy. Therefore, FDA is not proposing to change the current procedure of declaring amounts of dietary fiber to the nearest g.

VII. Labeling of Dietary Supplements of Vitamins and Minerals

A. History

The agency has a long history relating to the labeling of dietary supplements. In the **Federal Register** of November 22, 1941 (6 FR 5921), FDA promulgated regulations on food for special dietary uses under 403(j) of the act, which states that a food shall be deemed to be misbranded:

> * * * if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

In the **Federal Register** of August 2, 1973 (38 FR 20708 and 20730), FDA adopted new regulations to govern the labeling and composition of dietary supplements and other foods that purport or are represented to be for special dietary use because of vitamin or mineral properties (the 1973 regulations). These regulations were codified in §§ 80.1, 125.1, 125.2, and 125.3 (21 CFR 80.1, 125.1, 125.2, 125.3. They were recodified as §§ 105.3, 105.60, 105.77 and 105.85 (21 CFR 105.3, 105.60, 105.77, and 105.85) as part of the general agency reorganization and republication of its regulations in 1977 (42 FR 14302 at 14328 and 14331, March 15, 1977).

The 1973 regulations set forth definitions, standards of identity, and labeling statements for vitamin and mineral dietary supplements. The standards permitted only five basic types of preparations (a multivitamin supplement, a multimineral supplement, a multivitamin supplement with iron, and a supplement consisting of any single vitamin or mineral); prescribed the vitamin, mineral, and other ingredient composition of multinutrient supplements; and specified maximum and minimum potencies for vitamins and mineral ingredients. These potencies were stated in terms of U.S. RDA's which were derived by FDA from the recommended dietary allowances (RDA's) established by the Food and Nutrition Board of the NAS in 1968 (Ref. 24). In general, the minimum potency for a nutrient in a dietary supplement was established at 50 percent of the U.S. RDA for the nutrient, the maximum potency at 150 percent of the U.S. RDA.

Fifteen petitions for review of this rulemaking were filed in various United States courts of appeals and eventually consolidated in the United States Court of Appeals for the Second Circuit. After extensive briefing and oral argument, the Court on August 15, 1974, held that it was "broadly sustaining the regulations," but it remanded them to the agency for certain further actions (*National Nutritional Foods Association* v. *Food and Druq Administration*, 504 F.2d 761, 786 (2d Cir. 1974).

A petition for certiorari, asking the U.S. Supreme Court to review the decision by the U.S. Court of Appeals for the Second Circuit, was filed, but on February 24, 1975, it was denied (420 U.S. 946). Thereafter, FDA began the process of implementing the remand instructions of the U.S. Court of Appeals. On May 28, 1975, FDA published a preliminary notice in the **Federal Register** (40 FR 23244) (the 1975 proposal) inviting applications for additional formulations of dietary supplements as the court had directed, proposing certain other revisions in the regulations consistent with the court's opinion, and announcing the reopening of the administrative hearing on which the regulations were based.

While FDA was in the process of completing the hearing and revising the vitamin and mineral regulations pursuant to the instructions of the U.S. Court of Appeals, Congress enacted legislation (Pub. L. 94–278, title V, April 22, 1976) that became section 411 of the act (known as "the Proxmire Amendment"). This amendment restricted the agency s authority to limit both the maximum potency of vitamins and minerals in dietary supplements and the ingredient composition of multinutrient supplements that are offered for use by adults (other than pregnant or lactating women). Dietary supplements represented for use by pregnant or lactating women, by children under the age of 12, or by individuals in the treatment or management of specific diseases or disorders were excluded from the Proxmire Amendnent (i.e., the agency retained authority to limit the maximum potency and ingredient composition of these products).

The agency issued a final regulation in the **Federal Register** of October 19, 1976 (41 FR 46156), that amended the 1973 regulations to comply with the court's 1974 remand instructions and with the Proxmire Amendment. The agency received petitions to reconsider the propriety of issuing a final rule without having first issued a proposed rule. FDA denied these petitions on the ground that a proposed rule was unnecessary because the rule merely "recognized the will of Congress."

The petitioners appealed to the U.S. Court of Appeals for the Second Circuit, and the appeals were consolidated. On February 16, 1978, the Second Circuit vacated the regulations and remanded them to the agency for further proceedings (*National Nutritional Foods Association* v. *Kennedy*, 572 F. 2d 377 (2d Cir. 1978)). The court made clear that the agency had to issue proposed regulations, and that the issue for comment was whether the proposed regulations were "suitable in light of what Congress had done." In the **Federal Register** of March 16, 1979 (44 FR 16005), FDA revoked the 1976 regulations and reinstated portions of the 1973 regulations. The agency has not taken any further action on the 1976 regulations.

B. Legal Authority

Section 403(q)(5)(E) of the act states that if a food to which section 411 of the act applies (i.e., dietary supplements of vitamins and minerals) contains one or more of the nutrients required to be listed in nutrition labeling, "the label or labeling of such food shall comply with the requirements of subparagraphs (1) and (2) (of section 403(q) of the act) in a manner which is appropriate for such food and which is specified in regulations of the Secretary."

Currently, dietary supplements, including dietary supplements of vitamins and minerals to which section 411 of the act applies (except for dietary supplements in conventional food form, e.g., breakfast cereals), are exempt from the nutrition labeling regulations (21 CFR 101.9(h)(2)). FDA carried this exemption forward in the mandatory nutrition labeling proposal, redesignated as § 101.9(h)(5) (55 FR 29487 at 29516).

To now comply with the new section 403(q)(5)(E) of the act, the agency is proposing to amend § 101.9(h)(2), now redesignated as § 101.9(j)(5), to provide that dietary supplements of vitamins and minerals (except those in conventional food form) bear appropriate nutrition labeling. FDA is also proposing a new section, § 101.36 entitled "Nutrition labeling of dietary supplements of vitamins and minerals," under Part 101—Food Labeling, Subpart C—Specific Nutrition Labeling Requirements and Guidelines, to establish nutrition labeling regulations that the agency believes are appropriate for dietary supplements of vitamins and minerals.

In accordance with section 403(q)(5)(E) of the act, § 101.36(a) proposes that vitamin and mineral supplements provide nutrition labeling. Vitamin and mineral supplements that do not contain any of the 15 nutrients required to be in nutrition labeling are not required by section 403(q)(5)(E) of the act to bear nutrition labeling. However, the agency believes that these

supplements are required to bear nutrition labeling under section 403(q)(5)(C) of the act. This section provides that nutrition labeling is not required when a food contains insignificant amounts of all of the nutrients required to be listed in nutrition labeling unless a claim is made with respect to the nutritional value of the food. Thus, when such a claim is made, nutrition labeling is required. With respect to dietary supplements of vitamins and minerals, the agency believes that a statement of identity, such as "Vitamin E," on the label of a product is a claim about the nutritional value of the food. Therefore, such products must bear nutrition labeling under the act.

However, the agency is providing in § 101.9(j)(5) that such supplements are to be labeled in accordance with proposed § 101.36. Although the 1990 amendments are silent with respect to whether these products should bear nutrition labeling specific for dietary supplements or for conventional foods, because these products are more similar to those regulated under section 411 of the act than to conventional foods, the agency tentatively finds that it is appropriate that they bear nutrition labeling specific for dietary supplements in accordance with proposed § 101.36. The agency requests comments on this issue.

Under § 101.9(a)(4), dietary supplements to which vitamins and minerals have been added, and that contain 50 percent or more of the RDI of any one of the added vitamins or minerals, are foods for special dietary use to which section 403(j) of the act applies. Therefore, to the extent that the regulations that FDA is proposing apply to foods for special dietary use, FDA is proposing these regulations under section 403(j) of the act as well as section 403(q) of the act.

FDA is not proposing a specific exception for dietary supplements that do not contain vitamins or minerals. Under this proposal, these products are subject to the general provisions set forth in § 101.9(a).

The agency emphasizes that § 101.36 pertains only to the nutrition labeling of dietary supplements of vitamins and minerals. This section does not authorize the use of any particular vitamins or minerals as components of vitamin and mineral supplements. The use of vitamins and minerals in food must be in accordance with the appropriate regulations (i.e., food additive, generally recognized as safe, or prior-sanctioned food ingredient regulations). Dietary supplements of selenium, fluoride, and chromium, for example, are not permitted.

C. Provisions of Proposed Section 101.36

To reduce consumer confusion, the agency is proposing that nutrition labeling of vitamin and mineral supplements appear as similar as possible to the nutrition labeling of other foods.

The agency is proposing in § 101.36(b) to require that the overall heading of the nutrition label be "NUTRITION INFORMATION" rather than "NUTRITION INFORMATION PER SERVING." The agency is not proposing that the term "per serving" be used in the heading for vitamin and mineral supplements because the information presented may be declared per day as well as per unit (or serving). The agency prefers the use of the term "unit" rather than "serving" for supplements because the word "serving" is customarily used to describe conventional foods.

The agency is proposing in § 101.36(b)(1) that the listing of "Units per day" be required for supplements in place of "Serving (portion) size" as required in § 101.9(c)(1) because more than one unit of a supplement is often consumed per day, and it is important that the amount recommended by the manufacturer for consumption over the period of 1 day be clearly stated. Proposed § 101.36(b)(1) allows for the use of terms such as "tablets," "capsules," or "teaspoonsful," to be used in lieu of "units" throughout the nutrition label depending on whether the product is in tablet, capsule, or liquid form (e.g., the nutrition label on a bottle of vitamin tablets could state "Tablets per day"). The agency believes that use of the more precise terms will aid consumer understanding. The quantity specified must be reasonable and suitable for daily dietary consumption and consistent with any intake recommendations on the label or in labeling.

The agency is proposing in § 101.36(b)(2) to require the listing of "Units per container" in lieu of "Servings (portions) per container" as required in § 101.9(c)(2) for conventional foods. Again, the word "units" could be replaced with the appropriate term for the type of product.

The agency is proposing in § 101.36(b)(3) that only those nutrients or food components listed in § 101.9(c) that are present in more than insignificant amounts must be declared in the nutrition label of vitamin and mineral supplements. FDA is not proposing to require that the label of such supplements follow the simplified format described in proposed § 101.9(f) for conventional foods. Conventional foods that contain insignificant amounts of 8 or more of the 15 nutrients and food components required under proposed § 101.9(c) are required to declare 5 elements (i.e., calories, total fat, total carbohydrate, protein, and sodium) even when the amounts declared are zero (proposed § 101.9(f)(3)(i)). However, because vitamin and mineral supplements that are not in conventional food form generally do not contain the five food components required in the simplified format, FDA believes that it would not be confusing or misleading to consumers to omit the required declaration of these elements when they are absent or present in insignificant amounts. Therefore, FDA tentatively concludes it is not necessary to require that these elements be declared on such supplements when they are present in insignificant amounts.

Similarly, proposed § 101.9(f)(4) would require that when amounts of nutrients and food components other than the 15 required nutrients are declared in the simplified nutrition label on conventional foods, the statement "Not a significant source of _____" be included at the bottom of the nutrition label with the blank filled in by whichever of the following are present in insignificant amounts: Calories from total fat, saturated fat, cholesterol, complex carbohydrate, sugars, dietary fiber, vitamin A, vitamin C, calcium, and iron. FDA is not aware of any consumer expectations that these nutrients or food components are present in vitamin or mineral supplements if they are not, in fact, declared on the label. Therefore, the agency does not believe a statement declaring that these components are not present in the supplements in significant amounts is needed. Such a statement could even be confusing to consumers. FDA therefore is not proposing that vitamin and mineral supplements need to include the statement "Not a significant source of _____" as required by proposed § 101.9(f)(4).

FDA believes that what is needed for full consumer understanding of the content of dietary supplements of vitamins and minerals is full declaration of any of the 15 required nutrients as well as any additional vitamins and minerals for which RDI's are proposed that are present in more than insignificant amounts. Accordingly, FDA is proposing in § 101.36(b)(3) that the quantitative amounts of all nutrients and food components that must be included in nutrition labeling in accordance with § 101.9(c) be declared in addition to the percent of the RDI. The agency points out that § 101.9(c)(7)(iii) (redesignated here as

§ 101.9(c)(11)(ii)) requires the declaration within nutrition labeling of all vitamins and minerals that have been added as a nutrient supplement or that are the subject of a claim. Most dietary supplements currently include information on both the quantitative amounts and the percent of the U.S. RDA. The agency believes that continuation of this type of labeling will help to ensure that consumers are fully informed about the content of these products.

FDA also is proposing in § 101.36(b)(3) that the required nutrition information shall be presented in columns under the heading "PER UNIT." If more than one unit is specified for consumption per day, the information shall also be presented in a second set of columns under the heading of "PER DAY." The agency is requiring that nutrition information should be declared by both the unit and daily amounts where label directions suggest consumption of more than one unit per day to more fully inform the consumer.

FDA is proposing in § 101.36(b)(3)(i) that nutrients and food components to be declared in nutrition labeling of vitamin and mineral supplements be listed in the order that the nutrients and food components are listed in nutrition labeling of conventional foods (i.e., as specified in § 101.9(c)) with the exception that calcium and iron shall be listed with the other minerals following the complete list of vitamins present.

Proposed § 101.36(b)(3)(ii) specifies the manner in which the quantitative nutrition information shall be presented. FDA is proposing that the information be given in a column under the heading of "Amount." In addition, the quantitative amounts should be expressed in the increments and units of measure (e.g., mg) specified in proposed § 101.9(c). Although the agency is not requiring that the quantitative amounts of vitamins and minerals be included in nutrition labeling of conventional foods, the agency believes that this additional information is useful on the labels of supplements because these products are represented and sold for their vitamin and mineral content. FDA is proposing that the quantitative amounts of vitamins and minerals should be declared to the nearest unit of measure of the same level of significance as that given in § 101.9(c)(11)(iv) for that nutrient. For example, 2.775 mg of thiamin would be declared as 2.8 mg, whereas 2.775 niacin equivalents (mg NE) of niacin would be declared as 3 mg NE.

Proposed § 101.36(b)(3)(iii) would require that the percent of the RDI specified in § 101.9(c)(11)(iv) be declared for each vitamin and mineral present under the heading "Percent of Daily Value." In section III.C.2. above, the agency requested further comment on the appropriateness of the single term "daily value" on the label to represent both RDI's and DRV's. If the agency is persuaded by comments to specify a different term in § 101.9(c)(11) in the final regulations, the new terminology will also apply to proposed § 101.36(b)(3)(iii). FDA therefore requests comments on the use of the term "Daily Value" in the labeling of dietary supplements as well as conventional foods.

Proposed § 101.36(b)(3)(iii)(A) requires that, unless the supplement is represented or purported to be for adults and children 4 or more years of age, column headings must clearly specify the group for which the RDI values are being declared. This proposed requirement is consistent with the current practice of manufacturers of vitamin and mineral supplements and with regulations governing nutrition labeling of conventional foods. It is based on the reasonable assumption that a product is for use by the general population unless specified to the contrary.

Consistent with the manner in which percent RDI's are reported in nutrition labeling, FDA is proposing in § 101.36(b)(3)(iii)(B) that percent RDI's be expressed in 2 percent increments up to and including the 10-percent level, 5 percent increments above 10 percent and up to and including the 50-percent level, and 10 percent increments above the 50-percent level.

The agency is proposing in § 101.36(b)(3)(iv) that vitamin and mineral supplements intended for use by more than one group for which RDI's have been proposed must list the percent daily value for each group. This proposed requirement is consistent with proposed § 101.9(c)(11)(i) which requires that foods represented or purported to be for use by more than one group for which RDI's exist, state the percent of daily values based on the RDI values for each group separately and in equal prominence.

As discussed previously, the agency has tentatively decided to require that DRV's listed in § 101.9(c)(11)(i) be declared in nutrition labeling of conventional foods. If this requirement appears in the final rule for § 101.9, then dietary supplements of vitamins and minerals will also be required to present this information and the percent of the DRV for fat, saturated fat, cholesterol, carbohydrate, dietary fiber, and sodium provided by the supplement when they are declared (i.e., when they are present in the supplement in more than insignificant amounts). The agency requests comments on the usefulness of this information on the nutrition labeling of dietary supplements of vitamins and minerals.

Consistent with nutrition labeling of conventional foods, FDA is proposing in § 101.36(b)(3)(v) to allow the use of synonyms for certain nutrients. The synonyms to be allowed are "folacin" for "folate," "ascorbic acid" for "vitamin C," and "energy" for "calories." The agency's position on synonyms is spelled out in the mandatory nutrition labeling proposal (55 FR 29487 at 29502).

FDA believes dietary supplements of vitamins and minerals should be subject to the same compliance policies as conventional processed foods and is therefore proposing in § 101.36(c) that compliance shall be determined in accordance with proposed § 101.9(g).

The following hypothetical sample labels illustrate proposed nutrition labeling of dietary supplements of vitamins and minerals:

DAILY VITAMINS PLUS IRON, MULTIPLE VITAMINS PLUS IRON

Nutrition Information

Tablets per day: 1 Tablets per container: 365	Per unit	
	Amount	Percent of daily value
Calories	15	
Total fat	1 g	
Total carbohydrate	1 g	
Sugars	1 g	
Sodium	10 mg	
Vitamin A	875 μg RE	100
Vitamin C	60 mg	100
Vitamin D	6.5 μg	100
Vitamin E	9 mg α-TE	100
Thiamin	1.2 mg	100
Riboflavin	1.4 mg	100
Niacin	16 mg NE	100
Folate	180 μg	100
Vitamin B_{12}	2 μg	100
Pantothenic acid	5.5 mg	100
Iron	12 mg	100

B-VITAMINS—TAKE ONE WITH EACH MEAL

Nutrition Information

Tablets per day: 3 Tablets per container: 100	Per unit		Per day	
	Amount	Percent of daily value	Amount	Percent of daily value
Calories	10		25 [1]	
Total Carbohydrate, g	2		6	
Sugars, g	2		6	
Sodium, mg	15		45	
Thiamin	0.4 mg	35	1.2 mg	100
Riboflavin	0.5 mg	35	1.4 mg [1]	100
Niacin	5 mg NE	35	16 mg NE [1]	100

[1] Values are not a straight multiplication due to rounding rules.

VIII. Other Actions

A. Effective Date

In its July 19, 1990 proposals, FDA proposed to make these regulations effective 1 year after the publication of a final rule. FDA requested comment on this deviation from the agency's normal practice of making food labeling regulations effective on the uniform compliance date that follows publication of the final rule. However, section 10(a)(1)(A) of the 1990 amendments requires that these regulations become effective 6 months after the date of promulgation of all final regulations required to implement section 403(q) of the act, or, if no final regulations have issued by November 8, 1992, this proposal, which incorporates the RDI/DRV and the mandatory nutrition labeling proposals of July 19, 1990, is statutorily mandated to be considered a final rule on November 8, 1992, with an effective date of May 8, 1993. FDA invites comments on this effective date taking into consideration the provisions of section 10 of the act.

FDA notes, however, that in section 10(a)(3)(B) of the 1990 amendments, Congress provides that if the Secretary of Health and Human Services (the Secretary), and by delegation FDA, finds that requiring compliance with section 403(q) of the act, on mandatory nutrition labeling, or with section 403(r)(2) of the act, on nutrient content claims, 6 months after publication of the final rules in the **Federal Register** would cause undue economic hardship, the Secretary may delay the application of these sections for no more than 1 year. In light of the agency's tentative findings in its regulatory impact analysis that compliance with the 1990 amendments by May 8, 1993, will cost $1.5 billion, and that 6 month and 1 year extensions of that compliance date will result in savings that arguably out weigh the lost benefits, FDA believes that the question of whether it can and should provide for an extension of the effective date of sections 403(q) and (r)(2) of the act is squarely raised.

FDA has carefully studied the language of section 10(a)(3)(B) of the 1990 amendments and sees a number of questions that need to be addressed. The first question is the meaning of "undue economic hardship." FDA recognizes that the costs of compliance with the new law are high, but those costs derive in large measure from the great number of labels and firms involved. The agency questions whether the costs reflected in the aggregate number represent "undue economic hardship." Therefore, FDA requests comments on how it should assess "undue economic hardship." Should it assess this question on a firm-by-firm basis, as was provided in the bill that passed the House Committee on Energy and Commerce (H. Rept. 101-538, 101st Cong., 2d sess., 24 (1990)), an industry-by-industry basis, or should it assess this question on an aggregate basis? If the agency should take the latter approach, comments should provide evidence that would permit the agency to make a determination that there is "undue economic hardship" for most companies. FDA also points out that assessing hardship on a firm-by-firm basis would likely be extremely burdensome because of the likely number of requests.

FDA will consider the question of the meaning and appropriate application of section 10(a)(3)(B) of the 1990 amendments as soon as possible after the comment period closes. The agency intends to publish a notice in advance of any final rule announcing how it will implement this section to assist firms in planning how they will comply with the act. The early publication of this notice is to assist firms in avoiding any unnecessary expenses that could be incurred by trying to comply with a compliance date that may cause "undue economic hardship."

B. Consumer Education Program

Section 2(c) of the 1990 amendments directs the Secretary of the Department of Health and Human Services to carry out a consumer education program related to the nutrition label and its importance in maintaining healthy dietary practices. The agency discussed its intention to undertake such activities in its mandatory nutrition labeling proposal (55 FR 29487 at 29508). This program will require many varied activities, such as identification of key educational needs; target populations; appropriate educational strategies; educational messages; materials development; establishment of a food label education network to include representatives from health professionals and educators, consumers, and the food industry to assist in dissemination and implementation of educational materials and programs; and evaluation of the program's impact. FDA intends to begin to develop and implement these activities as quickly as possible, so that materials will be available to consumers as revised food labels begin appearing in the marketplace.

C. Preemption

In its July 19, 1990 proposal, FDA acknowledged the numerous comments that it received at the public hearings and as a result of its advance notice of proposed rulemaking (54 FR 32610, August 8, 1989) that suggested that Federal nutrition labeling rules should explicitly preempt any State nutrition labeling regulations. Because of the complexity of this issue, however, the agency requested additional comments on the appropriateness of preemption before deciding on a course of action.

Section 6 of the 1990 amendments settled the issue by amending the act to

include several provisions pertaining to Federal preemption of State and local labeling requirements. The 1990 amendments prohibit a State or a political subdivision of a State from establishing or continuing in effect any requirement for food in interstate commerce that would conflict with certain provisions of section 403 of the act. Specifically, section 403A(a)(4) of the act, which was added by the 1990 amendments, prohibits any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) of the act. The only exceptions provided in this section are for nutrition labeling of foods sold in restaurants, restaurant-type facilities, or ready-to-eat foods sold in retail establishments such as delicatessens that are exempt under section 403(q)(5)(A)(i) or (q)(5)(A)(ii) of the act from Federal nutrition labeling provisions (section 403A(a)(4) of the act).

Congress included the preemption provisions in the 1990 amendments because it recognized that it would be difficult or impossible for food companies to operate in interstate commerce if they were confronted with State and local requirements that were in conflict with, or were inconsistent with, the applicable Federal requirements (Ref. 25). However, Congress also recognized that Federal preemption should only apply in matters where a strong Federal regulatory system is in place (Ref. 25). Congress recognized a role for the States, permitting them to petition the Secretary for exemption from the preemption provisions in situations where a State requirement does not conflict with Federal law, does not burden interstate commerce, and addresses a need that is not met by the provisions of the act that have preemptive effect (section 403A(b) of the act).

The preemption provision concerning nutrition labeling of foods established under section 403(q) of the act becomes effective upon the effective date of the proposed regulations (section 10(b)(1)(D) of the 1990 amendments). Accordingly, the proposed revisions in § 101.9 that address nutrition labeling will preempt any State or local requirement to the contrary when these revisions become effective.

D. Redesignation

In the July 19, 1990 proposal, FDA did not republish existing § 101.9(i), which pertains to the circumstances in which labeling relating to the nutritional properties of a product can misbrand it. The agency had planned to revise this section as part of its rulemaking on health claims (see the **Federal Register** of February 13, 1990 (55 FR 5176)). However, in light of the 1990 amendments, FDA believes that it is appropriate to retain this paragraph and to deal with health claims in a separate section of the regulations. However, FDA believes that § 101.9(k)(1) is so closely related to the health claims issue that it is appropriate to discuss that provision in the proposal on health claims. Consequently, FDA is retaining paragraph (i) and redesignating it as paragraph (k) to reflect the other provisions of this proposal. However, FDA is reserving § 101.9(k)(1) and reproposing that provision in the companion document.

IX. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

X. Environmental Impact

The agency has previously considered the environmental effect of this rule as announced in the July 19, 1990, mandatory nutrition labeling proposal (55 FR 29487). No new information or comments have been received, nor have there been any changes effected by the 1990 amendments, that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

XI. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. to 4 p.m., Monday through Friday.

In accordance with section 2(b)(1) of the 1990 amendments, FDA must issue by November 8, 1992, final regulations for mandatory nutrition labeling. If the agency does not promulgate final regulations by November 8, 1992, the 1990 amendments provide that the regulations proposed in this document shall be considered as the final regulations. The agency has determined that 90 days is the maximum time that it can provide for the submission of comments and still meet this statutory timeframe for the issuance of final regulations. Thus, the agency is advising that it will not consider any requests under 21 CFR 10.40(b) for extension of the comment period beyond February 25, 1992. The agency must limit the comment period to no more than 90 days to assure sufficient time to develop a final rule based on this proposal and the comments it receives.

XII. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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and World Health Organization, Geneva, 1990.

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11. Market Facts, Inc., "Summary Report, FDA Nutrition Labeling Focus Groups," prepared under FDA Contract No. 223–89–2170, Washington, DC, Food and Drug Administration, U.S. Department of Health and Human Services, 1990.

12. Mensink, R. P., and M. B. Katan, "Effect of Dietary Trans Fatty Acids on High-Density and Low-Density Lipoprotein Cholesterol Levels in Healthy Subjects," *The New England Journal of Medicine*, 323:439–445, 1990.

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14. Levy, A. S., S. B. Fein, and R. E. Schucker, Division of Consumer Studies (HFF–240), Center for Food Safety and Applied Nutrition, Food and Drug Administration, "A Study of Nutrition Label Formats: Performance and Preference," 200 C St. SW., Washington, DC 20204, March 1991.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it proposed that 21 CFR Part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR Part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.9 is revised to read as follows:

§ 101.9 Nutrition labeling of food.

(a) Nutrition information relating to food shall be provided for all products that contain more than insignificant amounts of nutrients or food components required in paragraph (c) of this section, or whose label, labeling, or advertising contains a nutrition claim or any other nutrition information, in conformity with the requirements of this section unless an exemption is provided for the product in paragraph (j) of this section. An insignificant amount of a nutrient or a food component shall be that amount that allows a declaration of zero in nutrition labeling. A nutrition claim or any other nutrition information in any context, and in any form of expression, implicit, as well as explicit, shall subject a food to the provisions of this section.

(1) When food is in package form, the required nutrition labeling information shall appear on the label in the format specified in this section.

(2) When food is not in package form, the required nutrition labeling information shall be displayed clearly at the point of purchase (e.g., on a counter card, sign, tag affixed to the product, or some other appropriate device). Alternatively, the required information may be placed in a booklet, looseleaf binder, or other appropriate format that is available at the point of purchase.

(3) Solicitation of requests for nutrition information by a statement "For nutrition information write to _____" on the label or in the labeling or advertising for a food, or providing such information in a direct written reply to a solicited or unsolicited request, does not subject the label or the labeling of a food exempted under paragraph (j) of this section to the requirements of this section if the reply to the request conforms to the requirements of this section.

(4) If any vitamin or mineral is added to a food so that a single serving provides 50 percent or more of the Reference Daily Intake (RDI) for the age group for which the product is intended, as specified in paragraph (c)(11)(iv) of this section, of any one of the added vitamins or minerals, unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner, the food shall be considered a food for special dietary use within the meaning of § 105.3(a)(1)(iii) of this chapter.

(b) [Reserved]

(c) The declaration of nutrition information on the label and in labeling shall contain the following information except for that which is voluntary as set forth in this paragraph or for those food products where a simplified format shall be used as provided for in paragraph (f) of this section. Information shall be presented in the following order, using the headings specified and displayed with equal type size, under the overall heading of "NUTRITION INFORMATION PER SERVING (PORTION)." Alternatively, the terms "PER SERVING (PORTION)" may be placed directly below the terms "NUTRITION INFORMATION."

(1) "Serving (portion) size": A statement of the serving (portion) size.

(2) "Servings (portions) per container": The number of servings (portions) per container.

(3) "Caloric content" or "Calories": A statement of the caloric content per serving (portion), expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that

amounts less than 5 calories may be expressed as zero. Energy content per serving (portion) may also be expressed in kilojoule units, added in parentheses immediately following the statement of the caloric content. Caloric content may be calculated by using specific Atwater food factors or by using the general factors of 4, 4, and 9 calories per gram for protein, carbohydrate, and fat, respectively, as described in A. L. Merrill and B. K. Watt, "Energy Value of Foods—Basis and Derivation," USDA Handbook 74 (1955). The definition of carbohydrate is given in paragraph (c)(6) of this section. These methods of calculation are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the references are available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the **Federal Register**, 1100 L St. NW., Washington, DC.

(i) "Calories from total fat": A statement of the caloric content derived from the total fat content of the food per serving (portion), expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that label declaration of "calories from total fat" is not required on products that contain less than ½ gram of fat in a serving (portion) and amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories, or, alternatively, calories from fat may be declared adjacent to the statement of fat content and aligned with the statement of total calories, in a column headed "Calories." Except as provided for in paragraph (f) of this section, if "Calories from total fat" is not required and, as a result, not declared, the statement "Not a significant source of calories from total fat" shall directly follow the declaration of sodium (or potassium if declared) in the same type size.

(ii) "Calories from saturated fat," "Calories from unsaturated fat," "Calories from carbohydrate," and "Calories from protein" (VOLUNTARY): A statement of the caloric content derived from a serving (portion) of any one or more of the following components may be declared voluntarily: Saturated fat, unsaturated fat, total carbohydrate, and protein. Caloric values shall be expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero.

(A) "Calories from saturated fat" or "Calories from saturated": A statement of the caloric content derived from saturated fat as defined in paragraph (c)(4)(i) of this section. This statement shall be indented under the statement of calories from total fat, or alternatively the calories from saturated fat may be declared adjacent to the statement of saturated fat content.

(B) "Calories from unsaturated fat" or "Calories from unsaturated": A statement of the caloric content derived from unsaturated fat as defined in paragraph (c)(4)(ii) of this section. This statement shall be indented under the statement of calories from total fat, and follow calories from saturated fat, if present; or alternatively calories from unsaturated fat may be declared adjacent to the statement of unsaturated fat content.

(C) "Calories from total carbohydrate": A statement of the caloric content derived from total carbohydrate as calculated in paragraph (c)(6) of this section. This statement shall be indented under the statement of calories from total fat, and follow calories from saturated fat and unsaturated fat, if present; or alternatively calories from total carbohydrate may be declared adjacent to the statement of carbohydrate content and aligned with the statement of total calories, in a column headed "Calories."

(D) "Calories from protein": A statement of the caloric content derived from protein as calculated in paragraph (c)(8) of this section. This statement shall be indented under the statement of calories from total fat, and follow calories from saturated fat, unsaturated fat, and total carbohydrate, if present; or alternatively calories from protein maybe declared adjacent to the statement of protein content and aligned with the statement of total calories, in a column headed "Calories."

(4) "Total fat content" or "Total fat": A statement of the number of grams of total fat in a serving (portion) expressed to the nearest ½ gram. If the serving (portion) contains less than 0.5 gram, the content shall be expressed as zero.

(i) "Saturated fat content," "Saturated fat," or "Saturated": A statement of the number of grams of saturated fat in a serving (portion) calculated as triglycerides and defined as the sum of lauric, myristic, palmitic, and stearic acids, except that label declaration of saturated fat content information is not required for products that contain less than 1/2 gram of total fat in a serving if no claims are made about fat or cholesterol content, and if "calories from saturated fat" is not declared. Except as provided for in paragraph (f) of this section, if a statement of the saturated fat content is not required and, as a result, not declared, the statement "Not a significant source of saturated fat" shall directly follow the declaration of sodium (or potassium if declared) in the same type size. Saturated fat content shall be indented and expressed as grams per serving (portion) to the nearest 1/2 gram. If the serving (portion) contains less than 0.25 gram, the content shall be expressed as zero.

(ii) "Unsaturated fat content," "Unsaturated fatty acid," or "Unsaturated (VOLUNTARY): A statement of the number of grams of unsaturated fat in a serving (portion) calculated as triglycerides and defined as the sum of all polyunsaturated and monounsaturated fatty acids (both *cis* and *trans* isomers) may be declared voluntarily, except that when a claim is made on the label or in labeling about fatty acid or cholesterol content or when "calories for unsaturated fat" is declared, label declaration shall be required. Unsaturated fat content shall be indented and expressed as grams per serving (portion) to the nearest ½ gram. If the serving (portion) contains less than 0.25 gram, the content shall be expressed as zero. Alternatively, separate statements may be declared for polyunsaturated and monounsaturated fat, except that if a claim is made on the label or in labeling about a particular type of unsaturated fatty acid, separate statements shall be declared as follows in lieu of the collective term "Unsaturated":

(A) "Polyunsaturated fat" or "Polyunsaturated": A statement of the number of grams of polyunsaturated fat defined as *cis,cis*-methylene-interrupted polyunsaturated fatty acids, indented and expressed as grams per serving to the nearest 1/2 gram. If the serving (portion) contains less than 0.25 gram, the content shall be expressed as zero; and

(B) "Monounsaturated fat" or "Monounsaturated": A statement of the number of grams of monounsaturated fat defined as *cis*-monounsaturated fatty acids, indented and expressed as grams per serving to the nearest ½ gram. If the serving (portion) contains less than 0.25 gram, the content shall be expressed as zero.

(5) "Cholesterol content" or "Cholesterol": A statement of the cholesterol content in a serving (portion) expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is

not required for products that contain less than 2 milligrams cholesterol in a serving (portion) and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. Except as provided for in paragraph (f) of this section, if cholesterol content is not required and, as a result, not declared, the statement "Not a significant source of cholesterol" shall directly follow the declaration of sodium (or potassium if declared) in the same type size. If the food contains 2 to 5 milligrams of cholesterol per serving (portion), the content may be stated as "less than 5 milligrams."

(6) "Total carbohydrate content" or "Total carbohydrate": A statement of the number of grams of total digestible carbohydrate in a serving (portion) expressed to the nearest gram, except that if a serving (portion) contains less than 1 gram, the statement "Contains less then 1 gram" or "less than 1 gram" may be used as an alternative, or if the serving (portion) contains less then 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, dietary fiber, moisture, and ash from the total weight of the food. (This calculation method is described in A.L. Merrill and B.K. Watt, "Energy Value of Foods—Basis and Derivation," USDA Handbook 74 (1955) which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 except that total dietary fiber as described in paragraph (c)(7)(ii) of this section shall also be subtracted). Copies of the method may be obtained from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

(i) "Complex carbohydrate content" or "Complex carbohydrate": A statement of the number of grams of digestible complex carbohydrate, defined as the sum of dextrins (saccharide units of 10 or more) and starches, except that label declaration of complex carbohydrate content is not required for products that contain less than 1 gram of complex carbohydrate in a serving. Except as provided for in paragraph (f) of this section, if a statement of the complex carbohydrates content is not required and, as a result, not declared, the statement "Not a significant source of complex carbohydrate" shall directly follow the declaration of sodium (or potassium if declared) in the same type size. Complex carbohydrate content shall be indented and expressed to the nearest gram, except that if a serving (portion) contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving (portion) contains less than 0.5 gram, the content may be expressed as zero.

(ii)(A) "Sugars content" or "Sugars": A statement of the number of grams of sugars in a serving (portion), except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Except as provided for in paragraph (f) of this section, if a statement of the sugars content is not required and, as a result, not declared, the statement "Not a significant source of sugars" shall directly follow the declaration of sodium (or potassium if declared) in the same type size. Sugars shall be defined as the sum of all free mono- and oligosaccharides through four saccharide units (such as glucose, fructose, lactose, sucrose, and glucose polymers up to four saccharide units) and their derivatives whose use in the food is approved by the Food and Drug Administration or is generally recognized as safe that have similar sweetening, nutritional, and metabolic effects (such as sugar alcohols). Sugars content shall be indented and expressed to the nearest gram, except that if a serving (portion) contains less than 1 gram, the statement "Contains less then 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving (portion) contains less than 0.5 gram, the content may be expressed as zero.

(B) "Sugar alcohol content" or "Sugar alcohol" (VOLUNTARY): A statement of the number of grams of sugar alcohols in a serving (portion) may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the food, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of mannitol, sorbitol, xylitol, and any other sugar alcohols whose use in the food is approved by FDA or is generally recognized as safe and that meet the definition of sugars as described in paragraph (c)(6)(ii)(A) of this section. Sugar alcohol content shall be indented under sugars content and expressed to the nearest gram, except that if a serving (portion) contains less than 1 gram, the statement "Contains less then 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving (portion) contains less than 0.5 gram, the content may be expressed as zero.

(7) "Dietary fiber content" or "Dietary fiber": A statement of the number of grams of total dietary fiber in a serving (portion), expressed to the nearest gram, except that if a serving (portion) contains less than 1 gram, declaration of dietary fiber is not required or, alternatively, the statement "Contains less than 1 gram" or less than 1 gram" may be used, and if the serving (portion) contains less than 0.5 gram, the content may be expressed as zero. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required and as a result, not declared, the statement "Not a significant source of dietary fiber" shall directly follow the declaration of sodium (or potassium if declared) in the same type size.

(i) Soluble and insoluble fiber (VOLUNTARY): A statement of the number of grams of soluble and insoluble dietary fiber in a serving (portion) may be declared voluntarily except that when a claim is made on the label or in labeling about either type of fiber, label declaration of both types shall be required as follows:

(A) "Soluble fiber": A statement of the number of grams of soluble dietary fiber, indented and expressed to the nearest gram, except that if a serving (portion) contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving (portion) contains less than 0.5 gram, the content may be expressed as zero, and

(B) "Insoluble fiber": A statement of the number of grams of insoluble dietary fiber, indented and expressed to the nearest gram except that if a serving (portion) contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving (portion) contains less than 0.5 gram, the content may be expressed as zero.

(ii) Total dietary fiber, soluble dietary fiber, and insoluble dietary fiber content shall be determined by the method "Total Dietary Fiber in Foods, Enzymatic Gravimetric Method, First Action," in the *Journal of the Association of Official Analytical Chemists* (JAOAC), 68:399, 1985, as amended in JAOAC, 69:370 1986 and as modified in JAOAC 71:1017, 1988. These nethods are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW.,

Washington, DC 20204, or available for inspection at the Office of the **Federal Register**, 1100 L St. NW., Washington, DC.

(8) "Protein content" or "Protein": A statement of the number of grams of protein in a serving (portion), expressed to the nearest gram, except that if a serving (portion) contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving (portion) contains less than 0.5 gram, the content may be expressed as zero. When the protein in foods represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, the protein content statement shall be modified by an adjacent statement "not a significant source of protein" regardless of the actual amount of protein present. The same statement is required when the protein quality in a food as measured by the protein digestibility-corrected amino acid score is less than 40 percent of the reference standard (casein) for a food represented or purported to be for children greater than 1 but less than 4 years of age; or when the protein quality in a food as measured by Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a food represented or purported to be for infants. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the current edition of the Official Methods of Analysis of the Association of Official Analytical Chemists, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, except when the official procedure for a specific food requires another factor. Copies may be obtained from the Association of Official Analytical Chemists, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(8)(ii) of this section, calculated as a percentage of the RDI for protein and expressed as "Percent of Daily Value," may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be for use by infants or children under 4 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein. However, the percentage of the RDI for protein shall not be declared if the food is represented or purported to be for use by adults and children 4 or more years of age and the protein quality value is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or if the food is represented or purported to be for use by infants or children under 4 years of age and the protein quality value is less than 40 percent of the reference standard.

(ii) The "corrected amount of protein (gram) per serving (portion)" for foods represented or purported for adults and children 1 or more years of age is equal to the actual amount of protein (gram) per serving (portion) multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00 then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by the method given in "Protein Quality Evaluation," Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation, Rome, 1990, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC. For foods represented or purported for infants, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving (portion) multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject food protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the RDI, a value of 50 grams of protein shall be the RDI for adults and children 4 or more years of age, 16 grams of protein for children less than 4 years of age, and 14 grams of protein for infants.

(9) "Sodium content" or "Sodium": A statement of the number of milligrams of sodium in a specified serving (portion) of food expressed as zero when the serving (portion) contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving (portion) contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving (portion) contains greater than 140 milligrams.

(10) "Potassium content" or "potassium" (VOLUNTARY): A statement of the number of milligrams of potassium in a specified serving (portion) of food may be declared voluntarily, except that when a claim is made about potassium content, label declaration shall be required. Potassium content shall be expressed as zero when the serving (portion) contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving (portion) contains less than or equal to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving (portion) contains more than 140 milligrams.

(11) Under the heading "Percent of Daily Value": A statement of the amount per serving (portion) of the vitamins and minerals as described in this paragraph, expressed as a percent of the RDI.

(i) For purposes of declaration of Percent of Daily Value, foods represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's in paragraph (c)(11)(iv) of this section that are specified for the intended group. For foods represented or purported to be for use by both infants and children under 4 years of age, the Percent of Daily Value shall be presented by separate declarations based on the RDI values for infants from birth to 12 months of age and for children under 4 years of age. Similarly, the Percent of Daily Value based on both the RDI values for pregnant women and for lactating women shall be declared separately on foods represented or purported to be for use by both pregnant and lactating women. When such dual declaration is used on any label, it shall also be included in all labeling, and equal prominence shall be given to both values in all such labeling. All other foods shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a percent of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(11)(iv) of this section when they are added as a nutrient supplement, or when a claim is made about them. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(11)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(11)(iv) of this section.

(iii) The percentages shall be expressed in 2-percent increments up to

and including the 10-percent level, 5-percent increments above 10 percent and up to and including the 50-percent level, and 10-percent increments above the 50-percent level. Vitamins and minerals present in amounts less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk that refers to another asterisk that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." Except as provided for in paragraph (f) of this section, if vitamin A, vitamin C, calcium, or iron is omitted, the statement "Not a significant source of _____ (listing the vitamins or minerals omitted)" shall directly follow the listing of percentages of the RDI.

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

Nutrient	Unit of measurement [1]	Adults and children 4 or more years of age	Children less than 4 years of age [2]	Infants [3]	Pregnant women	Lactating women
Vitamin A	Retinol equivalents [4]	875	400	375	800	1,300
Vitmin C	Milligrams	60	40	33	70	95
Calcium	do	900	800	500	1,200	1,200
Iron	do	12	10	8.0	30	15
Vitamin D	Micrograms [5]	6.5	10	9.0	10	10
Vitamin E	α-Tocopherol equivalents [4]	9.0	6.0	3.5	10	12
Vitamin K	Micrograms	65	15	7.5	65	65
Thiamin	Milligrams	1.2	0.7	0.4	1.5	1.6
Riboflavin	do	1.4	0.8	0.5	1.6	1.8
Niacin	Niacin equivalents [4]	16	9.0	5.5	17	20
Vitamin B_6	Milligrams	1.5	1.0	0.5	2.2	2.1
Folate	Micrograms	180	50	30	400	280
Vitamin B_{12}	do	2.0	0.7	0.4	2.2	2.6
Biotin	do	60	20	13	65	65
Pantothenic acid	Milligrams	5.5	3.0	2.5	5.5	5.5
Phosphorus	do	900	800	400	1,200	1,200
Magnesium	do	300	80	50	320	355
Zinc	do	13	10	5.0	15	19
Iodine	Micrograms	150	70	45	175	200
Selenium	do	55	20	13	65	75
Copper	Milligrams	2.0	0.9	0.6	2.5	2.5
Manganese	do	3.5	1.3	0.6	3.5	3.5
Fluoride	do	2.5	1.0	0.5	3.0	3.0
Chromium	Micrograms	120	50	33	130	130
Molybdenum	do	150	38	26	160	160
Chloride	Milligrams	3,150	1,000	650	3,400	3,400

[1] The following abbreviations are allowed: "mg" for "milligrams"; "mcg" or "μg" for "micrograms"; "μg RE" for "retinol equivalents"; "mg α-TE" for "α-tocopherol equivalents"; "mg NE" for "niacin equivalents."
[2] The term "children less than 4 years of age" means persons 13 through 47 months of age.
[3] The term "infants" means persons not more than 12 months of age.
[4] 1 retinol equivalent = 1 microgram retinol or 6 micrograms β-carotene; 1 α-tocopherol equivalent = 1 milligram d-α-tocopherol; 1 niacin equivalent = 1 milligram niacin or 60 milligrams of dietary tryptophan.
[5] As cholecalciferol.

(v) The following synonyms may be added in parentheses immediately following the name of the nutrient or dietary component:

Vitamin C	Ascorbic acid
Folate	Folacin
Calories	Energy

(12) Under the heading "Nutrition Profile": A statement of the percent of the Daily Reference Value (DRV) present in a serving (portion) for food components for which DRV's are given in paragraph (c)(12)(i) of this section shall be declared, followed by a statement of the DRV for each component. The percent and DRV shall be declared for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, and sodium. Unsaturated fat and potassium also may be included. The percents of DRV's shall be expressed in 2-percent increments up to and including the 10-percent level, 5-percent increments above 10 percent and up to and including the 50-percent level, and 10-percent increments above the 50-percent level.

(i) The following DRV's are established for the following food components based on a reference caloric intake of 2,350 calories (**Note:** The caloric contribution from protein is assumed to be approximately 15 percent.):

Food component	Unit of measurement [1]	DRV
Total fat	grams	75
Saturated fat	do	25
Unsaturated fat	do	50
Cholesterol	milligrams	300
Total carbohydrate.	grams	325
Dietary fiber	do	25
Sodium	milligrams	2,400
Potassium	do	3,500

[1] The following abbreviations are allowed: "g" for "grams" and "mg" for "milligrams."

(ii) The following format shall be used to present a food product's nutrition profile:

Food component	Percent	Daily value
Total fat	(percent)	75 grams.[1]
Saturated fat	(percent)	25 grams.[1]
Cholesterol	(percent)	300 milligrams.
Total carbohydrate	(percent)	325 grams.[1]
Dietary fiber	(percent)	25 grams.[1]
Sodium	(percent)	2,400 milligrams.

[1] As part of a 2,350 calorie diet.

(iii) In addition, the percent of the DRV for unsaturated fat may be listed in the Nutrition Profile immediately following saturated fat and the percent

of the DRV for potassium immediately following sodium as follows:

Unsaturated fat...	(percent).....	50 grams.*
Potassium.....	(percent).....	3,500 milligrams.

(d) [Reserved]

(e) Products with separately packaged ingredients, with assortments of food, or to which other ingredients are added by the user may be labeled as follows:

(1) If a product consists of two or more separately packaged ingredients enclosed in an outer container or of assortments of food (e.g., assorted candy mixtures) in the same package, nutrition labeling of the total product shall be located on the outer container to provide information for the consumer at the point of purchase. However, when two or more food products are simply combined together in such a manner that no outer container is used, or no outer label is available, each product shall have its own nutrition information, e.g., two boxes taped together or two cans combined in a clear plastic overwrap.

(2) If a food is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the food as consumed in the same format required in paragraph (c) of this section for the food alone (e.g., a dry ready-to-eat cereal may be described with one set of Daily Values for the cereal as sold (e.g., per ounce), and another set for the cereal and milk as suggested in the label (e.g., per ounce of cereal and 1/2 cup of vitamin D fortified whole milk); and a cake mix may be labeled with one set of Daily Values for the dry mix (per serving) and another set for the serving of the final cake when prepared): *Provided*, That, the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(f)(1) The declaration of nutrition information shall be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: calories, calories from total fat, total fat, saturated fat, cholesterol, total carbohydrate, complex carbohydrate, sugars, dietary fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron.

(2) An "insignificant amount" shall be defined as that amount that may be rounded to zero in nutrition labeling.

(3) The simplified format shall include:

(i) Serving size, number of servings per container, calories, total fat (grams), total carbohydrate (grams), protein (grams), and sodium (milligrams);

(ii) Any other nutrients or food components identified in paragraph (f)(1) of this section that are present in the food in more than insignificant amounts; and

(iii) Any other vitamins and minerals listed in paragraph (c)(11)(iv) of this section when they are required to be added as a nutrient supplement to foods for which a standard of identity exists.

(4) Other nutrients or food components that are present in the food in more than insignificant amounts may be voluntarily declared as part of the simplified format. Any vitamins or minerals that are added to the food as nutrient supplements shall be declared as part of the simplified format. If additional nutrients or food components are declared as part of the simplified format for either of these reasons, the statement "Not a significant source of _____" (with the blank filled in with the name of any nutrient or food component identified in § 101.9(f)(1) present in insignificant amounts) shall be included at the bottom of the nutrition label.

(5) Nutrient information in the simplified format may be presented in vertical columns or in lines. When lines are used, any subcomponents declared shall be listed parenthetically after principal components (e.g., saturated fat shall be parenthetically listed after total fat).

(g) Compliance with this section shall be determined as follows:

(1) A collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, or in the absence of any common container code or marking, a day's production, constitutes a "lot".

(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by appropriate methods as given in the 15th edition 1990 of the Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC) which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures. Copies of the incorporation by reference are available from the Association of Official Analytical Chemists, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC. Alternative methods of analysis may be submitted to FDA to determine their acceptability.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added.

(4) A food with a label declaration of a vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, or potassium shall be deemed to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) unless it meets the following requirements:

(i) *Class I vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, or potassium.* The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) *Class II vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, or potassium.* The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label. *Provided*, That no regulatory action will be based on a determination of a nutrient value which falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(5) A food with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label.

(6) Reasonable excesses of a vitamin, mineral, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, or potassium over labeled amounts are acceptable within current good manufacturing practice.

Reasonable deficiencies of calories, sugars, total fat, saturated fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

(7) The compliance provisions set forth in paragraphs (g)(1) through (g)(6) of this section do not apply to products for which nutrition labeling is founded on FDA approved data bases and is computed following FDA guideline procedures and that have been handled in accordance with current good manufacturing practice to prevent nutrition loss. FDA approval of a data base shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the data base in writing. The approval will be granted where a clear need is presented (e.g., raw produce and seafood). Approvals will be in effect for a limited time, e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices. Approval requests shall be submitted in accordance with the provisions of § 10.30 of this chapter. Guidance in the use of data bases may be found in the "FDA Nutrition Labeling Manual—A Guide for Using Data Bases," available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(8) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to develop adequate nutrient profiles to comply with the requirements of paragraph (c) of this section, FDA may establish by regulation alternative means of compliance or additional exemptions to deal with the situation. Firms in need of such a regulation may submit a petition for initiation of rulemaking proceedings to the Dockets Management Branch in the form established by § 10.30 of this chapter.

(h) Nutrition information provided by a manufacturer or distributor directly to professionals (e.g., physicians, dietitians, educators) may vary from the requirements of this section but shall also contain or have attached to it the nutrition information exactly as required by this section.

(i) The location of nutrition information on a label shall be in compliance with § 101.2.

(j) The following foods are exempt from this section or are subject to special labeling requirements:

(1)(i) Food offered for sale by a person who has annual gross sales made or business done in sales to consumers which is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, *Provided,* That the food bears no nutrition claims or information on a label or labeling or in advertising.

(ii) For purposes of this paragraph, a person who offers food for sale, or who has business done in sales, to consumers is any person who manufactures, packs, or distributes food for ultimate sale to consumers at the retail level as well as any person directly involved in the retail sale of foods to consumers.

(iii) For purposes of this paragraph, calculation of the amount of sales shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years, reasonable estimates must indicate that annual sales will not exceed the amounts specified. For foreign firms that ship foods into the United States, the business activities to be included shall be the total amount of food sales, as well as other sales to consumers, by the firm in the United States.

(2) Food products provided by restaurants or other food service facilities offering restaurant-type services (e.g., delicatessens, bakeries, feeding facilities in organizations such as schools, colleges, hospitals, and transportation carriers (such as trains and airplanes)). Foods sold to restaurants by distributors who principally sell food to restaurants or other establishments in which food is served for immediate human consumption, and who do not manufacture, process, or repackage the food they sell.

(3) Food products provided by grocery stores that are offered for sale from:

(i) Self-service food bars (e.g., salad bars); or

(ii) Behind delicatessen or bakery counters.

(4) Foods, other than infant formula, represented or purported to be specifically for infants and toddlers less than 2 years of age shall bear nutrition labeling, except that such labeling shall not include calories from fat or saturated fat and cholesterol content information.

(5) Dietary supplements of vitamins and minerals that are labeled in compliance with § 101.36, except that the labeling of a dietary supplement of vitamins and minerals in food form, e.g., a breakfast cereal, shall conform to the labeling established in paragraph (c) of this section, including the order for listing vitamins and minerals established in paragraph (c)(11)(iv) of this section.

(6) Infant formula subject to section 412 of the act, as amended, except that such foods shall be labeling in compliance with part 107 of this chapter.

(7) Medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). A medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. A food is subject to this exemption only if:

(i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;

(ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

(iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;

(iv) It is intended to be used under medical supervision; and

(v) It is provided only to a patient receiving active and ongoing medical supervision wherein the patient seeks medical care on a recurring basis for, among other things instructions on the use of the medical food.

(8) Food products shipped in bulk form that are not for distribution to consumers in such form and that are to be processed, labeled, or repacked at a site other than where originally processed or packed.

(9) Food products that are supplied for institutional food service use only: *Provided,* That the manufacturer or distributor provides the nutrition information required by this section directly to those institutions on a current basis.

(10) Raw fruits, vegetables, and fish subject to section 403(q)(4) of the act, except that such foods should adhere to guidelines in § 101.45. The term "fish" includes freshwater or marine fin fish, crustaceans, and mollusks, including

shellfish, amphibians, and other forms of aquatic animal life.

(11) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches, *Provided*, That the labels for these foods bear no nutrition information. Nutrition labeling for foods that qualify for this exemption shall be presented to consumers in accordance with the provisions of paragraph (a)(2) of this section.

(12) Shell eggs packaged in a carton that has a top lid designed to conform to the shape of the eggs are exempt from outer carton label requirements where the required nutrition information is clearly presented in no less than 1/16 inch type size immediately beneath the carton lid.

(13) The unit containers in a multiunit retail food package where:

(i) The multiunit retail food package labeling contains all nutrition information in accordance with the requirements of this section;

(ii) The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and

(iii) Each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than 1/16 inch in height. The word "individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.

(14) Food products sold from bulk containers: *Provided*, That nutrition information required by this section be displayed to consumers either on the labeling of the bulk container plainly in view or in accordance with the provisions of paragraph (a)(2) of this section.

(k) A food labeled under the provisions of this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act if its labeling represents, suggests, or implies:

(1) [Reserved]

(2) That a balanced diet of ordinary foods cannot supply adequate amounts of nutrients.

(3) That the lack of optimum nutritive quality of a food, by reason of the soil on which that food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition. Ingredients or products such as rutin, other bioflavonoids, para-amino-benzoic acid, inositol, and similar substances which have in the past been represented as having nutritional properties but which have not been shown to be essential in human nutrition may not be combined with vitamins and/or minerals, added to food labeled in accordance with this section, or otherwise used or represented in any way which states or implies nutritional benefit. Ingredients or products of this type may be marketed as individual products or mixtures thereof: *Provided*, That the possibility of nutritional, dietary, or therapeutic value is not stated or implied, e.g., their labeling does not state that their usefulness in human nutrition has not been established and does not otherwise disclaim nutritional, dietary, or therapeutic value.

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin, or to differentiate in any way between vitamins naturally present from those added.

3. Section 101.36 is added to subpart C to read as follows:

§ 101.36 Nutrition labeling of dietary supplements of vitamins and minerals.

(a) The label and labeling of a dietary supplement of a vitamin or mineral that is listed in § 101.9(c)(11)(iv), other than one in conventional food form (i.e., breakfast cereals), shall bear nutrition labeling in accordance with this regulation.

(b) The declaration of nutrition information on the label and in labeling shall contain the following information, using the headings specified, and displayed with equal type size, under the overall heading of "NUTRITION INFORMATION."

(1) "Units per day": A statement of the number of units to be consumed per day. The quantity specified shall be a reasonable quantity suitable for and practicably of consumption within 1 day and shall be consistent with any intake recommendation on the label or in labeling. Appropriate terms, such as tablets, capsules, or teaspoonfuls, may be used here and elsewhere on the label in place of the term "units".

(2) "Units per container": The number of units per container.

(3) A listing of the quantitative amount and percent of the Reference Daily Intake (RDI), where appropriate, of all nutrients and food components required in § 101.9(c), including any vitamin and mineral listed in § 101.9(c)(11)(iv) present in the supplement, in a column under the heading of "PER UNIT" except that nutrients and food components that are present in the total number of units specified for consumption per day at insignificant amounts need not be declared. Insignificant amounts shall be defined as amounts that allow a declaration of zero in nutrition labeling as specified in § 101.9(c). Where label directions specify that more than one unit be consumed during a period of 1 day, the required nutrition information shall also be presented in a second column under the heading of "PER DAY."

(i) Nutrients and food components shall be listed in the order specified in § 101.9(c) except that calcium and iron, when present, shall follow the complete listing of vitamins.

(ii) The quantitative amounts of all nutrients and food components declared shall be presented in a column under the heading of "Amount." These amounts shall be expressed in the increments and units of measurement specified in § 101.9(c). Quantitative amounts of vitamins and minerals shall be expressed to the nearest unit of the same level of significance given in § 101.9(c)(11)(iv).

(iii) The percent of the RDI specified in § 101.9(c)(11)(iv) of all vitamins and minerals present shall be presented in a column immediately under the heading "Percent of Daily Value." This column shall be to the right of the column of quantitative amounts.

(A) Values shall be based on the percent of the RDI for adults and children 4 or more years of age unless the product is represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women in which case the column heading shall clearly state the intended group.

(B) The percentages of RDI's shall be expressed in 2 percent increments up to and including the 10-percent level, 5 percent increments above 10 percent and up to and including the 50-percent level, and 10 percent increments above the 50-percent level.

(iv) If the product is for persons within more than one group for which RDI's are established in § 101.9(c)(11)(iv), the percent of daily value for each group shall be presented in additional columns.

(v) The following synonyms may be added in parenthesis immediately following the name of the nutrient or dietary component:

Vitamin C	Ascorbic Acid
Folate	Folacin
Calories	Energy

(c) Compliance with this section shall be determined in accordance with § 101.9(g).

Dated: August 2, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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21 CFR Part 101

[Docket No. 90N-0165]

RIN 0905-AD08

Food Labeling; Serving Sizes

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this document as a reproposal of its proposed regulation entitled "Food Labeling; Serving Sizes" (55 FR 29517, July 19, 1990) in response to the recent enactment of the Nutrition Labeling and Education Act of 1990. The agency also is responding to public comments submitted in response to the July 19, 1990 serving sizes proposal and to the public meeting held on April 4, 1991, on serving sizes (56 FR 8084, February 26, 1991). FDA is proposing to: (1) Define serving and portion size on the basis of the amount of food customarily consumed per eating occasion; (2) establish reference amounts customarily consumed per eating occasion (reference amounts) for 131 food product categories; (3) provide criteria for determining label serving size from the reference amounts; (4) require the use of both common household and metric measures to declare serving size; (5) permit the declaration of serving (portion) size in U.S. measures; (6) permit the optional declaration of nutrient content per 100 grams (g), 100 milliliters (mL), 1 ounce (oz), or 1 fluid ounce (fl oz); (7) define a "single-serving container;" and (8) require that the use of claims such as "low sodium" be based on both the serving size declared on the label and the reference amount.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, 301-443-1751.

FOR FURTHER INFORMATION CONTACT: Youngmee K. Park, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0089.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 19, 1990 (55 FR 29487), FDA published a proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" to amend its food labeling regulations to require nutrition labeling on most food products that are meaningful sources of nutrients. In the same issue of the Federal Register (55 FR 29517), FDA published a technical supporting proposal entitled "Food Labeling; Serving Sizes" (hereinafter referred to as the 1990 proposal).

The 1990 proposal stated that in view of the many comments that the agency had received stating the need for more realistic and consistent serving sizes, FDA had concluded that reasonable and standardized serving sizes should be established. The agency proposed to amend the nutrition labeling regulations to: (1) Define serving and portion size on the basis of the amount of food commonly consumed per eating occasion by persons 4 years of age or older, by infants, or by children under 4 years of age (toddlers); (2) require the use of both U.S. (oz, fl oz) and metric measures to declare serving size; (3) permit the declaration of serving (portion) size in familiar household measures; (4) permit the optional declaration of nutrient content per 100 g or 100 mL; (5) define "single-serving containers" as those that contain 150 percent or less of the standard serving size for the food product; and (6) establish standard serving sizes for 159 food product categories to ensure reasonable and uniform serving sizes upon which consumers can make nutrition comparisons among food products. Interested persons were given until November 16, 1990, to submit comments to the agency on the serving size proposal.

On September 26, 1990, the National Academy of Sciences' Institute of Medicine (IOM) issued a report entitled "Nutrition Labeling, Issues and Directions for the 1990s" (hereinafter referred to as the IOM Report) (Ref. 1). The IOM report was written under contract to the Public Health Service, U.S. Department of Health and Human Services (DHHS) and the Food Safety and Inspection Service, U.S. Department of Agriculture (USDA). On October 5, 1990, FDA published a notice in the Federal Register (55 FR 40944), announcing the availability of the IOM report and requesting that interested persons comment on the implications of the report for the agency's July 19, 1990, proposals on food labeling. The report makes several recommendations related to serving sizes.

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (hereinafter referred to as the "1990 amendments") (Pub. L. 101-535). The 1990 amendments add section 403(q) to the Federal Food, Drug, and Cosmetic Act (the act). Section 403(q) of the act specifies, in part, that:

> * * * the serving size * * * is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or * * * if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food.

The 1990 amendments also require, in section 2(b)(1)(B), that FDA adopt regulations that: "* * * establish standards * * * to define serving size or other unit of measure for food, * * *."

While the requirements of the 1990 amendments that pertain to serving sizes are similar in many respects to FDA's 1990 proposal, differences do exist, and questions about the exact meaning and the implementation of these provisions have been raised.

On February 26, 1991 (56 FR 8084), FDA announced a public meeting to discuss issues related to how serving and portion size should be determined and presented as part of nutrition labeling. The notice stated that several issues arising from the comments on the serving size proposal and two other recent developments (the 1990 amendments and the IOM report) required further public comment. Therefore, FDA held a public meeting on serving sizes on April 4, 1991, to provide an opportunity to submit oral comments, as well as an opportunity for written comments, on the issues identified in the notice.

The notice of the public meeting outlined five major issues for discussion at the meeting: (1) Whether, in determining serving (portion) sizes (hereinafter referred to as "serving size" for simplicity) based on the amount of food customarily consumed, the agency should limit itself to national food consumption data, or whether there is other information that should be considered; (2) whether in declaring

serving sizes, weight units in addition to household measures should be required, and how the definition of "household measures" should be standardized; (3) whether deviation from the standard serving size should be allowed if standard serving sizes are required by regulations, and if so, how much deviation should be allowed; (4) whether, in addition to nutrient content per serving, the nutrition label should allow (or require) a column that lists nutrient content on a uniform weight (or volume) basis, such as per 100 g and 100 mL or per oz and fluid oz; and (5) how single-serving containers should be defined, and whether compliance with definitions for adjectival descriptors such as "low sodium" on single-serving containers should be based on the standard serving size or the entire content of a single-serving container. In the announcement, the agency solicited written comments on a sixth, essentially legal, issue involving questions of statutory construction: whether FDA should establish standard serving sizes for specific categories of foods or develop criteria for food manufacturers to use in determining their own serving sizes.

II. Rationale for Reproposal of Serving Sizes Regulation

FDA has carefully considered the serving size provisions of the 1990 amendments and the comments that it received in response to the **Federal Register** documents on serving sizes. As a result, the agency has decided to repropose the serving size regulation for two major reasons. First, FDA wishes to take advantage of the explicit legal authority to regulate the serving sizes used on the nutrition label that is provided by the 1990 amendments. Secondly, the agency has decided to make a number of changes in response to the comments received on the **Federal Register** documents and the public meeting on serving sizes and to explain its reasons for agreeing or not agreeing with the comments.

To implement the 1990 amendments, FDA is proposing to adopt regulations that provide standards for defining serving sizes. There are two basic elements to these proposed standards: (1) Reference amounts of food that are customarily consumed per eating occasion (reference amounts) for 131 product categories; and (2) procedures for determining serving sizes for use on product labels from the reference amounts. While the reference amounts are defined primarily in metric units, under the act, the serving size must be expressed in a common household measure that is appropriate to the particular food.

This reproposal also responds to many requests for changes in other aspects of the 1990 proposal. After careful consideration of all comments, the agency has tentatively concluded that it is desirable to make changes that include:

(1) Revising the definition for single-serving containers to increase the upper limit from "150 percent or less" to "less than 200 percent; and

(2) Revising the basis for evaluating label claims like "low sodium" to include both the declared serving size and the reference amount.

III. Evaluation of IOM Report and Review of Comments

A. FDA's Evaluation of the IOM Report

The agency has carefully reviewed recommendations related to serving size contained in the IOM report. The IOM recommended the continued use of serving size to present nutrition information, the expression of serving sizes in common household measures followed by weight in g in parentheses, and the establishment of a process for manufacturers to petition for deviations from the standard serving size or to create a new subclass of foods with its own serving size. This reproposal adopts these recommendations.

The IOM report also recommended that FDA and USDA jointly establish serving sizes for a limited (few) number of different food categories for ready product comparisons and reference purposes. In response to the IOM report recommendations, FDA established an interagency committee that included representatives of the Food Safety and Inspection Service and the Human Nutrition Information Service of the United States Department of Agriculture (USDA), as well as FDA members. This committee developed general principles and rules used to determine the reference amounts. The committee reviewed data on the amount of food customarily consumed per eating occasion and other information on serving sizes provided by FDA, e.g., serving sizes recommended in dietary guidance materials, serving sizes recommended in comments, serving sizes currently in use, and serving sizes used in Canada. On the basis of these considerations, the committee developed the product categories and the reference amounts listed in § 101.12(b). Interagency cooperation will continue during the development of the final regulation on serving sizes.

In addition, the IOM report recommended that research be conducted to determine consumers' comprehension of food labeling information and their interpretation of serving sizes declared on the food label. FDA has conducted both consumer focus groups and formal consumer research on the format of nutrition labeling, including consumer use and understanding of serving sizes. FDA will propose a label format regulation that reflects the results in the near future.

The IOM report made a few other recommendations that FDA is not proposing to adopt. The IOM report recommended that the quantities specified by dietary guidance recommendations serve as "the main criteria for selecting the amount of food to be described as a serving." FDA did not adopt this recommendation for several reasons:

1. Section 403(q)(1)(A)(i) of the act defines serving size as "an amount customarily *consumed*" (emphasis added). Thus, the act links serving size to the amount consumed and not to an amount recommended by the dietary guidance recommendations or any other system.

2. There is no single set of dietary guidance serving sizes, and, as seen in Table 7–1 of the IOM report (Ref. 1, pp. 206 and 207), the serving size for the same product may differ in accordance with the objectives and goals of the particular guidance.

3. Many serving sizes that do exist in dietary guidance recommendations are for very narrow food categories, e.g., for a specific type of cake, cookie, or cracker, or for a particular fruit or vegetable. Under the act, however, serving sizes have broad application.

4. There are no dietary guidance recommendations for many product categories, particularly processed packaged products for which nutrition labeling is mandatory (e.g., frozen entrees and dinners; snack foods; pickles; sweets; condiments; foods used as ingredients such as dessert toppings/fillings, sauces, and flour; and infant and toddler foods) (Ref. 2). However, in developing the reference amounts, FDA did consider serving sizes recommended in various dietary guidance materials (Refs. 3 through 8), including those identified in the IOM report.

The IOM report recommended establishing serving sizes for a limited number of broad food categories (e.g., fruit juices, breads, cereals, fruits, vegetables, spreads, and salad dressings). FDA does not believe that such broad categories are adequate to implement section 403(q)(1)(A)(i) of the act. This section defines serving size as an amount customarily consumed. The

amount customarily consumed varies widely among foods within the large categories recommended by the IOM. For example, the customarily consumed amount of fruit varies from 1.5 oz for dried fruits to 10 oz for watermelon. Therefore, to implement the act, FDA believes that many more than the limited number of the broad categories recommended by the IOM are necessary. In developing the references amounts, however, FDA took product comparability into consideration to promote nutritional comparison of similar products.

The IOM report also recommended that the number of servings per container be rounded down to the nearest whole number. FDA did not adopt this recommendation because it would introduce an unacceptably large error, as high as 45 percent (2.9 rounded down to 2), for the number of servings per container declared on the label. Instead, FDA is proposing to round to the nearest whole number which will limit the error to about 20 percent or less (2.4 rounded down to 2).

B. Summary of Comments

FDA has reviewed the written comments received on the serving size proposal, the written comments to the notice of public meeting on serving sizes, and the presentations at the public meeting.

FDA received about 370 comments on the serving size proposal. Approximately 39 percent were from domestic and foreign food industries and trade organizations; about 36 percent were from consumers and consumer organizations; about 17 percent were from health professionals, health and other professional organizations, and academia; and 8 percent were from domestic and foreign governments. Industry generally expressed reservations about some parts of the proposal and discussed technical issues, which were infrequently discussed by the other sectors (e.g., serving sizes for their specific products). Consumers, consumer organizations, and health professionals overwhelmingly expressed the need for FDA to regulate serving sizes and generally supported the provisions in the proposal. Comments from the international sources understandably focused on the international harmonization of food labeling (e.g., recommended the use of 100 g (or mL) as the basis for the nutrition information).

In response to the agency s request for comment on implications of the IOM report, only four from industry addressed issues related to serving sizes. Two comments favored serving sizes based on dietary guidance materials; one supported the use of serving sizes expressed in common household measures; and the other opposed FDA establishing serving sizes and proposed that the agency set criteria.

Thirty-one oral presentations were made at the April 4, 1991 public meeting on serving sizes, including 26 (about 85 percent) by representatives of food industries and trade organizations; three were by professional nutrition organizations; and two were by consumer organizations. A written transcript of the meeting is on file with Dockets Management Branch (address above). FDA also received about 80 written comments in response to the public meeting notice, primarily from the food industry and trade organizations but also from nutrition and consumer organizations, government agencies, and a few consumers. Industry comments generally were against FDA establishing specific serving sizes. These comments interpreted the 1990 amendments as requiring FDA to establish standards for serving sizes. Health professionals and consumers, on the other hand, continued to support FDA establishing specific serving sizes for product categories. Most comments also addressed the issue of the basis for determining serving sizes. Industry and health professionals favored considering additional information (e.g., "longstanding" industry serving sizes and dietary guidance recommendations) to food consumption data. Consumer organizations favored using only food consumption data. Comments from all sectors generally agreed that serving size should be expressed in common household units.

The agency will describe the comments on serving sizes in more detail and respond to them in the discussion of the reproposed regulation that follows.

IV. The Reproposed Regulation

A. Introduction

In the 1990 proposal, FDA proposed to retain the current requirement that nutrition information in the labeling of food be declared in relation to a serving or, where the food is customarily not consumed directly, in relation to a portion of the food. The 1990 amendments require that nutrition information be presented on a per serving basis. Therefore, § 101.9(b) of this reproposal codifies this requirement.

In the 1990 proposal, FDA identified five options for regulating serving sizes: (1) Permit manufacturers to establish their own serving sizes; (2) permit manufacturers to develop their own serving sizes by applying criteria established by FDA; (3) FDA adopt a single, uniform serving size (e.g., 100 g or 100 mL); (4) FDA develop standard serving sizes with a petition process to provide a mechanism to add or amend the established serving sizes; and (5) permit manufacturers to use dual declaration of nutrition information on the basis of both standard serving sizes developed by FDA and a uniform 100 g or 100 mL. FDA, choosing the fourth option, proposed to establish standard serving sizes with a petition process for adding to or amending them.

Of those commenting on the five options, a large majority agreed with FDA's approach. Virtually all comments from consumers, health professionals, and State government agencies stated that standard serving sizes are essential and generally supported FDA's proposal. Most food industry comments, however, supported the alternative options of maintaining the current system of allowing manufacturers to develop their own serving sizes or allowing manufacturers to develop their own serving sizes using criteria developed by FDA.

The 1990 amendments (section 2(b)(1)(B)) direct FDA to establish standards to define serving sizes. None of the regulatory options in the 1990 proposal except, the fourth option, the one chosen by FDA, fulfills this legal requirement. Therefore the alternative options are not valid under the 1990 amendments.

To implement this requirement of the 1990 amendments, in this reproposal FDA is proposing to establish regulations under which manufacturers will define the serving sizes that are most appropriate for their products by using the reference amounts and procedures for determining label serving sizes adopted by FDA. To comply with the act with respect to serving size, FDA developed the reference amounts to represent the amount customarily consumed of 131 different types of food, covering virtually everything in the food supply that is regulated by FDA. FDA believes that it is appropriate for it to develop these reference amounts that

provide the basis for serving sizes because the amount of food customarily consumed generally reflects the type of food involved and not who manufactured it. Thus, there is no reason why this amount should vary from manufacturer to manufacturer. Under this proposal, however, manufacturers will convert the reference amount into serving sizes in the common household units that are most appropriate and meaningful for their specific products using the conversion provisions of § 101.9(b)(2).

Several comments objected to FDA determining serving sizes. A trade association expressed concern that government-imposed serving sizes raise flexibility problems for the food industry without providing real benefit to consumers. The association stated that where foods in a category vary in richness and flavor, it is better to let the manufacturer select the serving size than to declare an artificially uniform serving size.

The agency does not agree that consumers will not benefit from a system that would ensure uniformity in serving sizes declared by different manufacturers. Consumers have repeatedly stated the need for uniform serving sizes, and that they perceive a benefit to themselves from FDA establishing standard serving sizes. According to consumers, uniform serving sizes will, among other things, allow them to make comparisons among similar products.

One company commented that the serving size upon which the nutrition information is based should be specific or "appropriate" to the product within the package and objected to establishing a uniform serving size for all products within a category.

FDA agrees that a serving size should be appropriate for the individual product. However, it does not agree that each individual product should have its own serving size. The agency believes that by grouping foods that have similar dietary usage into one category, as was done for the 1990 proposal, a reasonable and appropriate serving size for all foods within that category can be established. As stated above, a consistent serving size for similar products enables consumers to compare the nutritional value of foods that are used interchangeably in the diet.

Several food industry comments stated that FDA developed the 1990 proposal with no input from industry. One company suggested negotiated rulemaking on serving sizes to reach a consensus.

Given the conflicting views in the comments on the proposal, FDA decided that it would be helpful to receive further input before reproposing the serving size regulation. In part because of the time constraints imposed by the 1990 amendments, however, negotiated rulemaking was not a practical option. Instead, FDA decided to hold a public meeting on April 4, 1991, to provide an opportunity for all interested parties, including industry, to present their views and supporting data on various serving size issues. Although a general consensus was not achieved on the several issues that were discussed, this meeting provided the agency with valuable additional information that it used in formulating this reproposal. In addition, at the request of the food industry, FDA has met with many individual companies to discuss serving sizes (Refs. 9 through 16).

Moreover, the agency recognizes that, in certain circumstances, negotiated rulemaking may be a useful tool in developing new or amended reference amounts. Therefore, FDA is providing in proposed § 101.12(h)(14) that, as part of a petition to establish or amend a reference amount, the petitioner shall include information about the feasibility of negotiated rulemaking.

Some comments expressed the need for research on consumers' understanding and use of serving size.

FDA agrees that additional consumer research could be useful in developing the final regulation. The agency has conducted both consumer focus groups and formal consumer research on the format of the nutrition label, including consumer use and understanding of serving sizes. As mentioned earlier, FDA will propose a label format regulation that reflects these research results in the near future. The agency also solicits data on consumers understanding and use of serving sizes.

B. Definition of Serving Size

In § 101.9(b)(1) of the 1990 proposal, FDA proposed to define "serving" or "serving size" to mean the amount of food commonly consumed per eating occasion. Section 403(q)(1)(A)(i) of the act defines serving size as an amount of food "*customarily* consumed" (emphasis added). FDA interprets "an amount customarily consumed" to mean "an amount commonly consumed." Webster dictionaries define "customarily" as "usually," and, in turn, define "usual" as "common." The Webster's New Dictionary of Synonyms and Roget's International Thesaurus list "common" as a synonym for "customary." Thus, FDA's interpretation of "an amount customarily consumed" to mean "an amount commonly consumed" is consistent with the meaning of the word "customarily," as defined in standard authoritative dictionaries and thesauri.

However, to make the definition consistent with the one in the act, in § 101.9(b)(1), FDA is proposing to replace the term "commonly" in the 1990 proposed definition with the term "customarily" and to add a requirement for the expression of serving size in a common household measure. Thus, FDA has revised proposed § 101.9(b)(1) to state: "The term 'serving' or 'serving size' means an amount of food *customarily* consumed per eating occasion by persons 4 years of age or older *which is expressed in a common household measure that is appropriate to the food.*" When the article purports or is represented to be for infants or for toddlers, a "serving or serving size means an amount of food *customarily* consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age." (The underlined portion differs from the definition in the 1990 proposal.)

In § 101.9(b)(1) of the 1990 proposal, FDA proposed to define "portion" to mean "an amount of a food customarily used only as an ingredient in the preparation of other foods." This definition is consistent with the description in the act. Therefore, FDA is retaining the definition of "portion" in § 101.9(b)(1) of this reproposal but modifying it slightly to fit the language of the act. The modified definition reads "* * * The term 'portion' means an amount of a food that is not typically expressed in a serving size, i.e., a food customarily used only as an ingredient in the preparation of other foods (e.g., ¼ cup flour or ¼ cup tomato sauce)."

C. Definition of Single-Serving Container

In § 101.9(b)(2) of the 1990 proposal, FDA proposed to define a single-serving container as a container containing 150 percent or less of the standard serving size and to require that the entire content of the package be labeled as one serving. The agency proposed this definition on the basis of an informal survey that it conducted in the Washington, DC area and FDA's Food Labeling and Package Survey (Ref. 17). These surveys suggested that the 150 percent upper limit on single-serving containers would cover almost all packages whose contents are likely to be consumed at a single-eating occasion.

About two-thirds of the comments on the 1990 proposal supported FDA's definition. Several comments recommended a different cutoff level for single-serving containers however. Some comments stated that the upper

limit should be lowered, e.g., to 125 percent, while another comment suggested increasing the upper limit to 200 percent of the standard serving size. A few comments recommended a range such as 75 to 125 or 50 to 150 percent of the standard serving. The IOM report (Ref. 1) also recommended a range of 50 to 150 percent of the commonly consumed unit.

The agency has learned from its own observations in the marketplace and through comments and presentations at the public meeting on serving sizes, that single-serving packages and containers that are larger than 150 percent of the proposed standard serving sizes are not uncommon on the market and may be increasing in number. One company, for example, pointed out that single-serve buffet cans of canned fruits with pop-tops, which contain 200 percent of the proposed standard serving size, are relatively new on the market but are already extremely popular. Presenters at the public hearing also pointed to additional products intended for consumption at a single-eating occasion that exceed 150 percent of the proposed standard serving sizes, e.g., king-size candy bars. The agency is unable to predict the extent to which these types of larger single-serving products may become available but notes that an increasing number of foods are packaged for convenience to individuals in snacking and in eating away from home.

Because many single-serving packages exceed the proposed 150 percent level, the agency believes that it is not appropriate to lower the cutoff level for the definition of a single-serving container. Rather, in light of the evidence of the trend to larger packages, the agency believes that it is more appropriate to increase the upper limit to "less than 200 percent." This higher level, if adopted, will require that more small packages be labeled as a single-serving.

The agency is proposing to set the upper limit at "less than 200 percent" of the reference amount for two reasons. First, products that contain 200 percent of the reference amount are, by definition, 2 servings. Thus, they are not single servings. Second, there is a significant question as to whether these larger size products will usually be consumed at a single-eating occasion by one individual, considering that the customarily consumed amount is one-half or less than the package container. Thus, the agency believes that it would not be accurate to require that packages containing 200 percent or more, be labeled as single-serving containers.

Other concerns about the proposed upper limit of 150 percent of the standard serving size had to do with a possibility that some manufacturers might increase the size of their product to slightly more than this limit to be able to use a smaller standard serving size. This change would mean that the label information would be misleading to consumers who usually consume the entire amount in the container.

FDA is aware that such misrepresentations may occur in relation to any upper cutoff level that the agency may propose. The agency does not believe that there is a ready solution to this problem. The agency believes that the solution that it is proposing is the most fair, because a manufacturer who provides 200 percent or more of the reference amount is providing two servings of the food under the standards that FDA is proposing. That manufacturer is entitled to label its food accordingly.

Some food industries criticized the proposal to label the total content of a single-serving container as one serving because it would result in different nutritional values appearing on the labels of the same food product, depending upon the size of the container in which the product is packaged. The comments stated that consumers would be confused seeing nutrition information that differs on the same food.

In the notice of public meeting, the agency requested views and data on whether differences in the listing of the nutritional content of the same food would be confusing to consumers. No data on this issue were presented at the meeting or in written comments.

FDA continues to believe that nutrition information based on the entire content of the container for small containers that are usually consumed at a single-eating occasion is most meaningful to consumers because it reflects the nutrient content of the quantity of food that is customarily consumed in the circumstances. Moreover, a large number of consumers requested that FDA require that nutrition information on these products be provided for the entire contents of the container.

Some industry comments stated that it was unnecessary to define single-serving containers at all. One industry comment supported defining a single-serving container to be whatever a manufacturer chooses to call a single-serving. However, consumers repeatedly complained about multiple servings declared on some obviously single-serving products such as soft drinks. Therefore, FDA considers it essential to define single-serving containers.

One industry comment addressed the question of how to define single-serving containers using criteria not related to an amount consumed, e.g., whether the package is recloseable.

FDA does not believe such criteria would be practical or meaningful. With the introduction of the recloseable plastic bag and other type of closures, any container can be made recloseable regardless of the package size.

Comments suggested that FDA establish a lower cutoff level, or that it allow a smaller amount, such as 50 to 75 percent of the standard serving size to be labeled as a half serving. These comments were based on concerns about the possibility that serving sizes could be manipulated in a way that would result in the abuse of adjectival descriptors like "low sodium." Many consumers and health professionals who commented on single serving containers expressed concerns about such abuse.

In § 101.12(g), FDA is proposing that both the serving size declared on the label and the reference amount be used in determining whether a food meets the definition for an adjectival descriptor. Use of both the label serving size and the reference amount will prevent a single-serving container from qualifying for the descriptor based on package size alone. Also, elsewhere in this issue of the **Federal Register**, FDA is proposing regulations for adjectival descriptors that the agency believes will also prevent abuses in their use. Therefore, at this time, FDA does not consider it necessary to define a lower limit for single-serving containers. If a lower limit becomes necessary for reasons other than concern about adjectival descriptors, the agency will reconsider this issue.

Based on all of the information presented to the agency, FDA believes that: (1) Single-serving containers should be defined, (2) it is desirable to increase the upper limit, and (3) there is no basis to establish a lower limit at this time. Therefore, in § 101.9(b)(6) of this reproposal, FDA is proposing to require that manufacturers declare that there is a single-serving in a container or package that contains less than 200 percent of the reference amount proposed in § 101.12(b), and that they declare nutrition information based on the total content of the container.

A few industry comments stated that there should be no upper limit on single-serving containers.

The agency would not consider it appropriate to label a very large container, e.g., a half gallon of ice

cream, as a single-serving container. However, to provide flexibility, in § 101.9(b)(6) of this reproposal, the agency is proposing to allow the manufacturer to declare a single-serving on relatively small containers containing 200 percent or more of the reference amount if the entire content of the container can be expected, reasonably, to be consumed at a single-eating occasion. The determination for reasonableness should be based on food consumption data under actual conditions of use. Manufacturers should be prepared to provide the agency with the data that supports the single-serving claim upon request. The agency is aware that this allowance has a potential for misuse. The agency intends to consider regulatory action for misuse of this allowance.

FDA requests comments on the new upper limit for single-serving containers and on whether it is reasonable to allow the manufacturer to determine the single-serving status above that level.

D. Proposed Reference Amounts for Serving Sizes

1. Introduction

In § 101.12(b) of the 1990 proposal, FDA proposed standard serving sizes for 159 product categories that were primarily based on the amount commonly consumed by the relevant population (i.e., persons 4 or more years of age, infants, or toddlers) as reported in the 1977–1978 Nationwide Food Consumption Survey (NFCS) conducted by USDA. The proposed standard serving sizes were generally expressed in U.S. units.

The 1990 amendments require that FDA establish standards to define serving size (section 2(b)(1)(B) of the 1990 amendments). To implement this requirement, FDA is proposing to establish procedures under which manufacturers would derive the appropriate serving size from the reference amounts in § 101.12(b), instead of establishing specific serving sizes.

Before discussing the reference amounts and the other procedures for determining serving size, FDA wishes to respond to comments that it received on the methodology that should be used in determining serving sizes.

1. About two-thirds of the comments on the 1990 proposal, that addressed the methodology question agreed with FDA's approach of using food consumption data. The other comments suggested that other or additional sources be used, such as longstanding industry serving sizes, serving sizes currently in use, the serving sizes in dietary guidance or educational materials, diabetic food exchange lists, and USDA Handbook number 72, entitled "Nutritive Value of Foods."

Discussion at the public meeting focused largely on this issue. Two consumer organizations supported FDA's use of food consumption data as the basis for establishing serving sizes. One organization stated that the 1990 amendments require the use of only food consumption data in establishing serving sizes. However, most other presenters stated that, in addition to food consumption data, other information such as those listed above, should be used as supplementary sources for determining serving sizes for nutrition labeling purposes.

Section 403(q)(1)(A)(i) of the act has the effect of requiring the use of food consumption data as the primary basis for the serving size determination. FDA believes that without such data, it is impossible to determine the amount of food that is customarily consumed. However, FDA believes that other information related to serving size can be useful, particularly when food consumption data are inadequate. The agency used several additional sources of information in arriving at the reference amounts proposed in § 101.12(b). These additional sources, and when and how they were used, are described in sections IV.D.3.c. and IV.D.3.d. of this document.

With regard to longstanding industry serving sizes, in the February 26, 1991 notice for the public meeting, FDA requested comments and supporting data on the definition of "longstanding" serving size. One comment stated that longstanding serving size should include serving sizes used before 1973, as a minimum, and presented three examples of serving size used before that date.

Since it had no established definition or sufficient data to define longstanding serving sizes, the agency took into consideration all serving sizes suggested in comments regardless of their history of use and serving sizes currently on product labels in arriving at the reference amounts (Ref. 2).

FDA does not consider the diabetic exchange lists to be an appropriate source to use in determining serving size under the act for several reasons. Serving sizes contained in the diabetic exchange lists are tailored so that each food choice within an individual exchange list will provide similar amounts of calories, protein, carbohydrate, and fat (Ref. 5). Therefore, the driving force in determining the serving size for the exchange lists is calorie content and content of energy-producing macronutrients, not an amount of food customarily consumed as required by the act. Consequently, many different specific serving sizes are given for individual foods that belong to the same category. For example, several serving sizes are given for frozen desserts, ¼ cup for sherbet, ⅓ cup for frozen yogurt, and ½ cup for ice cream. Also, the serving size for some foods is very small, e.g., one-half English muffin, which does not represent an amount customarily consumed by the general population. In addition, FDA does not believe that serving sizes designed to meet a special dietary need of a subpopulation that has a unique health problem are appropriate to use as serving sizes for the nutrition labeling of products for the general population.

FDA does not consider the serving sizes in any USDA Handbooks, including number 72, to be an appropriate source given the definition of "serving size" in the act. Because these Handbooks are not intended to reflect "amount customarily consumed," the serving sizes in them are not based on food consumption data and are not necessarily representative of an amount customarily consumed. In addition, these handbooks list a limited number of the prepared and packaged foods (e.g., frozen entrees) that are subject to mandatory nutrition labeling.

2. Some industry comments contended that many currently used serving sizes have been used for many years and are familiar to consumers, and therefore that changing them could be confusing.

The act defines serving size as an amount customarily consumed. Thus, the primary basis for serving size must be consumption data, not current labeling practices. Furthermore, a professional nutrition association commented that its members have reported that consumers are generally unaware of the serving sizes that are used by industry. At the public meeting, a consumer organization presented similar data from its own informal survey. Based on this information, the agency does not believe that it would be confusing to consumers to make changes in currently used serving sizes.

3. Industry comments also stated that some of the serving sizes in current use were established cooperatively with FDA.

The agency acknowledges that, in the absence of a formal regulation and upon the request of different segments of the food industry, it has provided advisory opinions on serving size on a food-by-food basis. These advisory opinions have not gone through rulemaking procedures. FDA is now required by law to develop a serving size regulation for all food products based on an amount

that is customarily consumed. Therefore, the proposed reference amounts listed in § 101.12(b), and the label serving sizes derived under the procedures proposed in this document, will supersede all advisory opinions previously given to the industry.

4. Some industry comments objected to the use of only food consumption data in determining serving sizes on the basis that:

(1) Food consumption data have known inaccuracies;

(2) The amount per eating occasion does not reflect the multiple servings or "helpings" that may be consumed at a single-eating occasion;

(3) The data used for the proposal were more than a decade old and eating habits may have changed; and

(4) Food consumption data are not the recommended amounts in terms of diet and health. Some nonindustry comments also supported the use of more recent data such as data from 1987–1988 NFCS.

FDA acknowledges that the 1987–1988 NFCS data may have inaccuracies (e.g., underreporting of intakes) as food consumption surveys usually do. However, food consumption survey data, such as NFCS, provide objective estimates of amounts of food customarily consumed. The NFCS is nationally representative and represents the most comprehensive data on food consumption practices of the U.S. population that are available to the agency. In using the food consumption data, the agency sought to ensure that the amount reported was reasonable (see section IV.D.3.d. of this document). As for multiple helpings or servings, it is very likely that some people reported amounts that represented multiple helpings or servings because the total reported by such people represents the amount that they customarily consume at a single eating occasion.

Since the 1990 proposal was published, USDA has released the final data tape for the 1987–1988 NFCS. FDA analyzed this new survey data in developing the proposed reference amounts, as discussed in section IV.D.3.a. of this document.

The argument that serving sizes should be recommended amounts in terms of diet and health is not consistent with the requirement of the act. The act defines serving size as "an amount customarily consumed" and not an amount recommended to promote health.

5. Several comments on how to calculate customarily or commonly consumed amounts included suggestions for: (1) the use of the median instead of the mean because mean is more likely influenced by outlier values than the median, (2) the use of the mode (that is, the most frequently consumed amount), (3) inclusion of the sample size in the criteria, (4) consideration of the demographics of "key" consumers and avoidance of data skewed by nonprimary users, and (5) the use of the lowest common denominator in household measures for a product (e.g., 1 oz for cheese, one slice for bread).

In determining the standard serving sizes proposed on July 19, 1990, FDA used the amount consumed per eating occasion (hereinafter referred to as "consumed serving size (CSS)") by an individual as the basis for serving size. To estimate the amount commonly consumed by a population group, the agency used both the mean and the median CSS for the group, with the mean as the driving force and the median as a guide in rounding the value to a meaningful household measure. For example, if the mean was 2.3 oz and the median was 1.6 oz, the agency rounded the mean down to 2 oz rather than up to 2.5 oz. FDA believes that both the mean and the median CSS are valid values for determining the customarily consumed amount, and that the exclusion of one or the other is not desirable.

Regarding the suggestion for use of the mode, FDA performed additional data analysis for this reproposal to include the mode. The mode was not useful, however, as the sole criterion for determining the reference amount because most food groups had two or more modes, and there usually was no obvious or rational basis to choose one over the other. However, the mode did provide additional guidance in determining the reference amount. The agency also took the sample size into consideration in developing the reference amounts, as discussed in sections IV.D.3.d. of this document.

Concerning the suggestion to consider the demographics of "key" consumers and avoidance of data skewed by nonprimary users, the NFCS survey design took into consideration the demographics of all users, and "key" users usually determine the customarily consumed amounts (i.e., mean, median, and modal CSS values). The mean is influenced by outliers, but this influence is lessened as sample size increases. The consideration of sample size, and the median and modal CSS values, which are less influenced by the outliers or skewed data, further improved the determination of the reference amounts in this reproposal.

Finally, with respect to the suggested use of the lowest common denominator, in light of the requirement of the act that serving size be the amount customarily consumed, FDA does not believe that use of the lowest common denominator is legally allowable except when it represents the customarily consumed amount.

6. Another industry comment stated that a weighted average is not appropriate for determining serving size because there are too many varieties of a product/food item.

FDA is well aware of the large variety of food products in the marketplace. One reason why the agency could not establish serving sizes for a limited number of broad categories as recommended by the IOM report is the large variety of food products (see section III.A. of this document). Consequently, the agency performed extensive data analysis to ensure that only foods similar in dietary usage and consumption size were included in a proposed product category. FDA continues to believe that a reasonable reference amount can be established for all product categories by grouping foods that are similar in dietary usage and consumption size.

7. Several oral presentations at the public meeting and written comments that FDA received in response to the meeting notice stated that the amount "customarily consumed" is highly variable and is related to a number of factors such as the age and sex of the individual. Some industry comments stated that the amount of food customarily or typically consumed is also affected by such factors as how a food is packaged and positioned in the marketplace (e.g., as a snack or entree), and that the average consumed amount is difficult to define for many food products because of their many uses and varying consumption at different times of day.

FDA acknowledges that the high variability among individuals in the amounts that are customarily consumed may reduce the value of a reference quantity to any one individual who is not consuming servings of foods that are approximately the size of that reference quantity. Therefore, FDA is also proposing to permit manufacturers to present nutrient values based on a uniform unit (e.g., 100 g or 1 oz), in addition to the declaration of nutrients on the basis of a serving. Such presentations may, in some circumstances, facilitate comparisons of different kinds of the same food. Furthermore, such presentations may also facilitate comparisons of foods belonging to different food groups.

In addition to the variability among individuals, FDA recognizes that the diverse nature of food products also complicates the process for determining

reference amounts. However, national food consumption surveys, including USDA's NFCS, have many factors built into the survey design that make it possible to estimate food consumption patterns representative of the U.S. population. Sample persons in the survey are selected by statistical procedures that ensure representation of all ages, both sexes, and other demographic and socio-economic characteristics of the U.S. population. Dietary intake information is collected throughout the day so as to cover many different uses (e.g., as snacks vs. entrees) and varying consumption at different times of day (e.g., breakfast vs. dinner). Therefore, many concerns raised in the comments are addressed by the design of the NFCS survey.

The agency is willing to consider any data that may give a better estimate of an amount customarily consumed for a specific product category. Although FDA received some data in the comments, these data were unacceptable for various reasons. For example, the estimates were not representative of the food consumption practices of the relevant population group; the data were inappropriate because of flaws in the study design; or there was poor documentation of the methodology. In section K (Petition Process), the agency is proposing general guidelines on how to conduct a survey and to collect data to support a request for change in a proposed reference amount or to establish a reference amount for a subcategory of food or a product category not covered by this reproposal.

FDA is well aware of the fact that an amount of food customarily consumed is highly variable among people who differ by age, sex, body build, life style, and other attributes. The agency wishes to make it clear that it is not trying to estimate accurately serving sizes that apply to any particular individual. As pointed out in the 1990 proposal, neither the reference amount nor the serving size declared on the product label are to be interpreted as recommended amounts for consumption. Rather, given the particular product category, the reference amount, which may be modified somewhat as the serving size on the product label because of the size and shape of the product, represents the amount of that type of food that is customarily consumed by persons in a particular population group (e.g., by all persons 4 years of age or older).

8. One of the general principles that FDA followed in arriving at the standard serving sizes in the 1990 proposal was that a serving size should be based on only the edible portion of food, and not bone, seed, shell, or other inedible components. The National Fisheries Institute commented that serving sizes for fish cannot always be based on edible weight because bones cannot be separated from flesh.

FDA believes that the fish industry should be able to estimate the edible portion of the fish from its own data or other standard statistical data that provide percent refuse information, e.g., USDA Handbook No. 102 entitled "Food Yields Summarized by Different Stages of Preparation" (Ref. 18).

9. Some comments that agreed with the use of food consumption data expressed reservations about some specific aspects of the 1990 proposal. The Association of State and Territorial Officials stated that the basis for serving sizes should be the average amount consumed by an adult. A few health professionals commented that it was unrealistic to calculate average amounts from food consumption data that include all persons 4 years of age and older because of the large differences in the amount of food eaten.

FDA proposed two sets of standard serving sizes in the 1990 proposal, one for infant and toddler foods and one for the general food supply. Infant and toddler foods were presented separately because these foods differ from the general food supply in that they are specially processed for consumption by infants or by very young children. Children 4 years of age and older generally eat from the same food supply as the rest of the family.

FDA acknowledges that there are large differences in the amounts consumed among persons 4 years of age or older. Having several sets of serving sizes for different age subgroups of the general population category would likely produce serving sizes more realistic for each subgroup. However, several columns of nutrition information, one for each age subcategory, would be required on the labels of many products. These additional columns would be unreasonable and impractical. As pointed out earlier, neither the reference amount nor the serving size declared on the product label are amounts recommended for consumption. They represent reasonable quantities of foods for declaring nutritional values. Accordingly, FDA is proposing one set of reference amounts for all persons 4 or more years of age.

10. A baby food manufacturer commented that the amount customarily consumed is not appropriate for foods intended for infants and children because their intakes vary markedly, and mothers could interpret the serving size as a recommended amount.

FDA believes that this comment misunderstands the purpose of a serving size. The serving size declared on the product label is not an amount recommended for consumption. It is, by statute, the amount customarily consumed.

FDA believes that this type of misunderstanding can best be addressed through public education. The agency's promulgation of nutrition labeling regulations will be followed by a consumer education program to assist consumers in using the nutrition information on the label.

The company suggested using the jar (i.e., the entire content of the jar) as the serving size. The act requires serving size to be the amount customarily consumed and, therefore, jar size cannot be used as the basis for determining the reference amount which, in turn, determines the label serving size, unless the jar size agrees with the customarily consumed amount. The reference amounts for baby foods in § 101.12(b) are the amounts customarily consumed by infants, from which the manufacturers are to determine the label serving size for their products. Because most small jars currently in the marketplace meet the definition for single-serving containers, nutrition information for most baby foods would be provided on a per jar basis. However, an increasing number of multi-serving containers of baby foods are entering the market. The label serving size based on the reference amount enables nutritional comparison of these products.

11. One industry comment on the 1990 proposal stated that, because FDA selected foods having a high frequency of consumption to represent the category instead of using all foods appropriate for the category, the agency results were incorrect. The company further claimed that FDA's misclassification of the pourable salad dressings category led the agency to inappropriately set the serving size for pourable salad dressings at 2 tablespoons rather than 1 tablespoon. The company submitted results of its own analysis which supported 1 tablespoon.

FDA reexamined its original food selection scheme and repeated the data analysis using all foods relevant for the category. The results reaffirmed the appropriateness of the original food selection strategy and the accuracy of the results published in the 1990 proposal (Ref. 19).

12. A government agency commented that some product categories were not sufficiently descriptive, making it difficult to make proper categorization of products. A few industry comments stated that they had difficulty in identifying the product category in which their products belong and requested additional categories. Products cited in the comments were fish sticks and sandwiches.

Fish sticks are included in the category of "Fish, shellfish, and meat or poultry substitutes: entrees (cooked) without sauce" (renamed in this reproposal as "Fish, Shellfish, and Meat or Poultry Substitutes: Entrees without sauce"). In the 1990 proposal, sandwiches were included in the category of "Meal type trays: Lunch or dinner trays, Sandwich." For this reproposal, sandwiches are included in the category of "Mixed dishes: Not measurable with cup * * *."

To help manufacturers and others to identify the category in which their specific products fit, the agency has provided an extensive list of products for each product category (Ref. 20). FDA has also modified the names of some product categories to be more descriptive.

13. A few industry comments stated that there should be two serving sizes for some foods (e.g., rice), one for its use as a side dish and one for its use as an entree.

FDA rejects this suggestion for three reasons. First, one of the uses of the reference amount is to determine the appropriateness of nutrient content and health claims made for food products. Such a determination cannot be made on two or more different bases (i.e., standards), e.g., a smaller reference amount to evaluate a claim for a side dish and a larger reference amount to evaluate a similar claim on a similar product labeled as an entree.

Secondly, there is no assurance that a product labeled as a side dish will not be consumed as an entree, and vice versa. Thirdly, FDA does not believe that this suggestion is in the best interest of the consumers. Two reference amounts will interfere with the goal that there be uniformity among serving sizes declared on similar products by different manufacturers.

The agency would not object, however, to manufacturers providing a second column of nutrition information based on an alternative serving size as a side dish or as an entree. However, the agency wants to make it clear that it will use the reference amount to evaluate whether the product meets FDA standards for any claim made for the product.

14. A consumer organization pointed out that a manufacturer of liquid cream substitutes uses 1 tablespoon as the serving size for nutrition labeling but promotes the product for use with breakfast cereal. Because the amount of the cream substitute consumed with the breakfast cereal is much larger (e.g., 1/2 cup or 8 tablespoons) than when used as a coffee whitener, the nutrition information based on 1 tablespoon is misleading to consumers who use the product with breakfast cereals.

FDA agrees with the comment that nutrition information based on 1 tablespoon, which is the customarily consumed amount of this food, is misleading to consumers who use the product with breakfast cereals as suggested by the manufacturer. This type of promotion can happen to any product. To prevent such misleading labeling, in § 101.9(b)(11) of this reproposal, FDA is proposing that if a product is promoted on the label, labeling, or advertising for a use that differs in quantity by twofold or greater from the use upon which the reference amount in § 101.12(b) is based (e.g., liquid cream substitutes promoted for use with breakfast cereals), the manufacturer must provide a second column of nutrition information based on the amount customarily consumed in the promoted use, in addition to the nutrition information per serving derived from the reference amount in § 101.12(b).

15. An industry comment pointed out that portion size varies greatly for all foods used as ingredients.

FDA acknowledges that ingredient usage of a food varies widely depending on the recipe, and food consumption surveys do not usually provide information useful for determining portion size. When survey data were not available, FDA used various alternative approaches to estimate the portion sizes in the 1990 proposal such as the portion size for flour. FDA used similar methods in determining the reference amounts for portion sizes in this reproposal. The technical report on this reproposal (Ref. 2) documents the basis for each portion size proposed.

16. A manufacturer of "cooking sauce" e.g., soy sauce, teriyaki sauce) suggested using the average amount used in recipes to determine a portion size of cooking sauce.

Some "cooking sauces" (e.g., soy sauce) are used both in the form as purchased and as an ingredient of other foods. As discussed above, ingredient usage varies widely depending on the recipe and there is no easy way to determine the customarily consumed amount of these sauces using recipes. NFCS does provide some estimates of the consumed serving size of these sauces in the form purchased. Therefore, the NFCS data are the best information available, and FDA used them to determine the reference amount for the "cooking sauces."

2. General Principles Considered in Developing Reference Amounts

The act defines serving size as the amount customarily consumed which is expressed in a common household measure that is appropriate to the food. Although the amount customarily consumed is similar in weight or volume, in many instances, the customarily consumed amounts in household measures differ for different products within the same category because they come in different shapes and sizes. For example, food consumption data show that the amount customarily consumed for vegetables without sauce is about 85 g. A common household measure for this amount of green peas and cut corn would be about 1/2 cup, whereas many other vegetables come in the form that cannot be measured with a cup, e.g., brussels sprouts and broccoli spears. A common household measure appropriate for the latter vegetables would be pieces or oz. Because there is no uniform household measure that can be used for vegetables, the most reasonable approach for this type of food is to establish the reference amount in g and to let the manufacturers determine the label serving size in a common household measure that is most appropriate to their specific products.

FDA, therefore, decided to propose reference amounts that represent the amount customarily consumed of the products within the category, which manufacturers can use as the guide to determine the label serving size in common household measures that are most appropriate for their specific products. To determine the reference amount of food, FDA used the general principles and procedures described in this and following sections. The general principles, which are reflected in proposed § 101.12(a), are:

a. The reference amount represents the amount of food that is customarily consumed per eating occasion by the relevant (target) population group as determined by data from an appropriate national food consumption survey. This principle links the reference amount, and thus the label serving size, to food consumption data as required by the act.

b. An appropriate food consumption survey is one that includes a large sample size representative of the demographic and socio-economic characteristics of the target population

group for which the food is intended and that is based on consumption data under actual conditions of use. Use of such a survey will ensure that the customarily consumed amount determined is a reliable estimate that is representative of all sectors of the U.S. population that consume the food and that reflects the amount that they actually consume.

c. Three target population groups, infants, toddlers, and the general population are relevant for estimating customarily consumed amounts of food. In another technical supporting proposal published in the **Federal Register** of July 19, 1990, entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (55 FR 29476), FDA identified five age groups for nutrition labeling purposes. The five groups are infants, toddlers, pregnant, lactating, and the general population group. The agency is not aware of any foods in the food supply which are specially processed for use by pregnant or lactating women. Therefore, customarily consumed amounts will be estimated only for three age groups: foods intended for the general population, i.e., persons 4 years of age or older; foods specifically formulated or processed for use by infants up to 12 months of age; and foods specially formulated or processed for use by toddlers 1 through 3 years of age.

d. To determine the reference amount, all three statistical estimates that represent an amount customarily consumed, the mean (i.e., average), the median (i.e., 50th percentile value), and the mode (i.e., most frequently consumed amount) of the consumed amount per eating occasion should be considered.

e. In addition to food consumption data, other relevant information on serving sizes of food, such as that listed below in section IV.D.3.c. of this document, should be taken into consideration, particularly when survey data are insufficient to give a reliable estimate of the amount customarily consumed.

f. The reference amount and, in turn, the serving size declared on the product label must be based on the edible portion of the food because the inedible parts, such as bone, seed, shell, or rind, are not consumed and thus do not contribute to the nutritional value of the food.

g. Many foods are consumed both as a serving (i.e., in the form as purchased) and as a portion (i.e., as an ingredient of other foods). For example, butter and margarine are consumed in the form as purchased and as ingredients of foods such as cookies and cakes. Because the amount of such foods used as an ingredient (i.e., portion size) varies from recipe to recipe, and there usually is no easy way to determine the amount customarily consumed using recipes, the most reasonable approach for estimating the reference amount for these foods is to base it on the amount customarily consumed in the form purchased.

h. The reference amount must reflect the major dietary use of the food when this information is available because the major usage determines the customarily consumed amount. For example, milk may be used as a beverage or as a liquid to add to coffee or cereal. Because the major usage of milk is as a beverage, the reference amount for milk must reflect the amount consumed as a beverage.

i. The reference amount must be uniform for foods that are similar in dietary usage, product characteristics, and customarily consumed amount. For example, chips and other similar snacks (e.g., pretzels and extruded snacks) must have the same reference amount because these foods are consumed in similar manner, are used interchangeably in the diet, and have similar customarily consumed amounts. Uniformity in reference amounts for similar products will enable consumers to make nutritional comparisons of these products.

3. Determination of Reference Amounts for Serving Sizes

This section describes the detailed procedures that FDA used to apply the general principles described above in determining the reference amounts.

a. *Selection of food consumption data base.* FDA needed a food consumption data base that contained individual food intake data representative of the food consumption practices of the three age groups of interest. In determining "standard serving sizes" for the 1990 proposal, FDA chose, from the several national food consumption survey data bases then available, USDA's 1977–1978 NFCS (Refs. 21 through 24). FDA did so because this data base contained: (1) The largest number of persons, 30,777; (2) data on 3-day dietary intakes; and (3) data for all ages. Data from more recent nationwide food consumption surveys (e.g., the NFCS conducted by USDA in 1987–1988 and the third National Health and Nutrition Examination Survey (NHANES III) conducted by the Department of Health and Human Services) were not available. Since the 1990 proposal was published, USDA released the final data tape for the 1987–1988 NFCS (Ref. 25). Dietary intake data from NHANES III are not yet available.

FDA used the 1987–1988 NFCS as a source of food consumption data representative of more recent food consumption practices of the three age groups identified for nutrition labeling purposes. This new survey, however, had an unusually low response rate (Refs. 26 and 27). If the 1987–1988 NFCS had a higher response rate, the new survey data would have been preferable to the 1977–1978 NFCS data for determining the reference amounts of food because of its recency. However, the low response rate limited the use of the new NFCS data base because there is no way to know if respondents and nonrespondents behave in the same way. If the consumption behavior of nonrespondents is different than that of respondents, the results of the 1987–1988 NFCS are not representative of the amount customarily consumed of all users in the relevant population group.

Therefore, FDA used both the 1977–1978 and 1987–1988 survey data in developing the reference amounts. When the results from the 1987–1988 NFCS suggested a change in food consumption practices since the 1977–1978 NFCS (e.g., consumption increased or decreased substantially), FDA used other recent USDA data that did not have a response rate problem, namely, the 1985 and 1986 Continuing Surveys of Food Intakes by Individuals (CSFII's) (Refs. 28 and 29) to confirm the trend change. As discussed in the technical report prepared in support of the 1990 proposal (Ref. 17), the CSFII could not be used as the data base for determining customarily consumed amounts of food because it included neither the infant population nor the whole population of persons 4 years of age or older. However, it is an appropriate data base for the limited purpose that FDA used it. If the validity of the trend was supported by the CSFII data, FDA used the 1987–1988 NFCS data. Such a validity check to confirm the trend change observed in the 1987–1988 NFCS was recommended by an expert ad hoc committee that evaluated impact of nonresponse in the 1987–1988 NFCS (Ref. 26).

b. *Determination of the product categories.* This section provides a detailed description of how FDA applied the general principles outlined above to develop the 131 product categories.

i. *Step 1.* FDA started out with the 9 major food groups used by the USDA for the NFCS (Ref. 2). The 9 groups are milk and milk products; meat, poultry, fish, and mixtures containing these products; eggs, mixtures with eggs, and egg substitutes; dry legumes, nuts, and seeds; grain products; fruits; vegetables;

fats, oils, and salad dressings; and sugars, sweets, and beverages.

FDA further divided the foods within each of these major food groups into smaller groups by product class. For example, it divided milk and milk products into such groups as milks, cheeses, and ice creams. The agency then further divided foods within each of these product classes into subgroups according to dietary usage and other characteristics that were likely to affect the levels of consumption of foods within the product class. For example, FDA divided cream and cream substitutes into two subgroups, fluid forms and powdered forms; and pickles into 5 subgroups: dill pickles, sour pickles, sweet pickles, relishes, and olives. The agency grouped the foods in this way to assure that only those foods that were likely to have similar levels of consumption were included in the final food group used to determine the amount customarily consumed. The resultant food groups represented the preliminary product categories.

USDA's major food grouping system classified foods by the major ingredients of the food. Thus, under this system some foods that belong to the same product category, like soups, are not listed together but rather are separated into several major food groups depending on the major ingredients. For example, meat, poultry, or seafood-based soups are included in the meat, poultry, and fish group. Split pea soup is included in the dry legumes, nuts, and seeds group; grain-based soups are included in the grain products group; and vegetable soups are included in the vegetable group. In identifying preliminary product categories, FDA grouped all soups into one category.

ii. *Step 2.* FDA further refined the preliminary product categories by selecting foods available in the marketplace to represent the category. This selection was necessary because the NFCS lists foods on an as consumed basis, and thus, many foods that are not available in the marketplace are on the list. For example, breads are listed both in toasted and untoasted forms. FDA did not use toasted breads for the CSS analysis because this form is not available in the marketplace. In addition, when incomplete information was obtained from survey respondents, foods in the NFCS data base were often described as "not further specified (NFS) as to * * *." When these NFS foods were likely to contain foods that may differ in consumed serving size, FDA excluded them from the CSS analysis. For example, "salad dressing, not further specified" (food code 831-0010) was not used to estimate the CSS value for pourable dressings (e.g., French dressing, Italian dressing) or for nonpourable dressings (e.g., mayonnaise) because this food code is likely to contain both pourable and nonpourable dressings which may differ in consumed serving size.

iii. *Step 3.* FDA determined the mean, median, and modal CSS per eating occasion for each preliminary product category (see Ref. 2 for more detailed description and data).

iv. *Step 4.* The survey data expressed the amount of food consumed in g. Therefore, FDA converted the g weight of the mean, median, and modal CSS values determined in step 3 to measures that are more meaningful for nutrition labeling purposes, i.e., to household measures such as oz, fl oz, cups, tablespoons, and teaspoons. The agency used the gram-to-household measure, described in USDA's manuals showing the relationship for the common measure and g weight (Refs. 30 and 31), to convert g weights to household measures. This conversion of the g weight to household measures was done to ensure that foods similar in CSS values in household measures are grouped together and that the reference amounts derived from the survey data are meaningful in household measures, which are the label serving size units required by the act. For example, the median CSS value for mixed dishes without sauce appears to be much lower than that for mixed dishes with sauce in g weight (157 g vs. 249 g), giving a false impression that the two products have different CSS values. However, when converted to a cup measure, which is the common household measure for these products, the CSS values for the two products are more uniform (0.9 vs. 1.1 cup). This similarity reflects the fact that while the g weight of 1 cup of mixed dishes without sauce is much lower (about 150 to 200 g) than the g weight of 1 cup of mixed dishes with sauce (about 220 to 250 g), they are consumed in similar amounts in terms of volume. Therefore, expressing CSS values in household measures showed clearly that the same reference amount applies to both mixed dishes with and without sauce.

In converting the g weight to the household measure for the purpose of developing reference amounts, the agency used the following general criteria in determining whether weight or volumetric measures should be used: It used volumetric measures: (1) for beverages (in fl oz) and (2) if all foods in the food group are usually measured on a volume basis by consumers, e.g., honey, syrups, preserves, and salad dressings. It used weight measures: (1) if foods in the food group are usually not measured on a volume basis or are in distinct units, e.g., fish, muffins and pizzas; or (2) if some foods in the group are often measured by weight, but others are measured by volume (e.g., for fruits and vegetables, small berries and green peas may be measured by volume (cup), but many whole fruits and vegetables (e.g., broccoli spears) cannot).

v. *Step 5.* FDA collapsed the product categories further to combine product categories that had similar dietary usage or CSS values in household measures to reduce the number of product categories. For example, mayonnaise, sandwich spread, and mayonnaise-type dressings, in the fats and oils category, had similar CSS values, and thus FDA combined them into one product category.

vi. *Step 6.* Because food consumption surveys report amounts of foods as consumed, many foods that are primarily used as ingredients (e.g., flour, pie crust) were not on the NFCS food list. FDA added categories for these and a few other products that were not reported in the NFCS but that were identified through comments and informal checking of the products available in the Washington, DC metropolitan area to the preliminary category list. The resulting list of product categories represented the final product categories.

c. *"Other information" related to serving size.* To respond to recommendations in the IOM report and to comments requesting the use of other relevant information in addition to food consumption data and to promote international harmonization, in addition to the food consumption data, FDA used the following information in developing the proposed reference amounts in § 101.12(b).

i. Serving sizes recommended by dietary guidance recommendations and other authoritative systems or organizations (Refs. 3 through 8).

ii. Serving sizes recommended in comments on the 1990 proposal and in response to the notice of public meeting.

iii. Serving sizes currently used by manufacturers (e.g., product labels) and grocers (e.g., major supermarket chains).

iv. Serving sizes used by other countries (e.g., Canada).

d. *Procedure for determining reference amounts.* To determine the reference amounts that are proposed, FDA examined both the survey data (CSS values) obtained by the procedures described in section IV.D.3.b. of this

document and the other information listed above. Using the general guidelines described below, the agency determined the proposed reference amount for each product category. The CSS values and the detailed description of how the proposed reference amount was determined for each product category are contained in FDA's technical report (Ref. 2).

i. Because the act requires that food consumption data be used as the primary data source for the serving size determination, in determining the reference amounts for specific product categories, FDA first considered food consumption data and whether it provided an appropriate basis from which to derive reference amounts. In deciding whether the data provided an appropriate basis, FDA considered the adequacy of the sample size and the consistency of the data.

ii. FDA believes that a sample size (number of eating occasions) of 140 or larger is large enough to provide reasonable assurance for a reliable estimate for the customarily consumed amount. This sample size is the same as the minimum sample size used by USDA to present the 5th and the 95th percentile values for the NFCS data (Ref. 32). Although FDA did not use the 5th and the 95th percentile values in developing the reference amounts, it did use the mode. Many product categories had multiple modes, which, to be reliable, must be based on a larger sample size than that which would be necessary to ensure the reliability of the mean or the median values. Therefore, to ensure that the modal values were reliable, FDA used 140 as the cutoff for the adequate sample size, which is the largest minimum sample size required for presenting the NFCS data (Ref. 32).

FDA believes that a sample size of 40 through 139 (intermediate range) may not be large enough to provide reasonable assurance of a reliable estimate of the customarily consumed amount considering the multiple modes observed for many product categories. The lower cutoff level for the intermediate range (40) is the same as the minimum sample size used by USDA to present the 25th and the 75th percentile values for the NFCS data (Ref. 32).

FDA believes that a sample size of less than 40 is inadequate to provide reasonable assurance of a reliable estimate of the customarily consumed amount.

iii. *Steps followed in selecting survey data.* As mentioned earlier, FDA used both the 1977–1978 NFCS and the 1987–1988 NFCS as the source of food consumption data because the 1987–1988 NFCS could not be used alone given the low response rate problem in this survey. The agency used the following guidelines in selecting the survey data for determining the reference amount for each product category:

(A) If the 1987–1988 NFCS data did not substantially differ from the 1977–1978 NFCS data, and the sample sizes for both surveys were equally adequate, data from both surveys were used. The use of data from both surveys increased the data points, i.e., provided two sets of the mean, median, and modal CSS values, rather than one set from a single survey. Therefore, the reliability of the reference amount determined was strengthened.

(B) If the 1987–1988 NFCS data suggested a change in consumption practices since the 1977–1978 NFCS (i.e., CSS values increased or decreased), and the validity of the change was supported by the CSFII data, the new survey data were used because the trend change observed in the 1987–1988 NFCS is likely to be a real change in consumption practices. For example, CSS values from the 1987–1988 NFCS for the popsicles and snow cones category showed a slight but consistent increase in the consumption of these foods. This trend increase was supported by the 1985 and 1986 CSFII's (Ref. 2). Therefore, FDA used the 1987–1988 NFCS data to determine the reference amount for this category.

(C) If the new survey data suggested a change in consumption practices, but the change was not or could not be supported by the CSFII data, the agency made its best judgment based on the available evidence, and it documented the basis for its judgment (Ref. 2). For example, both the median and modal CSS values from the 1977–1978 NFCS (N=98) suggested 2 tablespoons to be a reasonable reference amount for the condensed milk category. The data from the 1987–1988 NFCS suggested a much smaller reference amount, about ½ tablespoon. However, the sample size for the new survey was grossly inadequate (N=11), and thus, this smaller value could not be used. The CSFII had only one observation, and therefore, could not provide any information to support or deny the smaller CSS values observed in the 1987–1988 NFCS. There was no consistency in the serving size recommended in comments, serving size currently in use by the manufacturers and grocers, and the Canadian serving size. The applicable serving sizes from these sources ranged from ¼ cup to ½ cup. Although the sample size fell in the intermediate range, the 1977–1978 NFCS consistently suggested 2 tablespoons to be a reasonable reference amount for the category. Condensed milk is usually used as an ingredient of other foods. Two recipies on the product label showed 2 to 2.5 tablespoons of condensed milk is needed to make 1 serving (Ref. 2). FDA, therefore, chose 2 tablespoons as the reference amount.

(D) If appropriate data were not available in the 1977–1978 NFCS, FDA used the 1987–1988 NFCS data.

iv. If the sample sizes were adequate and CSS values were consistent (i.e., any two of the three types of CSS values (i.e., mean, median, and mode) agreed), the consistent CSS values were used. For example, if the median and mode were 2 oz and the mean was 3 oz, and sample sizes were adequate (i.e., 140 or larger), FDA chose 2 oz as the reference amount for the category. If the sample sizes were adequate, but CSS values did not agree, all three types of CSS values were considered in deciding the proposed amount. For example, if the mean, median, and mode were 2.5 oz, 2 oz, and 1.5 oz, respectively, and the sample sizes were adequate (i.e., 140 or larger), FDA took all 3 values together and chose 2 oz as the reference amount for the category.

v. If the sample sizes were in the intermediate range (i.e., 40 through 139), but CSS values were consistent, the consistent values were used. However, if the survey data were inconsistent, FDA used its best judgment in determining the reference amount and documented the basis for its judgment (Ref. 2). For example, the sample size for the food group that represented the product category "Cake, very light weight, less than 4 g per cubic inch" fell in the intermediate range, but mean, median, and modal CSS values consistently suggested a reference amount of 2 oz. Therefore, FDA chose 2 oz as the reference amount for the category. The sample size for the food group "sundae" fell in the intermediate range and the CSS values ranged from about 1 cup to 1¼ cup. FDA believes that 1 cup is more convenient household measure than 1¼ cup and therefore, is proposing 1 cup as the reference amount for the category.

vi. If the sample sizes were inadequate (i.e., less than 40), FDA used the survey data cautiously. Other relevant information such as those listed in section IV.D.3.c. of this document, was given more weight. FDA documented the basis for its selection of the reference amount on a case-by-case basis (Ref. 2). For example, the food group powdered butter replacement had an inadequate sample size (N=10). The only other relevant information

available was the serving size currently in use by manufacturers, which ranged from ½ teaspoon to 1 teaspoon. Although the sample size fell in the inadequate range, the median and modal CSS values consistently suggested 1 teaspoon to be a reasonable reference amount which is within the range of the serving size currently in use by the manufacturers. FDA, therefore, chose 1 teaspoon as the reference amount for the category.

vii. If multiple food groups represented a product category and CSS values varied among food groups, the food groups having the largest sample sizes were used as the driving force in determining the reference amount for the product category. For example, the product category "cookies, sweet crackers, or sandwich type crackers" includes three food groups: cookies, sweet crackers, and sandwich type crackers. CSS values for these three groups ranged from 0.5 oz to about 2 oz. However, the cookie group had the largest sample size which was about 10 to 50 times as large as the sample sizes for the other two food groups. The CSS values for the cookie group consistently suggested 1 oz. as the reference amount for the category. Therefore, using the cookie group as the driving force, FDA determined the reference amount for the category to be 1 oz.

viii. FDA tried to select a reference amount that approximates a household measure, e.g., the weight of whole units for products in discrete units; ¼ cup increments for products measurable in cups; in whole tablespoons for quantities less than ¼ cup but greater than or equal to 1 tablespoon; in whole teaspoons for quantities less than 1 tablespoon but greater than or equal to 1 teaspoon. These efforts were made to establish reference amounts that are meaningful when expressed in common household measures on the product label.

ix. When survey data were insufficient or not available, FDA followed the following general principles and documented the specific actions that it took (Ref. 2):

(A) If there was no compelling reason to change the standard serving size proposed on July 19, 1990, that is, if no objections had been raised on the proposed serving size, or comments generally supported the proposed serving size, the proposed serving size is being reproposed as the reference amount.

(B) FDA considered any available relevant information. For example, no appropriate information was available to determine the reference amount for cooking wine. A major chain grocer used 1 oz. (which is about equal to 1 fl. oz.) as the serving size for cooking wine in its information booklet. Based on this information, 1 fl. oz. appears to be a reasonable amount for this food for nutrition labeling purposes, and therefore, FDA chose 1 fl. oz. as the reference amount for the cooking wine category.

(C) If there were no consumption data, no other relevant information, and no appropriate alternative, FDA is proposing the reference amount that it believes is the most reasonable for nutrition labeling purposes and has documented the basis for such belief (Ref. 2). For example, there was no information from food consumption surveys or from any other relevant sources, such as those listed in section IV.D.3.c., that could be used in determining the reference amount for the product category, "Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations." Customarily consumed amounts for these products are likely to vary considerably depending on how they are used by consumers. FDA believes that 1 teaspoon of these products is sufficient to decorate one reference amount of cookies (i.e., 3 medium-size cookies). Therefore, the agency is proposing 1 teaspoon or 4 g (g equivalent to 1 teaspoon sugar) if the decoration cannot be measured by teaspoon as the reference amount for the category.

x. Several other factors were also taken into consideration in arriving at the reference amounts proposed in § 101.12(b). These factors when used were documented for case-by-case (Ref. 2).

(A) Proposed reference amounts for related products (e.g., consideration of proposed reference amounts for other fruit categories in determining the reference amount for a fruit category).

(B) Whether the amount is comparable to the reference amounts for products that are used interchangeably and are similar in product characteristics (e.g., potato salad and pasta salad).

(C) For products containing two or more foods, whether the amount approximates the sum of the proposed reference amounts of the component foods. For example, the proposed reference amount for a pie should approximate the sum of the reference amount for pie crust and the pie filling.

e. *Expressing the Reference Amounts.* FDA followed the following principles in expressing the proposed reference amounts that were developed using the general principles and procedures described above.

i. Reference amounts are expressed in metric units (g, mL).

ii. Reference amounts for fluids are expressed in mL. Reference amounts for other foods are expressed in g as much as possible. However, when foods within a product category vary considerably in density, and the CSS values for different products are more uniform when expressed in volume than in grams, reference amounts are expressed in household volumetric measures such as cups, tablespoons, and teaspoons instead of g. For example, the median CSS values for three subcategories of ready-to-eat breakfast cereals weighing less than 3 oz. per cup ranged from 25 g to 56 g, but the CSS values in terms of cups were 1 cup for all three categories (Ref. 2). Therefore, the agency is listing the reference amount for breakfast cereals weighing less than 3 oz. per cup in terms of volume, i.e., 1 cup.

iii. When FDA found that the reference amount was best expressed in mL, it followed the following principles:

(A) For volumes of greater than 30 mL, the volume is expressed as a multiple of 30 mL. FDA has done so to assure that when the reference amounts are converted to the label serving sizes in common household measures, they will be in ¼ cup increments as required in § 101.9(b)(5) and in a whole number of fl. oz., if manufacturers voluntarily provide the equivalent fl oz. measure.

(B) For volumes of less than 30 mL, the volume is expressed in mL equivalent to a whole number of teaspoons or one tablespoon. For example, FDA found 1 teaspoon as a reasonable reference amount for lime and lemon juice and therefore, the reference amount is expressed as 5 mL, the mL equivalent to 1 teaspoon.

iv. In expressing reference amounts in g, FDA used the following principles:

(A) For quantities of greater than 10 g, weights are expressed in the nearest 5 g increment to avoid the appearance of an overly exact g weight. For example, FDA expressed reference amounts that it determined to be 2 and 3.5 oz. as 55 g and 100 g, respectively, instead of 56 g and 98 g. FDA believes that the use of an exact g weight is not desirable because it implies an accuracy that the food consumption data and other relevant information sources used to develop the reference amount do not really provide.

(B) For quantities of less than 10 g, exact g weights are used because rounding to the nearest 5 g increment would introduce too much error to the customarily consumed amount.

4. Presentation of Reference Amounts

The reference amounts developed through use of the general principles and procedures described above are proposed in § 101.12(b). Paragraph (b) contains two tables. Table 1 lists proposed reference amounts for foods represented or intended for use by infants and toddlers, and Table 2 lists proposed reference amounts for foods intended for use by persons 4 years of age and older. For both tables, the agency based the calculations on the appropriate CSS values reported for the particular group. Because there are only a few products on the market specifically intended for toddlers, the agency grouped these foods with baby foods. However, in analysis of consumption of toddler foods, the agency used the amounts customarily consumed by children 1 through 3 years.

Unless the reference amount is specifically stated for the unprepared form (e.g., dry form) of the product, the reference amounts proposed in Tables 1 and 2 represent the amount of the ready-to-serve, or almost ready-to-serve (i.e., "heat and serve," "brown and serve"), form of the product. Heat and serve products include products which are fully cooked and require only heating before consumption, e.g., a fully cooked frozen entree. For a few categories of dry products, such as dry pastas, dry rice products, and dry regular coffee and tea, that have relatively uniform composition, the reference amount is proposed for both dry and prepared forms of the food. The proposed reference amount for the dry form is based on the amount needed to prepare the reference amount for the prepared form (Ref. 2). To convert the amount as consumed to the amount in dry form, FDA used the percent yield reported in "Food Yield Summarized by Different Stages of Preparation" published by USDA (Ref. 18) and other pertinent information (e.g., manufacturer's directions). However, in general, dry mixes and concentrated products such as cake mixes, dry beverage mixes, and frozen concentrated fruit juices are not listed.

Other unprepared forms of products (e.g., fresh pastas, fresh or frozen doughs, and batters), imitation or substitute food, altered food (e.g., "low sodium"), foods for special dietary use, and most products containing two or more foods having individual reference amounts, are also not listed in § 101.12(b). The next three sections of this preamble discuss reference amounts for these types of products.

In determining the reference amounts for two product categories, FDA deviated from the principles and rules described above.

1. The carbonated beverage category, primarily represented by soft drinks, had a large sample size, and the mean, median, and modal CSS values were consistently 12 fl oz, reflecting the preponderance of soft drink consumption in 12 fl oz containers. However, the modal analysis showed two additional smaller peaks at both 8 and 16 fl oz. FDA is proposing 8 fl oz (240 mL) as the reference amount for the carbonated beverage category based on the following reasons:

FDA is proposing 8 fl oz as the reference amounts for all other beverages including fruit and vegetable juices based on their CSS values and the principles and procedures described in sections IV.D.2. and IV.D.3. of this document. Although food consumption data consistently supported 12 fl oz as the reference amount for the carbonated beverage category, the 12 fl oz value may have been unduly influenced by the wide use of 12 fl oz single-serving containers as indicated by the sales data. Industry data showed that 12 fl oz was the largest single-serving container size sold and represented about 32 percent (45 percent in terms of dollar volume) of the total quantity of all soft drinks sold in the U.S. during the same time period as when the 1987–1988 NFCS was conducted (Ref. 33).

Consumer complaints related to soft drinks focused on the 6 fl oz serving size currently used on these products that results in multiple serving declarations on 12 fl oz cans which are obviously consumed as a single-serving. This concern is addressed by proposed § 101.9(b)(6) which requires that a container containing less than 200 percent of the reference amount be declared as one serving. In addition, several comments, including the IOM report, suggested a uniform serving size for all beverages.

Considering the reference amounts of 8 fl oz for all other beverages, consumer concerns, and several recommendations for a uniform serving size for all beverages, FDA believes that a uniform 8 fl oz reference amount for all beverages would be more reasonable for nutrition labeling purposes. Such a reference amount would help consumers make nutritional comparisons across all beverage categories. Therefore, the agency is proposing 8 fl oz (240 mL) as the reference amount for carbonated beverages.

2. The other reference amount that deviated from the general principles and procedures described in sections IV.D.2. and IV.D.3. of this document is the category of "butter, margarine, oil, and shortening." Of the products included in this category, butter and margarine had the largest sample sizes, but the mean, median, and modal CSS values for these products did not agree. When all three types of CSS values (excluding whipped type) were considered together, 2 teaspoons could be proposed as the reference amount for this category. Two teaspoons would also be consistent with the Canadian serving size which is 1 to 2 teaspoons. However, although sample sizes were much smaller, data on whipped butter, oils, and shortening consistently supported 1 tablespoon as a more reasonable reference amount. Although butter and margarine are also used as spread, all four types of fats and oils are used interchangeably in food preparation. Therefore, a uniform serving size for all four types of fats and oils would be reasonable and would allow nutritional comparisons of different types of fats and oils.

Most products in this category bearing nutrition labeling have been using 1 tablespoon as the serving size. Accordingly, regulatory decisions to date have been based on a 1 tablespoon serving size (Refs. 34 and 35). Serving size suggestions in comments were split between 1 teaspoon by the butter industry and 1 tablespoon by a trade association representing the shortening, edible oil, and margarine industries. Considering the regulatory history, industry practices, and the recommendation by the fats and oils industry, the agency is proposing 1 tablespoon as the reference amount for the category.

FDA solicits comments on the proposed reference amounts, including the two discussed above, and on any product or product categories that should be added to the reference amount list in § 101.12(b). Comments recommending additions to the list should submit information listed in § 101.12(h) to assist the agency to determine the appropriate reference amounts.

5. Reference Amounts for Products Requiring Further Preparation

Products that require further preparation include dry mixes, concentrates, and fresh or frozen pastas, doughs, and batters. Dry mixes and concentrates vary greatly in their ingredients and degree of concentration. An increasing number of other unprepared forms of products, such as fresh or frozen pastas, doughs, and batters, are being introduced into the retail market. Percent yields of these products may vary among products

within the product category, and appropriate yield information is not available. It is, thus, not possible or practical to determine reference amounts for these types of products.

In § 101.12(c) of the 1990 proposal, the agency proposed that the serving or portion of a product that requires cooking or the addition of water or other ingredients be the amount required to prepare one serving of the final product as established by regulation. In § 101.12(c), FDA is reproposing this provision modified to reflect the changes made in this reproposal. Thus, the agency is proposing that the reference amount for a product that requires cooking or the addition of water or other ingredients is that amount required to prepare one reference amount of the final product as established by regulation. For example, FDA proposed the reference amount for pancakes to be 110 g as prepared. For dry pancake mixes, the reference amount would be the amount of the dry mix that is needed to make 110 g of pancake as prepared. If 40 g of pancake mix is needed to make 110 g of prepared pancake, the reference amount for this pancake mix will be 40 g.

6. Reference Amounts for Imitation or Substitute Food, Altered Food, and Foods for Special Dietary Use

Section 101.12 (d) and (e) of the 1990 proposal provided that the serving size of an imitation or substitute food, and an altered version of a food, such as "low calorie" version, must be the same as that of the food for which the imitation or altered food substitutes.

As discussed in section III.A. of the 1990 proposal, and echoed in comments on that proposal, some manufacturers appear to have manipulated the serving sizes of their products so that the per serving content would allow claims such as "low calorie" or "low sodium." To address these concerns, and similar concerns regarding imitation or substitute foods (as defined in § 101.3(e)), in § 101.12 (d) and (e), FDA is reproposing the same provisions for these types of foods, with slight modification to be consistent with this reproposal. Thus, these proposed sections provide that the reference amount for an imitation or substitute food, and for an altered version of the food, must be the same reference amount as that of the regular counterpart food.

Certain foods for special dietary or medical use are exempt from § 101.9 (55 FR 29487) and therefore, they do not have counterparts listed in § 101.12(b). Dietary supplements are subject to proposed § 101.36 *Nutrition labeling of dietary supplements of vitamins and minerals* in FDA's proposal on Mandatory Nutrition Labeling published elsewhere in this issue of the **Federal Register**. Infant formulas and other foods represented for use as the sole item of the diet, and foods represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions, are subject to special labeling requirements, which are set out elsewhere in title 21, chapter I of the Code of Federal Regulations.

A company requested special exemption on serving sizes of products sold only as part of a weight-control program that prescribes a complete meal plan with serving sizes and which are available only to persons enrolled in their program. The agency has studied this request and has tentatively concluded that the serving size requirements that apply to foods intended for weight control or weight reduction that are available in the marketplace should also apply to the products sold only as part of a weight-control program. Reference amounts for these products should be the same as the reference amounts for their regular counterparts. Dual columns of nutrition information, based on both the reference amount and the serving size prescribed by the program, could, however, be useful and educational to the enrollees. Therefore, FDA would not object to such labeling.

7. Reference Amounts for Products Consisting of 2 or More Foods Having Individual Proposed Reference Amounts

There are three types of products currently in the marketplace that consist of two or more distinct foods, each of which has a proposed reference amount. One type usually consists of two distinct foods placed in the same container that are intended to be consumed together. Examples of such products are peanut butter and jelly, cracker and cheese snack packages, and frozen pancakes and syrup. They are sold in single-serving and multi-serving containers. The 1990 proposal did not address this type of product. In § 101.12(f) of this reproposal, FDA is proposing that the reference amount for this type of product is the sum of the reference amounts for the individual foods, as listed in § 101.12(b). For example, the reference amount for peanut butter and jelly would be the weight in g equivalent to the sum of the proposed reference amounts for peanut butter (30 g and for jelly (1 tablespoon).

The second type is meal-type products (e.g., breakfast, lunch, or dinner trays). Meal-type products are usually sold in single-serving containers. In the 1990 proposal, FDA proposed standard serving sizes for these products under the category of "Meal type trays." However, in this reproposal, the agency is not proposing to establish reference amounts for these products. Because of the wide variety and varying sizes of these products, it would be difficult to determine the amount customarily consumed. Instead, in a proposed regulation entitled "Food Labeling: Nutrient Content Claim, General Principles, Petitions, Definition of Terms" published elsewhere in this issue of the **Federal Register**, FDA is proposing a definition for such products and a compliance system that do not require a reference amount for evaluating nutrient content and health claims. Under proposed § 101.9(b)(3), label serving size for meal-type products is the entire content of the package.

Entrees such as spaghetti, macaroni and cheese, burrito, pizza, and sandwich, which are marketed in single-serving and multi-serving containers, are not considered to be meal-type products. The USDA NFCS's used to derive reference amounts proposed in § 101.12(b) contained information on the amount of food consumed per eating occasion for entrees. Following the general principles and procedures described in sections IV.D.2. and IV.D.3. of this document, FDA is proposing two reference amounts for entrees, one for products that can be measured in a cup and one for products that cannot be measured in a cup. Under this proposal, the serving size of entrees that can be measured in a cup, such as spaghetti and macaroni and cheese, will be based on the reference amount for the category of "Mixed Dishes: Measurable with cup." The serving size of entrees that cannot be measured in a cup, such as burrito, pizza, and sandwich, will be based on the reference amount for the category of "Mixed Dishes: Not measurable with cup."

Some frozen entrees are packaged in separate pouches and contain more than one distinct food per package (e.g., rice or pasta with sauce or toppings). The component foods are packaged separately for technical reasons such as differences in required cooking times for the different components and better preservation of the texture and flavor during storage. However, the components from all pouches in a package are consumed as one product, and the serving size of these products will be based on the reference amount for the category of "Mixed Dishes: Measurable with cup."

The third type is products that contain two or more foods that are not

necessarily intended to be consumed together. An example of this type of product is one having multi-compartments, with each compartment containing a different food such as cheese sauce in one compartment and salsa in the other compartment. Another example of this type of product is a variety pack of single-serving products, e.g., a package containing several varieties of single-serving dry instant hot cereals. These products represent different products in individual containers that are placed together and sold as a single product for convenience, for example, to suit the preference of different family members. Because the food in each individual container within the product package represents a unique product, under proposed § 101.9(b)(4), nutrition information for this type of product is to be provided for each product using its own reference amount. A major manufacturer of a variety pack of dry instant hot cereals is currently providing nutrition information on the variety pack in this manner.

E. Procedures for Converting the Reference Amount to Serving Size

In § 101.9(b)(2) of this reproposed regulation, FDA is proposing procedures that manufacturers must follow in converting the reference amounts listed in § 101.12(b) to the serving sizes in common household measures appropriate for their specific products. These procedures will ensure that the conversions are made in a way that will provide consistency in the serving sizes declared for different brands within a product category.

Many comments, including one from a supermarket chain with many years of consumer experience, stated that consumers want to be able to make nutritional comparisons among the same types of products. Consistency in serving size among products within a food category is necessary for making such comparisons.

Many industry comments opposed the fixed standard serving sizes in the 1990 proposal on the basis that standardized serving sizes do not take into consideration the varied shapes and characteristics of different products within a product category. The procedures in proposed § 101.9(b)(2) permit the manufacturer to take these factors into consideration in converting the reference amount to serving size in common household measures.

For the purpose of developing procedures for converting the reference amount to label serving sizes, FDA grouped all multi-serving products into three categories according to the shape and characteristics of products and the way products are usually served. The agency is proposing separate procedures for each category to ensure that the serving size declared on the label is most appropriate for the specific type of product. Single-serving containers have already been discussed in section IV.C. of this document, and thus, they are not included in this discussion. Procedures for nutrition labeling of products containing multi-serving assorted varieties (e.g., assorted candies) and multi-component gift boxes are addressed in the supplementary proposal for Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision in proposed § 101.9(e)(1) (published elsewhere in this issue of the **Federal Register**) and are not covered by proposed § 101.9(b).

1. Products in Discrete Individual Units

Comments from all sectors stated that nutrition information on products in discrete individual units (e.g., muffin, egg, sliced bread, and most fruits) should be labeled per unit because that is how these foods are customarily eaten and that is the measure that consumers most prefer for nutrition information on these products. Other products that belong in this category include sliced or individually shaped mini pizzas and individually wrapped or packaged products in multi-serving containers. Section 403(r)(1)(A)(i) of the act requires that serving size be declared in common household measure that is appropriate to the food. FDA agrees with the comments that the measure most appropriate for products in discrete units would be the unit itself (i.e., piece).

However, these products come in many different sizes. For example, the size of most sliced breads ranges from 0.5 oz to 1.3 oz per slice, and the size of muffins ranges from 0.4 oz to 6 oz each. If nutrition information for these products is expressed on a single unit basis, there would be no uniformity in serving sizes declared on these products, and consumers would have to compare the nutritional value of a 0.4 oz muffin with that of a 6 oz muffin.

To assure uniformity in the serving size used for different sizes of similar products, FDA is proposing in § 101.9(b)(2)(i) that serving sizes for products that come in discrete units be the number of units that most closely approximates the reference amount in § 101.12(b) applicable to the product. For example, the label serving size for sliced bread weighing 1 oz per slice will be 2 slices because the weight of 2 slices (56 g) most closely approximates the reference amount for breads (55 g).

Under this proposed provision, only products in units that weigh at least 67 percent of the reference amount can use 1 unit as their serving size. If two units of a product each weigh 67 percent of the reference amount, their total weight is 34 percent more than the reference amount. However, one of these units weighs 33 percent less than the reference amount. Thus, one unit more closely approximates the reference amount than 2 units. However, for a product whose units weigh 66 percent of the reference amount per unit, 2 units weigh 32 percent more than the reference amount, while 1 unit weighs 34 percent less than the reference amount. Therefore, the label serving size for a product whose units weigh 66 percent of the reference amount. per unit is 2 units.

To further promote uniformity in the serving sizes declared for these products, FDA is also proposing in § 101.9(b)(2)(i) that all products in discrete individual units that weigh less than 200 percent of the reference amount must declare 1 serving per unit. This upper limit is the same as the upper limit for a single-serving container which is discussed in section IV.C. of this document.

Most of the products in discrete individual units weigh less than 200 percent per unit. As discussed in section IV.C. of this document, the agency is proposing to set the upper limit at "less than 200 percent" of the reference amount for two reasons. First, a unit that weighs 200 percent of the reference amount is by definition 2 servings. Thus it is not a single-serving product. Secondly, there is a significant question as to whether these larger units will be consumed at a single-eating occasion by one individual, considering that the customarily consumed amount is one-half or less than the unit. Thus, the agency believes that it would not be accurate to require that units that weigh 200 percent or more be labeled as one serving.

However, some exceptionally large pieces weigh more than 200 percent of the reference amount. For example, a large muffin may weigh more than 4 oz, which is more than 200 percent of the reference amount for muffins, and many people may eat the whole muffin at a single-eating occasion. Therefore, FDA is proposing to allow the manufacturer to declare one unit as a serving for products that weigh 200 percent or more of the reference amount if the whole unit reasonably can be consumed at a single-eating occasion. As discussed above, the agency is aware that this allowance

creates a potential for misuse by a manufacturer who claims that an unreasonably large unit is a single-serving in order to show a high content of a nutrient such as fiber and calcium. The agency will consider regulatory action on a case-by-case basis for misuse of this allowance.

The determination of the reasonableness of a single-serving should be based on food consumption data under actual conditions of use. Manufacturers should be prepared to provide the agency with the data that supports the single-serving claim upon request. FDA requests comments on the upper limit for single-serving declaration for products in discrete units, and whether it is reasonable to allow the manufacturer to determine the single-serving status above that level.

2. Products in Large Discrete Units That Are Usually Divided for Consumption

Foods in large discrete units such as cake, pie, pizza, melon, and cabbage are usually divided into slices or pieces for consumption. For example, a 2-layer cake may be divided into 12 pieces, or a 9-inch pie may be divided into 8 slices for consumption. FDA believes that the household measure most meaningful for these products is a fraction of the whole unit. In § 101.9(b)(2)(ii), FDA is proposing that the serving size for these products be expressed as the fraction of the whole food, such as 1/12 cake, 1/8 pie, 1/4 pizza, and 1/4 melon, that most closely approximates the reference amount in § 101.12(b). For example, the proposed reference amount for pizza is 140 g. A 1/4 slice of a pizza weighing 21 oz weighs 147 g and a 1/5 slice of this pizza weighs 118 g. The 1/4 slice is closer to the reference amount than the 1/5 slice. Therefore, the serving size for this pizza would be 1/4 pizza.

3. Nondiscrete Bulk Products

In § 101.9(b)(2)(iii), FDA is proposing that the serving size for all products that are not in individual or large discrete units and are packaged in multi-serving containers (e.g., flour, sugar, breakfast cereals with the exception of large biscuit types) be the amount in common household measure most closely approximating the reference amount for the product category. For example, the proposed referenced amount for mayonnaise is 15 g. One tablespoon mayonnaise weighs about 14 g and therefore, the label serving size for mayonnaise will be 1 tablespoon.

F. Declaration of Serving Size on the Product Label

1. Label Statement of Serving Size

FDA proposed in § 101.9(b)(3) of the 1990 proposal to require the declaration of serving size in U.S. units (oz or fl oz), followed by the equivalent metric quantity in parenthesis (with weight expressed in g and volume in mL). In addition, the agency proposed that manufacturers could voluntarily declare, in parenthesis, household measures such as cups, tablespoons, slices and pieces. Section 403(q)(1)(A)(i) of the act requires that serving sizes be expressed in common household measures. FDA stated in the announcement of the public meeting on serving sizes that in light of the variability that is likely in household measures, the agency continues to believe that a parenthetical listing of weight equivalent to the household measure is necessary for compliance reasons. The agency also pointed out that the declaration of metric quantity would promote international harmonization of food labeling, and that consumers would not have to deal with these measures since the label serving sizes would be declared in common household measures.

Most comments that addressed this issue opposed the use of metric units for serving sizes on the basis that few U.S. consumers understand the metric system, and therefore such information would not be useful to consumers. A number of comments opposed using metric units and supported the continued use of U.S. units.

The presentations and discussion at the public meeting on serving sizes also generally did not favor the use of metric units for serving sizes. However, a health professional at the public meeting stated that metric units would be very useful to immigrants, who make up a substantial portion of the population in some parts of the country, because they come from countries where metric units are used. Some presenters at the meeting stated that if household measures are used, some sort of parenthetical weight measure is needed because of the variability in common household measures, e.g., in the size of a bagel.

The IOM report recommended the use of metric units in parenthesis after the household measure. A Canadian government comment also supported the use of metric units in serving sizes. Comments from other foreign sources urged requiring the use of the metric system and stated that to do otherwise would decrease international harmonization and raise non-tariff trade barriers. A few U.S. comments also supported the use of metric units.

FDA acknowledges that many consumers are unlikely to use the metric information. However, the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100–418) declared that the metric system is the preferred measurement system for U.S. trade and commerce. Federal agencies are required to use the metric system in procurement, grants, and other business-related activities to the extent economically feasible by the end of fiscal year 1992.

As stated earlier, the agency believes that it needs an additional precise weight statement for compliance purposes because of the variability in weight of different brands in common household units. To comply with the requirements of the Omnibus Trade and Compliance Act and for compliance purposes, the agency is proposing in § 101.9(b)(7) to require that manufacturers provide the equivalent metric quantity, in parentheses, after the common household measure, e.g., 1 cup (28 g). The agency is also proposing to allow manufacturers voluntarily to list the equivalent U.S. measure in parentheses after the metric measure. The agency believes that metric measures on food labels will contribute to educating children, as well as older consumers, about the metric system.

A Canadian government comment supported using metric units rounded to a convenient size when converting from a common household measure to a metric measure (e.g., rounding from an actual weight of 172 g for a slice of pizza to 170 g). If this proposal is adopted, however, metric weight will be used by the agency for compliance purposes, such as in evaluating adjectival descriptors used on the label. Therefore, the metric measure needs to reflect accurately the common household measure, and the agency is not proposing to permit the rounding of the metric measures.

2. Definition of Household Measures

Section 403(q)(1)(A)(i) of the act requires that the serving size be expressed in a common household measure that is appropriate to the food, or if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food. Numerous comments also expressed preference for household measures, which were described in terms of familiar units including oz, cup, tablespoon, teaspoon, slice, and piece.

In § 101.9(b)(4) of the 1990 proposal, FDA proposed definitions for several household measures, including teaspoon, tablespoon, cup, fl oz, and oz.

In § 101.9(b)(5) of this reproposal, FDA is proposing the terms "common household measure" and "common household unit" to mean cup, tablespoon, teaspoon, piece, slice, fraction (e.g., ¼ pizza), oz, and other common household equipment used to package food products, such as jar and tray. As in the 1990 proposal, the agency is proposing in § 101.9(b)(5)(iv) 1 teaspoon to mean 5 mL; 1 tablespoon to mean 15 mL; a cup to mean 240 mL; 1 fl oz to mean 30 mL; and 1 oz in weight to mean 28 g.

One comment stated that 1 oz in weight should be defined as 28.35 g to be consistent with the agency policy for declaring the net weight of the package. FDA does not believe that such accuracy is needed for nutrition labeling purposes, or that the small difference (0.35 g) in the g equivalency to 1 oz between the serving size and the net weight statement would present confusion or a regulatory problem. For simplicity, the agency believes that, for nutrition labeling purposes, 28 g is a more desirable g equivalency to 1 oz than 28.35 g. Therefore, the agency is reproposing that 1 oz be defined as 28 g.

3. Rules for Declaring Household Measures

FDA is proposing in § 101.9(b)(5) of this reproposal, several rules for expressing serving size in common household measures. These rules are intended to assure as much uniformity as possible in label serving sizes within a product category. Without such rules, the same quantity of serving size could be expressed in cups by one manufacturer and in tablespoons by another. Also, one manufacturer may choose to use ⅓ cup as the serving and another manufacturer may choose to use ¼ cup for similar quantities of products. To prevent such inconsistencies in serving sizes, the agency is proposing the following rules for expressing serving sizes in common household measures.

a. Whenever possible, cups, tablespoons, or teaspoons must be used. Numerous comments on the 1990 proposal and at the public meeting requested preferential use of these common household measures in expressing serving sizes on food products. For uniformity in expressing these measures, cups should be expressed in ¼ cup increments, tablespoons in whole number of tablespoons for quantities less than ¼ cup but greater than or equal to 1 tablespoon, teaspoons in whole number of teaspoons for quantities less than 1 tablespoon but greater than or equal to 1 teaspoon, and in ¼ teaspoon increments for quantities less than one teaspoon.

b. If cups, tablespoons, or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction of the whole piece or package, as appropriate, are to be used. These units are the common household measures that are most appropriate for products not measurable by a cup, tablespoon, or teaspoon.

c. If (a) and (b) are not applicable, oz are to be used with an appropriate visual unit of measure such as a dimension of a piece, e.g., 2 oz (56 g) (about 1 inch slice) for unsliced bread. Such an approach will provide the most readily understandable description for consumers. Ounce measurements must be expressed in 0.5 oz increments most closely approximating the reference amount, with rounding indicated by use of the term "about" (e.g., about 2.5 oz). Such increments are necessary to limit the use of fractional numbers such as 2.3 oz. Consumers repeatedly complained about use of fractional numbers. However, use of fractional numbers is necessary to reduce the error in the equivalent oz measure provided. The agency believes that rounding to the nearest half-ounce increments is reasonable and it will also prevent use of unusually accurate fractional numbers (e.g., 2.1 oz) in serving size.

To promote consistency in the use of units, if a manufacturer elects to use abbreviations for units, the following abbreviations should be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, oz for ounce, and fl oz for fluid ounce.

G. Listing Nutrient Contents Based on 100 Grams, 100 Milliliters, 1 Ounce, or 1 Fluid Ounce

The agency also proposed in § 101.9(b)(6) of the 1990 proposal to allow another separate, additional column of figures to be declared on the nutrition label based on 100 g or 100 mL of the food as packaged or purchased.

Most comments from consumers and health professionals did not directly address this issue, but a few comments from both groups expressed opposition to the additional column of nutrition information, primarily because they felt that the additional information would not be useful to consumers. Several industry comments suggested using a uniform unit of weight/volume (e.g., 1 oz and 1 fl oz or 100 g and 100 mL) for all products, either with or in lieu of serving sizes. The international comments favored the use of metric units and the use of 100 g or 100 mL rather than requiring serving sizes, citing the fact that 100 g or 100 mL is required in nutrition labeling in many other countries and the need for international harmonization. Some comments said that manufacturers should have the choice of using 100 g or 100 mL in agreement with the nutrition labeling guidelines of Codex Alimentarius (Ref. 36).

The notice of a public meeting on serving sizes raised the issue of presenting nutrition information in a second column based on a uniform weight or volume basis such as 100 g or 100 mL. Written comments and discussion of this issue at the public meeting essentially reiterated the same positions as those in the comments on the 1990 proposal. Consumer and nutrition professional organizations did not support the use of metric units or of an additional column of numbers because they felt that the information was unlikely to be useful to consumers and would present too much information on the label. Representatives from the food industry and trade organizations generally also did not support requiring a second column, citing the space limitations on many food labels. A representative of the pizza industry, however, stated that a uniform weight would be useful on products such as pizza because of the lack of uniformity and the many size and weight variations in these types of foods.

On this issue, it is obviously impossible for the agency to be responsive to all positions. After carefully considering the statutory requirement, and in light of the comments from several sectors opposing metric usage, FDA is reproposing in § 101.9(b)(10) to allow manufacturers to list voluntarily a second column of values. Such values may be based on either 100 g or 100 mL or on 1 fl oz or 1 oz in weight. An important consideration in FDA's tentative decision to provide for such information in a unit (oz) is that the measure is familiar to most Americans to facilitate understanding of the information presented in the nutrition label. Allowing manufacturers to use values based on the metric measures, 100 g or 100 mL, is also consistent with the Omnibus Trade and Competitiveness Act of 1988. Values based on the metric unit also will contribute to international harmonization. Although at the present time many manufacturers may not elect to list nutrition information based on metric measures, and not many consumers in the near future may be likely to use the information, these conditions are likely to change as the

U.S. adopts the metric system. Therefore, the agency believes that it is important to provide manufacturers with this option. The agency also believes that the additional column could become an important educational tool for consumers as they become more familiar with the metric system.

The presentation of nutrition information on a uniform weight or volume basis would allow consumers to make nutritional comparisons not only across different brands of the same food but also across all classes of food products. These types of comparisons could be very useful to persons who wish to make healthful food substitutions in their diet.

H. Declaration of Number of Servings per Container

FDA proposed in § 101.9(b)(5) of the 1990 proposal that the number of servings per package or container should be declared in the nearest 0.5 serving (e.g., 2.5 servings, not 2.3 servings; 7 servings not 7.2 servings), with rounding indicated by use of the term "about" (e.g., about 7 servings).

Many consumer comments complained that they did not like to see a fractional number of servings on the product label. The IOM report recommended that the number of servings per container be rounded down to the nearest whole number. Because this recommendation introduces an unacceptably large error to the number of servings declared on the product label, FDA decided not to adopt the IOM recommendation (see section III.A. of this document for FDA's evaluation of the IOM report).

FDA, therefore, is proposing in § 101.9(b)(8) that the number of servings per package or container be declared to the nearest whole or approximate whole number. Manufacturers would be allowed to either declare the approximate serving size in household measure that results in a whole number of serving per package (e.g., serving size: approximately ½ cup; number of servings per container: 10) or to declare the exact serving size in household measures and the approximate number of servings per container (e.g., serving size: ½ cup; number of servings per container: approximately 10).

Several comments stated that regulation of the number of servings per package must be flexible to accommodate products, such as cheese, in random weight packages. Cheese industry representatives stated that for some types of foods, such as cheeses from large wheels cut in random weights, manufacturers would have a problem in declaring number of servings per package. The agency had not previously considered this special problem that relates to random-weight packages. As a means for dealing with it, FDA is proposing in § 101.9(b)(8) a special exception for random weight packages that would allow manufacturers to declare the number of servings per container as "varied" provided the nutrition information is based on the reference amount expressed in oz. The agency is soliciting comments on whether this exception is a reasonable provision for these types of packages, and, if not, what provision should be made for random weight packages.

I. Use of Serving Size to Evaluate Nutrient Content and Health Claims

FDA proposed in § 101.12(f) of the 1990 proposal that for any container with more than one serving, the proposed standard serving size would be used to determine the appropriateness of a nutrient content claim (descriptor) such as "low sodium." For single-serving containers containing 100 percent or less of the standard serving, evaluation of the label claim would be based on the standard serving size. However, for single-serving containers containing more than 100 percent, but 150 or less percent of the standard serving, the claim would be evaluated on the basis of the entire content of the package.

A majority of comments on FDA's proposal supported the proposed basis for evaluation of descriptors. However, many food industry and trade organization comments objected to the proposed evaluation criteria. These comments generally argued that the established serving size, not the package content, should be used to evaluate descriptor claims on all sizes of packages.

Manufacturers pointed out that under the rule proposed in 1990, the same food product that could be labeled as "low sodium" (or a similar adjectival descriptor) on the basis of a standard serving size might not qualify for "low sodium" labeling when packaged in a single-serving container containing between 100 percent and 150 percent of the standard serving size. For example, an 8 fl oz container of skim milk containing 126 milligrams (mg) of sodium would meet the definition of "low sodium," but a 10 fl oz single-serving container of the same milk that contains 158 mg of sodium would not.

In the notice of public meeting, FDA raised the question of whether these differences in the use of descriptors on food products would be confusing and asked for data to support any views presented. No data on this issue were presented at the meeting. FDA also suggested two alternative solutions to the concerns expressed about use of label descriptors on single-serving containers: (1) To label single-serving containers that do not contain the standard serving with the nutritional content in both the total container and in the standard serving and to permit descriptor use based on the standard serving; or (2) to provide a weight factor on the label that consumers could use to determine the nutritional values based on a standard serving size (e.g., multiply by ⅔ for a single-serving that contains 150 percent of the established serving size). Comments generally offered little support, or opposed, such additional information on the nutrition label. The general sense of the comments was that most consumers would not understand or use this additional information, and that it would contribute to label overload and confusion.

A manufacturer suggested, as resolution for the issue, that FDA establish reference serving sizes, and that both the reference serving size and the serving size declared on the product label be required to be used to evaluate the compliance with FDA criteria for the descriptors. The agency believes that this suggestion represents a reasonable approach to regulating the use of nutrient content and health claims not only on single-serving containers but also all other products when the serving size declared on the label differs from the reference amount (e.g., products in discrete units). Therefore, FDA is proposing in § 101.12(g) that if the serving size declared on the product label differs from the reference amount, the amount of the nutrient or substance in both the reference amount listed in § 101.12(b) and the serving size declared on the product label must meet the FDA criteria for nutrient content and health claims, as set forth in regulations relating to such claims, for the food to qualify for the claim.

The agency recognizes that the proposed approach could result in differences in claims made on the same product depending on the package or unit size. For example, a product which contains the same or less than the reference amount may bear a claim such as "low sodium," whereas a single-serving container of the same product that contains one and a half times the reference amount may not. As mentioned earlier, many industry comments opposed such differences. The agency considered using the reference amount to evaluate whether a label claim meets the criteria for the

claim. Industry generally supported this option. This option will allow the same product to bear the same claim regardless of the package or unit size. However, it also presents major problems.

If the label serving size of the product differs from the reference amount, and the product does not meet the criteria for the claim per serving, it would require an additional statement on the label such as "this package content does not meet the FDA standard for the claim," to inform consumers properly. Such an additional statement would make the label more complicated. Considering other additional label information required by the act, e.g., disclaimers, many products, particularly small single-serving containers, would not have enough space for all of the additional information. Also, such an additional statement is likely to be ineffective if it is present all the time. Furthermore, a product that contains an undesirably large amount of a nutrient from the public health standpoint could bear a claim for which it is qualified only on the basis of the reference amount. For example, based on the reference amount, a product could qualify for use of a "low sodium" claim, which is defined by FDA as 140 mg or less per serving. The same product in a large single-serving container could contain more than 140 mg of sodium and would not qualify but would still be able to bear the "low sodium" claim. This result would be misleading and undesirable from the public health standpoint. Therefore, FDA decided not to adopt this option. The agency solicits comments on this option and on the approach it has chosen to evaluate nutrient content and health claims on food labels.

J. Other Related Issues

1. Nutrition Information on an as Packaged Versus an as Consumed Basis

In § 101.9(b)(6) of the 1990 proposal, FDA proposed that nutrient and food component quantities be declared on the basis of the food as packaged or purchased. Some comments stated that the declaration should be based on the food as consumed.

Many products come in a form (e.g., dry mixes and concentrates) that requires further preparation or an addition of other ingredients before consumption. In many cases, the nutrient content of these products as consumed differs from the nutrient content as packaged. The agency recognizes that consumers will benefit from the nutrition information on an as consumed (prepared) basis since this information reflects the nutrient content of the product actually consumed. Manufacturers usually provide directions for preparation on the package. These directions could be used as a compliance tool for regulating products on an as consumed basis if there is only one direction for preparation and that is the only preparation method that consumers use. Some manufacturers, however, provide multiple directions for preparation (e.g., using different types of fats such as butter and margarine) and different directions often yield different nutrient contents following the preparation. There is no obvious basis for selecting a particular direction for regulatory purpose such as for use in providing nutrition information and for evaluating label claims. Furthermore, a product may be used by consumers in many different ways and the agency has no control over how a product is used after purchase. Consequently, FDA cannot effectively regulate products on an as consumed basis. Therefore, FDA is maintaining the "as packaged or purchased" requirement redesignated as § 101.9(b)(9), with the exception of raw fish covered under § 101.42 and canned fish, canned maraschino cherries, pickled fruits, olives, and canned or pickled vegetables. The serving size for raw fish is discussed in a separate rulemaking concerning voluntary nutrition labeling of raw fruit, vegetables, and fish that is published elsewhere in this issue of the **Federal Register**. For purposes of the voluntary nutrition labeling program; the agency has defined "raw fish" as fish in the natural state that have received minimal or no processing (56 FR 30468 at 30470). This definition includes "whole or filleted fish that are fresh (unpackaged or packaged by the retailer), fresh frozen (unpackaged or packaged by the retailer), or alive in the retail store (e.g., lobster, crab); shrimp that have been shelled and deveined; and lobster, crab, and shrimp that have been thermally processed or shelled, but not otherwise processed or prepared. (56 FR 30468 at 30470). Other forms of fish, such as packaged frozen fillets, are not included in the proposed exemption in § 101.9(b)(9).

Some foods such as canned fish, canned maraschino cherries, pickled fruits, olives, and canned or pickled vegetables, are usually packed in water, brine, or oil, but the liquid is usually discarded before consumption. Therefore, the nutrient content of these foods as consumed may differ from the nutrient content as packaged. FDA believes that the label serving size most meaningful for these products would be the serving size based on the drained solids. Proposed § 101.9(b)(9) exempts these foods from the requirement for nutrition information on an as packaged basis. Nutrition information for these products will be based on the drained solids. Reference amounts for these products are based on the drained solids as customarily consumed, as noted in the footnote to table 2.

For the benefit of the consumers who follow the package directions in preparing these products, the agency encourages manufacturers voluntarily to provide nutrient content of their products on an as consumed basis using the package directions for preparation and in the case of multiple directions, using the direction that most likely represents the major usage of the product.

Section 101.9(d)(2) of the proposed nutrition labeling regulation (55 FR 29487) provides for the use of an additional column of figures to declare nutrition information on the basis of food as consumed, e.g., cereal with milk or cake mix prepared according to instructions.

2. Flexibility in Serving Size Declared on the Product Label

Some industry comments on the 1990 proposal expressed the need for greater flexibility in serving sizes because of differences, for example, in package sizes and differences in size between pieces within packages. In the notice of public meeting, the agency raised the issue of whether deviation from the standard serving size should be allowed and, if allowed, how much.

A consumer representative at the public meeting stated that FDA should allow some deviation in serving size within a product category, but that it should be minimal and should result in a size close to the amount customarily consumed to protect consumers from both economic deception and misrepresentation of nutrition and health claims. Another consumer representative stated that there is no reason to allow deviation, except for foods like pizza and pies. An industry representative stated that a manufacturer must be permitted deviation from a uniform serving size when a feature of a food distinguishes it, so that a different serving size that more accurately reflects the amount that is customarily consumed may be used, e.g., a prewrapped slice of cheese would be the amount that is customarily consumed. However, the agency has not received any data on what might be a feasible deviation for various food

categories if such deviations were allowed.

The agency agrees that it should provide some flexibility for the serving size declared on the product label to account for differences in package sizes and differences in size between pieces within packages. However, under the act, the serving size declared on the product label must at least approximate the amount customarily consumed, i.e., the reference amount established for the product category. The agency believes that the procedures for converting the reference amount to serving size for use on the product label proposed in § 101.9(b)(2) of this reproposal provide sufficient flexibility to account for the varied characteristics of different products while assuring a relative uniformity of serving sizes used for different brands within a product category.

3. Range Versus Fixed Reference Amount

The Minister of Health and Welfare of Canada submitted as comments Canada's guidelines to the food industry on serving sizes. The Canadian guidelines allow declaration of serving sizes within established ranges, e.g., 40 to 100 g for a muffin and 200 to 250 mL for milk.

FDA is proposing to establish specific reference amounts for 131 product categories, not ranges of values. As mentioned earlier, the reference amounts, if adopted, will serve two purposes: (1) They will be used by manufacturers in determining serving size for their specific products, and (2) they will be used in determining whether food products meet the definitions for nutrient content and health claims. Both of these purposes require a specific reference amount, not a range of values. Therefore, FDA is not proposing to adopt the Canadian approach of using a range.

In addition, it is difficult to determine an appropriate range value for each product category to cover all of the different shapes and varied characteristics of products within each category. FDA also does not know whether any set range would be appropriate for products that will enter the market in the future. FDA believes that the procedures in proposed § 101.9(b)(2) for converting the reference amounts to serving sizes provide the flexibility necessary to deal with diverse shapes and characteristics of specific products. Therefore, FDA has tentatively concluded that ranges are not needed. Furthermore, the procedures that FDA is proposing can be applied to any products that enter the market as well as to those currently in the market.

K. The Petition Process

In § 101.12(g) of the 1990 proposal, FDA proposed to establish a petition process for manufacturers to use to add to or amend a standard serving size. Provision for a petition process was supported by the IOM report and by comments on the 1990 proposal, as well as by comments to the notice of the public meeting on serving sizes. In § 101.12(h), FDA is proposing an updated petition process for manufacturers to use to add to or amend a reference amount listed in § 101.12(b) or to establish a new subcategory if a reference amount for a product category does not apply to a particular product. Section 101.12(h) describes information needed by FDA to evaluate a need for the change or addition requested in the petition and to determine the appropriate reference amount for the petitioned food if the change or addition is judged to be needed.

As discussed earlier, a few manufacturers submitted supporting data with their request for changes in standard serving sizes in the 1990 proposal. However, these data could not be used in developing the reference amounts in this reproposal because of problems in the methodology used to collect or to process data (see the introduction to section IV.D. of this document). To help guide manufacturers in conducting research to collect or process food consumption data to determine the suggested reference amount in support of a petition, FDA is providing the following general guidelines:

1. Sampled population should be representative of the demographic and socio-economic characteristics of the relevant population group (i.e., infants, toddlers, or people 4 or more years of age) for which the food is intended.

2. Sample size (i.e., number of eaters) should be large enough to give a reliable estimate of the amount of food that is customarily consumed.

3. The study protocol should identify potential biases and describe how these potential biases are controlled for, or, if they cannot be controlled for, how they will affect interpretation of results. For example, a survey that asks the participants to measure the amount of food that they usually consume or serve per eating occasion is likely to be biased by downsizing a food having a negative nutritional connotation (e.g., high fat, high calorie foods) and upsizing for foods with positive connotations.

4. Methodology used to collect or process data, including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

V. Other Affected Rules

In the 1990 proposal, the agency proposed to revise 21 CFR 101.8(a) to provide that where nutrition information is required, and firms elect to place statements on product labels concerning the number of servings in a package in other locations in addition to the location where nutrition information is placed, such statements must be in the same terms as used for nutrition information. FDA proposed this revision to prevent consumer confusion over serving size. For completeness, FDA is once again including § 101.8(a) as part of this reproposal on serving size regulations.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24 that this proposed rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required. The proposed requirements pertaining to serving sizes to be used on food labels qualify for a categorical exclusion under 21 CFR 25.24(a)(11), and the proposed requirements pertaining to petitions that seek to establish or amend a reference amount qualify for exclusion under 21 CFR 25.24(a)(8).

VII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

VIII. Effective Date

In the 1990 proposal, FDA proposed to make the serving size regulation effective 1 year after the publication of a final rule. FDA requested comment on this deviation from the agency's normal practice of making food labeling

regulations effective on the uniform compliance date that follows publication of the final rule. The agency is proposing that any final rule that may be issued based upon this proposal become effective 6 months following its publication in the **Federal Register.**

FDA notes, however, that in section 10(a)(3)(B) of the 1990 amendments, Congress provides that if the Secretary of Health and Human Services (the Secretary), and by delegation FDA, finds that requiring compliance with section 403(q) of the act, on mandatory nutrition labeling, or with 403(r)(2) of the act, on nutrient content claims, 6 months after publication of the final rules in the **Federal Register** would cause undue economic hardship, the Secretary may delay the application of these sections for no more than 1 year. In light of the agency's tentative findings in its regulatory impact analysis that compliance with the 1990 amendments by May 8, 1993, will cost $1.5 billion, and that 6 month and 1 year extensions of that compliance date will result in savings that arguably outweigh the lost benefits, FDA believes that the question of whether it can and should provide for an extension of the effective date of sections 403(q) and (r)(2) of the act is squarely raised.

FDA has carefully studied the language of section 10(a)(3)(B) of the 1990 amendments and sees a number of questions that need to be addressed. The first question is the meaning of "undue economic hardship." FDA recognizes that the costs of compliance with the new law are high, but those costs derive in large measure from the great number of labels and firms involved. The agency questions whether the costs reflected in the aggregate number represent "undue economic hardship." Therefore, FDA requests comments on how it should assess "undue economic hardship." Should it assess this question on a firm-by-firm basis, as was provided in the bill that passed the House Committee on Energy and Commerce (H. Rept. 101-538, 101st Cong., 2d sess., 24 (1990)), an industry-by-industry basis, or should it assess this question on an aggregate basis? If the agency should take the latter approach, comments should provide evidence that would permit the agency to make a determination that there is "undue economic hardship" for most companies. FDA also points out that assessing hardship on a firm-by-firm basis would likely be extremely burdensome because of the likely number of requests.

FDA will consider the question of the meaning and appropriate application of section 10(a)(3)(B) of the 1990 amendments as soon as possible after the comment period closes. The agency intends to publish a notice in advance of any final rule announcing how it will implement this section to assist firms in planning how they will comply with the act. The early publication of this notice is to assist firms in avoiding any unnecessary expenses that could be incurred by trying to comply with a compliance date that may cause "undue economic hardship."

IX. Comments

Interested persons may, on or before February 25,1992, submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

X. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the provisions of § 101.12(h) relating to submission of petitions to FDA will be submitted for approval to the Office of Management and Budget (OMB). These provisions will not be effective until FDA obtains OMB approval. FDA will give notice of OMB approval of these requirements in the **Federal Register** as part of any final rule that is based on this proposal.

XI. References

The following information has been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Committee on the Nutrition Components of Food Labeling, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, "Nutrition Labeling: Issues and Directions for the 1990s," National Academy Press, Washington, DC, 1990.

2. Park, Youngmee K., memo to file, October 30, 1991.

3. U.S. Department of Agriculture, "Developing the Food Guidance System for 'Better Eating for Better Health,' a Nutrition Course for Adults," Administrative Report No. 377, U.S. Department of Agriculture, Hyattsville, MD, 1985 (A condensed version published by Cronin, F. J., Shaw, A. M., Krebs-Smith, S. M., Marsland, P.M., and Light L., "Developing a Food Guidance System to Implement the Dietary Guidelines," *Journal of Nutrition Education*, 19:281-302, 1987).

4. U.S. Department of Agriculture, "Good Sources of Nutrients," Administrative Report No. 371, U.S. Department of Agriculture, Hyattsville, MD, 1989.

5. American Diabetes Association, Inc. and American Dietetic Association, "Exchange Lists for Meal Planning," American Diabetes Association, Alexandria, VA, 1989.

6. U.S. Department of Agriculture, "Food, The Hassle-Free Guide to a Better Diet," Home and Garden Bulletin No. 228, U.S. Department of Agriculture, Hyattsville, MD 1979.

7. U.S. Department of Health and Human Services/National Heart, Lung, and Blood Institute, "National Cholesterol Education Program, Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction," NIH Publication No. 90-3047, National Institutes of Health, Bethesda, MD, 1991.

8. U.S. Department of Agriculture and U.S. Department of Health and Human Services, "Nutrition and Your Health: Dietary Guidelines for Americans," 3 ed., U.S. Government Printing Office, Washington, DC, 1990.

9. Dennis, D. Adele., memorandum of meeting dated October 5, 1990.

10. Thompson, Susan, memorandum of meeting dated October 15, 1990.

11. Stephenson, Marilyn G., memorandum of meeting dated October 23, 1990.

12. Park, Youngmee K., memorandum of meeting dated November 5, 1990.

13. Park, Youngmee K., memorandum of meeting dated December 13, 1990.

14. Johnson, Carl B., memorandum of meeting dated March 13, 1991.

15. Stephenson, Marilyn G., memorandum of meeting dated April 12, 1991.

16. Stephenson, Marilyn G., memorandum of meeting dated June 26, 1991.

17. Park, Youngmee K., memo to file, June 15, 1990.

18. Agricultural Research Service, "Food Yields Summarized by Different Stages of Preparation," Agriculture Handbook No. 102, U.S. Department of Agriculture, Washington, DC, 1975.

19. Park, Youngmee K., memo to file, March 7, 1991.

20. Park, Youngmee K., memo to file, October 20, 1991.

21. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual—Spring Quarter 1977-1978, accession no. PB80-190218/HAE, National Technical Information Service, Springfield, VA, 1980.

22. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual—Summer Quarter 1977-1978, accession no. PB80-197429/HAE, National Technical Information Service, Springfield, VA, 1980.

23. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual—Fall Quarter 1977-1978, accession no. PB80-200223/HAE, National Technical Information Service, Springfield, VA, 1980.

24. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual—Winter Quarter 1977-1978.

accession no. PB81-118853/HAE, National Technical Information Service, Springfield, VA, 1981.

25. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual Intake—1987-1988, accession no. PB90-504044, National Technical Information Service, Springfield, VA, 1990.

26. Life Sciences Research Office, "Impact of Nonresponse of Dietary Data from the 1987-1988 Nationwide Food Consumption Survey," Federation of American Societies for Experimental Biology, Bethesda, MD, 1991.

27. United States General Accounting Office, " Nutrition Monitoring, Mismanagement of Nutrition Survey Has Resulted in Questionable Data," GAO/RCED-91-117, Washington, DC, 1991.

28. U.S. Department of Agriculture, CSFII: four days food intake for women and their children 1-5, 1985, accession no. PB88-201249/HAE, National Technical Information Service, Springfield, VA, 1988.

29. U.S. Department of Agriculture, CSFII: four days food intake for women 10-50, children 1-5, 1986, accession no. PB89-154355/HAE, National Technical Information Service, Springfield, VA, 1989.

30. U.S. Department of Agriculture, "Manual of Food Codes and Conversions of Measures to Gram-weight for use with Individual Food Intake Data from the 1977-1978 Nationwide Food Consumption Survey," working copy, November 1, U.S. Department of Agriculture, Hyattsville, MD, 1979.

31. U.S. Department of Agriculture, "Manual of Food Codes for Individual Intake," Nationwide Food Consumption Survey 1987-1988, machine-readable version, U.S. Department of Agriculture, Hyattsville, MD (unpublished).

32. U.S. Department of Health and Human Services/U.S. Department of Agriculture, "Nutrition Monitoring in the United States, An Update Report on Nutrition Monitoring," DHHS Publication No. (PHS) 89-1255, U.S. Government Printing Office, Washington, DC, 1989, p. 25.

33. Marmen, Linda L., Youngmee K. Park, memo to file, October 15, 1991.

34. Serving Size Recommendations: Giant, dated August 5, 1980.

35. Oliver, Janice F., letter to Peter S. Janzen dated June 6, 1991.

36. Codex Alimentarius Commission, Codex Alimentarius, vol. VI, Codex Standards and Guidelines for the Labeling of Foods and Food Additives, 2 ed., reference No. CAC/GL1985, Food and Agriculture Organization of the United Nations/World Health Organization, Rome, Italy, 1985.

List of Subjects in 21 Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.8 is amended by revising paragraph (a) to read as follows:

§ 101.8 Labeling of food with number of servings.

(a) The label of any package of a food that bears a representation as to the number of servings contained in such package shall bear in immediate conjunction with such statement, and in the same size type as is used for such statement, a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving; however, such statement may be expressed in terms that differ from the terms used in the required statement of net quantity of contents (for example cups, tablespoons) when such differing term is common to cookery and describes a constant quantity. Such statement may not be misleading in any particular. Where nutrition labeling information is required in accordance with the provisions of § 101.9, however, the statement of the net quantity of each serving shall be consistent with the requirements for serving size expression set forth in that section (e.g., 10 1-cup (240 milliliters) servings). A statement of the number of units in a package is not in itself a statement of the number of servings.

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3. Section 101.9 is amended by revising paragraph (b) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(b) All nutrient and food component quantities shall be declared in relation to a serving or, where the food is customarily not consumed directly, to a portion, as defined in this section.

(1) The term "serving" or "serving size" means an amount of food customarily consumed per eating occasion by persons 4 years of age or older which is expressed in a common household measure that is appropriate to the food. When the food is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age. The term "portion" means an amount of a food that is not typically expressed in a serving size, i.e., a food customarily used only as an ingredient in the preparation of other foods, (e.g., ¼ cup flour or ¼ cup tomato sauce).

(2) Except as provided in paragraphs (b)(3) and (b)(4) of this section, serving (portion) size declared on a product label shall be determined from the "Reference Amounts Customarily Consumed Per Eating Occasion" (reference amounts) that appear in § 101.12(b) using the following procedures:

(i) For products in discrete units (e.g., muffin, sliced bread, apple), serving size shall be the number of units that most closely approximates the reference amount for the product category. If a unit weighs 67 percent or more, but less than 200 percent of the reference amount, serving size shall be one unit. If a unit weighs 200 percent or more of the reference amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion.

(ii) For products in large discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), the serving (portion) size shall be the fractional slice of the food (e.g., 1/12 cake, ⅛ pie, ¼ pizza, ¼ melon, ⅙ cabbage) that most closely approximates the reference amount for the product category.

(iii) For nondiscrete bulk products (e.g., breakfast cereal, flour, sugar), serving (portion) size shall be the amount in household measure that most closely approximates the reference amount for the product category.

(3) Serving size for meal-type products as defined in proposed § 101.13(1) of this chapter shall be the entire content (edible portion only) of the package.

(4) A variety pack such as a package containing several varieties of single-serving packages and a product having two or more compartments with each compartment containing a different food shall provide nutrition information for each variety or food per serving size that is derived from the reference amount in § 101.12(b) applicable for each variety or food.

(5) For labeling purposes, the term "common household measure" or "common household unit" means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., ¼ pizza), ounce (oz), or other common household equipment used to package food products (e.g., jar, tray). In expressing serving (portion) size in household measures, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate. Cups shall be expressed in ¼ cup increments, tablespoons in whole number of tablespoons for quantities less than ¼ cup but greater than or equal to 1 tablespoon, and teaspoons in

whole number of teaspoons for quantities less than 1 tablespoon but greater than or equal to 1 teaspoon and in ¼ teaspoon increments for quantities less than 1 teaspoon.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If paragraphs (b)(5)(i) and (b)(5)(ii) of this section are not applicable, oz may be used with an appropriate visual unit of measure such as a dimension of a piece, e.g., 2 oz (56 g) (about 1 inch slice) for unsliced bread. Ounce measurements shall be expressed in 0.5 oz increments most closely approximating the reference amount, with rounding indicated by use of the term "about" (e.g., about 2.5 oz).

(iv) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL); a tablespoon means 15 mL; a cup means 240 mL; 1 fluid ounce (fl oz) means 30 mL; and 1 oz in weight means 28 g.

(6) A product that is packaged or sold individually and that contains less than 200 percent of the applicable reference amount shall be considered to be a single-serving, and the entire content of the product shall be labeled as one serving. Small packages sold individually that contain 200 percent or more of the applicable reference amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

(7) A label statement regarding a serving (portion) shall be the serving (portion) size expressed in common household measures as set forth in paragraphs (b) (2) through (b)(6) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in mL and all other foods in g). In addition, serving (portion) size may be declared in oz and fl oz, in parenthesis, following the metric measure where other common household measures are used as the primary unit for serving (portion) size, e.g., 1 cup (28 g) (1 oz). If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, oz for ounce, and fl oz for fluid ounce.

(8) In declaring the number of servings per container, a manufacturer may use either of the two options listed below, choosing the one most meaningful for a specific product. In either case, whole numbers must be used with the exception of random weight products. For random weight products, a manufacturer may declare "varied" for the number of servings per container provided the nutrition information is based on the reference amount expressed in oz.

(i) Declare serving (portion) size as the approximate whole household measure that results in a whole number of servings in the container (e.g., serving size: approximately ½ cup; number of servings per container: 10) or

(ii) Declare serving (portion) size in exact household measure and approximate the number of servings per container (e.g., serving size: ½ cup; number of servings per container: approximately 10).

(9) The declaration of nutrient and food component content shall be on the basis of food as packaged or purchased with the exception of raw fish covered under § 101.42 and foods that are packed or canned in water, brine, or oil but the liquid is not customarily consumed such as canned fish, maraschino cherries, pickled fruits, olives, and canned or pickled vegetables. Declaration of nutrient and food component content of raw fish shall follow the provisions in § 101.45. Declaration of nutrient and food component content of foods that are packed in liquid but the liquid is not customarily consumed, shall be based on the drained solids.

(10) Another column of figures may be used to declare the nutrient and food component information on the basis of 100 g or 100 mL or of 1 oz or 1 fl oz of the food as packaged or purchased, in the same format as required by paragraph (c) of this section.

(11) If a product is promoted on the label, labeling, or advertising for a use that differs in quantity by twofold or greater from the use upon which the reference amount in § 101.12(b) was based (e.g., liquid cream substitutes promoted for use with breakfast cereals), the manufacturer shall provide a second column of nutrition information based on the amount customarily consumed in the promoted use, in addition to the nutrition information per serving derived from the reference amount in § 101.12(b).

* * * * *

4. Section 101.12 is added to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

(a) The general principles and factors that FDA considered in arriving at the reference amounts customarily consumed per eating occasion (reference amounts) which are set forth in paragraph (b) of this section, are that:

(1) FDA calculated the reference amounts for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These reference amounts are based on data set forth in appropriate national food consumption surveys.

(2) FDA calculated the reference amounts for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These reference amounts are based on data set forth in appropriate national food consumption surveys. Such reference amounts are to be used only when the food is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey must include a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, FDA considered the mean, median, and mode of the consumed amount per eating occasion.

(5) When survey data were insufficient, FDA took various other sources of information on serving (portion) sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the reference amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The reference amount is based on the major intended use of the food (e.g., milk as a beverage and not as an addition to cereal).

(8) The reference amounts for products that are consumed as an ingredient of other foods, but that may also be consumed in the form in which they are purchased (e.g., butter), are based on use in the form purchased.

(9) FDA sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform reference amount.

(b) The following reference amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: INFANT AND TODDLER FOODS [1 2 3]

Product category	Reference amount
Cereal, dry instant	15 g
Cereal, prepared, ready to serve	110 g
Other cereal and grain products, dry ready-to-eat, e.g. ready-to-eat cereals, cookies, teething biscuits, and toasts.	7 g
Dinner, dessert, fruit, vegetable or soup, dry mix.	15 g
Dinner, dessert, fruit, vegetable or soup, ready-to-serve, junior type.	110 g
Dinner, dessert, fruit, vegetable or soup, ready-to-serve, strained type.	60 g
Dinner, fruit, vegetable, stew or soup for toddlers, ready-to-serve.	170 g
Egg/egg yolk, ready-to-serve	55 g
Juice, all varieties	120 mL

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry cereal) is the amount required to make one reference amount of the prepared form.

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1 2 3]

Product category	Reference amount
Bakery Products:	
Breads (excluding sweet quick type), biscuits, rolls, croissants, bagels, tortillas, soft bread sticks, soft pretzels.	55 g.
Breakfast bars and toaster pastries.	55 g.
Brownies	40 g.
Cake, heavy weight, more than or equal to 10 g per cubic inch.	125 g.
Cake, medium weight, more than or equal to 6 g but less than 10 g per cubic inch.	110 g.
Cake, light weight, more than or equal to 4 g but less than 6 g per cubic inch, and eclairs.	75 g.
Cake, very light weight, less than 4 g per cubic inch.	55 g.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1 2 3]—Continued

Product category	Reference amount
Coffee cakes, doughnuts, Danish, sweet rolls, sweet quick type breads, muffins, hushpuppies, cornbread.	55 g.
Cookies, sweet crackers, and sandwich type crackers.	30 g.
Crackers, all varieties excluding sweet and sandwich type—includes hard bread sticks and ice cream cones [4].	15 g.
Croutons	7 g.
French toast, pancakes.	110 g.
Pies, cobblers, turnovers, other pastries.	125 g.
Pie crust	⅙ of 8 inch crust. ⅛ of 9 inch crust.
Pizza crust	55 g.
Taco shell	30 g.
Waffles	85 g.
Beverages:	
Carbonated beverages (excluding water), wine cooler.	240 mL.
Noncarbonated beverages—see fruits and fruit juices category	
Coffee or tea, regular or flavored without sugar or cream/cream substitute.	240 mL prepared or 2 tbsp ground coffee or 2 tsp dry instant coffee or 2 g dry instant or leaf tea.
Coffee or tea, flavored and sweetened.	Amount to make 240 mL prepared.
Water, all types	240 mL.
Cereals and Other Grain Products:	
Breakfast cereals (hot cereal type), hominy grits.	1 cup prepared or 40 g plain dry cereal or 55 g flavored, sweetened cereal'
Breakfast cereals, ready-to-eat (weighing less than 3 oz per cup).	1 cup.
Breakfast cereals, ready-to-eat (weighing more than or equal to 3 oz per cup).	½ cup.
Breakfast cereals, ready-to-eat, not measurable with cup, e.g., biscuit type.	50 g.
Bran or wheat germ	15 g.
Flours or cornmeal	30 g.
Grains, e.g., rice, barley, plain or seasoned.	140 g prepared or 45 g dry.
Pastas, without sauce	140 g prepared or 55 g dry.
Pastas, dry, ready-to-eat, e.g., fried canned chow mein noodles.	25 g.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1 2 3]—Continued

Product category	Reference amount
Starch, e.g., cornstarch, potato starch, tapioca, etc..	10 g.
Stuffing	100 g.
Dairy Products and Substitutes:	
Cheese, cottage	110 g.
Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese.	55 g.
Cheese, grated hard, e.g., Parmesan, Romano.	5 g.
Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread.	30 g.
Cheese sauce—see sauce category	
Cream or cream substitute, fluid.	15 mL.
Cream or cream substitute, powder.	2 g.
Cream, half & half	30 mL.
Eggnog	120 mL.
Milk, condensed, undiluted.	30 mL.
Milk, evaporated, undiluted.	15 mL.
Milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa.	240 mL.
Shakes or shake substitutes, e.g., dairy shake mix, fruit frost mix.	240 mL.
Sour cream	25 g.
Yogurt	225 g.
Desserts:	
Ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (e.g., bars, sandwiches, cones).	½ cup—includes the volume for coatings and wafers for the novelty type varieties.
Sundae	1 cup.
Custard, gelatin or pudding.	½ cup.
Dessert Toppings and Fillings:	
Cake frosting or icing	35 g.
Other dessert toppings, e.g., fruits, syrups, marshmallow cream, nuts, dairy and non-dairy whipped toppings.	2 tbsp.
Pie fillings	85 g.
Egg and Egg Substitutes:	
Egg mixture, e.g., egg foo yung, scrambled egg, omelet.	110 g.
Eggs (all sizes) [4]	50 g.
Egg substitutes	An amount to make 1 large (50 g) egg
Fats and Oils:	
Butter, margarine, oil, shortening.	1 tbsp.
Butter replacement, powder.	2 g.
Dressings for salad	30 g.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1 2 3] Continued

Product category	Reference amount
Mayonnaise, sandwich spread, mayonnaise-type dressing.	15 g.
Spray type	0.25 g.
Fish, Shellfish, and Meat or Poultry Substitutes:	
Bacon substitute, canned anchovy,[5] anchovy paste, caviar.	15 g.
Dried, e.g., jerky	30 g.
Entrees (cooked) with sauce, e.g., fish with cream sauce, shrimp with lobster sauce.	140 g.
Entrees (cooked) without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake.	85 g.
Fish and shellfish, canned [5].	85 g.
Substitute for luncheon meat, sandwich spread, Canadian bacon, sausage and frankfurter.	55 g.
Smoked or pickled fish[5] or shellfish.	55 g.
Substitutes for bacon bits—see miscellaneous category	
Fruits and Fruit Juice:	
Candied or pickled[5]	30 g.
Dehydrated fruits—see snacks category	
Dried	40 g.
Fruit for garnish or flavor, e.g., maraschino cherries[5].	4 g.
Fruit relishes, e.g., cranberry sauce, cranberry relish.	70 g.
Fruits used primarily as ingredients e.g., avocado, cranberries, lemon, lime.	55 g.
Watermelon	280 g.
All other fruits (except those listed as separate categories), fresh, canned or frozen.	140 g.
Juice, nectar, fruit drinks, or fruit-flavored drinks.	240 mL.
Juice used as ingredients, e.g., lemon juice, lime juice.	5 mL.
Legumes:	
Bean cake (tofu) [5]	85 g.
Beans, plain [5] or in sauce.	½ cup.
Miscellaneous category:	
Baking powder, baking soda, pectin.	1 g.
Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations.	1 tsp or 4 g if not measurable by teaspoon.
Batter mixes, bread crumbs, meat, poultry, and fish coating mixes, dry.	30 g.
Cooking wine	30 mL.
Drink Mixers (without alcohol).	Amount to make 240 mL drink (without ice).
Gum	3 g.
Salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits.	7 g.
Salt, salt substitute, seasoning salt (e.g., garlic salt).	1 g.
Seasoning mixes dry, e.g., chili seasoning mix, pasta salad seasoning mix.	Amount to make one reference amount of the final dish.
Mixed Dishes:	
Measurable with cup, e.g., casserole, hash, macaroni and cheese, pot pie, spaghetti with sauce, stew, etc.	1 cup.
Not measurable with cup, e.g., burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches.	140 g, add 55 g for products with gravy or sauce topping, e.g., enchilada with cheese sauce, crepe with white sauce.[6]
Nuts and Seeds:	
Nuts, seeds and mixtures.	40 g
Nut and seed butter, paste, or cream.	30 g.
Used primarily as ingredient, e.g., coconut, nut and seed flour, etc.	15 g.
Potatoes and Sweet Potatoes/Yams:	
French fries, hash browns, skins, or pancake.	70 g.
Mashed, candied, stuffed, or with sauce.	140 g.
Plain, fresh, canned,[5] or frozen.	110 g.
Salads:	
Pasta or potato salad	140 g.
All other salad, e.g., egg, fish, shellfish, bean, fruit, or vegetable salad.	100 g.
Sauces, Dips, Gravies and Condiments:	
Barbecue sauce, Hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa), marinade.	2 tbsp.
Major main entree sauce e.g., spaghetti sauce.	½ cup.
Minor main entree sauce (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce.	¼ cup.
Major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, etc..	1 tbsp.
Minor condiments, e.g., horseradish, hot sauce, mustard, worcestershire sauce, etc..	1 tsp.
Snacks:	
All varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks (e.g., fruit chips), grain-based snack mixes.	30 g.
Soups:	
All varieties	1 cup.
Sugars and Sweets:	
Baking candies (e.g., chips) and hard candies.	15 g.
All other candies	40 g.
Confectioner's sugar	2 tbsp.
Honey, jams, jellies, fruit butter, molasses.	1 tbsp.
Marshmallows	30 g.
Popsicles, snow cones	85 g.
Sugar	8 g.
Sugar substitute	An amount equivalent to one reference amount for sugar in sweetness.
Syrups	60 mL.
Vegetables:	
Vegetables primarily used for garnish or flavor, e.g., pimento, chili pepper, green onion, parsley: fresh or canned [5].	30 g.
All other vegetables without sauce: fresh, canned,[5] or frozen.	85 g.
All other vegetables with sauce: fresh, canned, or frozen.	110 g.
Vegetable juice	240 mL.
Olives [5]	15 g.
Pickles, all types [5]	30 g.
Pickles, relish	15 g.
Vegetable pastes, e.g., tomato paste.	30 g.
Vegetable sauce or puree, e.g., tomato sauce, tomato puree.	60 g.

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the USDA.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If

not listed separately, the reference amount for the unprepared form (e.g., dry mixes, concentrates, dough, batter, fresh and frozen pasta) is the amount required to make one reference amount of the prepared form.

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Label serving size for ice cream cones and eggs of all sizes will be one unit.

[5] Because this product is packed or canned in liquid, and the liquid is not customarily consumed, the reference amount is for the drained solids except for canned cream-style corn and canned or stewed tomatoes. Both the solids and liquid of canned cream-style corn and canned or stewed tomatoes are customarily consumed and therefore, the reference amount for these vegetables will be 130 g (i.e., g weight equivalent to ½ cup).

[6] Pizza sauce is part of the pizza and is not considered to be sauce topping.

(c) The reference amount of a product that requires cooking or the addition of water or other ingredients shall be the amount required to prepare one reference amount of the final product as established in paragraph (b) of this section.

(d) The reference amount for an imitation or substitute food shall be the same as that of the food for which it is offered as a substitute.

(e) The reference amount for an altered version of a food, such as a "low calorie" version, shall be the same as for the food for which it is offered as a substitute.

(f) The reference amount for products that represent two or more foods packaged and presented to be consumed together (e.g., peanut butter and jelly, cracker and cheese pack, pancakes and syrup) shall be the sum of the reference amounts for individual foods in the package.

(g) The reference amount set forth in paragraphs (b) through (f) of this section shall be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and health claims. If the serving size declared on the product label differs from the reference amount, both the reference amount and the serving size declared on the product label shall be used to determine whether the product meets the FDA criteria for a claim.

(h) The Commissioner of Food and Drugs, either on his or her own initiative or on behalf of any interested person who has submitted a petition pursuant to part 10 of this chapter, may issue a proposal to establish or amend a reference amount in § 101.12(b). A petition to establish or amend a reference amount shall include:

(1) Objective of the petition;

(2) A description of the product;

(3) A complete sample product label including nutrition label, using the format established by regulation;

(4) A description of the form (e.g., dry mix, frozen dough) in which the product will be marketed;

(5) The intended dietary uses of the product with the major use identified (e.g., milk as a beverage and chips as a snack);

(6) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(7) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(8) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(9) The suggested reference amount (the amount of edible portion of food as consumed, excluding bone, seed, shell, or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested reference amount. In determining the reference amount, general principles and factors in paragraph (a) of this section should be followed;

(10) The suggested reference amount shall be expressed in metric units. Reference amounts for fluids shall be expressed in milliliters (mL). Reference amounts for other foods shall be expressed in grams (g) except when common household units such as cups, tablespoons, and teaspoons, are more appropriate or are more likely to promote uniformity in serving (portion) sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as ready-to-eat breakfast cereals and frozen desserts.

(i) In expressing the reference amounts in mL, the following rules shall be followed:

(A) For volumes greater than 30 mL, the volume shall be expressed in multiples of 30 mL.

(B) For volumes less than 30 mL, the volume shall be expressed in mL equivalent to a whole number of teaspoons or one tablespoon, i.e., 5, 10, or 15 mL.

(ii) In expressing the reference amounts in g, the following general rules shall be followed:

(A) For quantities greater than 10 g, the quantity shall be expressed in nearest 5 g increment.

(B) For quantities less than 10 g, exact g weights shall be used.

(11) A petition to create a new subcategory of food with its own reference amount shall include the following additional information:

(i) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the reference amount for the parent category to warrant a separate reference amount. Data must include sample size; and the mean, median, and modal consumed amount per eating occasion for the petitioned product and for all products in the category, excluding the petitioned product. All data must be derived from the same survey data.

(ii) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the petitioned product from the rest of the products in the category.

(12) A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter; and

(13) In conducting research to collect or process food consumption data in support of the petition, the following general guidelines should be followed.

(i) Sampled population selected should be representative of the demographic and socio-economic characteristics of the target population group for which the food is intended.

(ii) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(iii) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(iv) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(14) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule consistent with the Negotiated Rulemaking Act (Pub. L. 101-648).

Dated: November 4, 1991.
David A. Kessler,
Commissioner of Food and Drugs.
Louis W. Sullivan,
Secretary of Health and Human Services.
[FR Doc. 91-27157 Filed 11-26-91; 8:45 am]
BILLING CODE 4160-01-M

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21 CFR Parts 5, 101, and 105

[Docket No. 91N-0384]

RIN 0905-AD08

Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing: (1) To amend its food labeling regulations to define nutrient content claims and to provide for their use on food labels; (2) to provide definitions for specific nutrient content claims that include the terms "low," "free," "reduced," "light" or "lite," "source," and "high;" (3) to provide for comparative claims using the terms "less," "fewer," and "more;" (4) to set forth specific requirements for sodium and calorie claims; (5) to establish procedures for the submission and review of petitions regarding nutrient content claims; (6) to revise 21 CFR 105.66, which covers special dietary foods with usefulness in reducing or maintaining caloric intake or body weight; (7) to establish criteria for the appropriate use of the term "fresh;" and (8) to address the use of the term "natural". FDA is addressing claims for cholesterol, fat, and fatty acid content in a separate proposal published elsewhere in this issue of the **Federal Register**. This action is part of the food labeling initiative of the Secretary of the Department of Health and Human Services (the Secretary) and in response to the Nutrition Labeling and Education Act of 1990.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may be issued based on this proposal become effective 6 months following its publication in accordance with the provisions of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0229.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

FDA has a long history of interest in prescribing label statements concerning the dietary properties of food. As early as 1940 (5 FR 1199, March 28, 1940), FDA held a hearing to discuss what label statements might be used to inform purchasers of the value that a particular food purports to have. Initially, these label statements were concerned with foods that purported or were represented to be for special dietary use by humans. While these statements focused to a large extent, but not exclusively, on vitamins and minerals, the early rulemaking also dealt with control of body weight and the value of food for use in dietary management of disease through controlling the intake of various nutrients.

By 1953 (18 FR 7249, November 14, 1953), FDA had begun to focus on specific nutrients such as sodium. The 1953 notice, for example, announced a hearing on label statements relating to certain foods used as a means of regulating the intake of sodium for the purposes of dietary management with respect to disease. On July 1, 1954 (19 FR 3999), FDA issued a final regulation recognizing that sodium restricted diets were widely used for dietary management of edema associated with some types of heart, liver, and kidney diseases; and that food purporting to be, or represented for, special dietary use in regulating the intake of sodium in dietary management should bear information concerning its sodium content.

In 1973 (38 FR 20708, August 2, 1973), FDA issued a final regulation, which was temporarily stayed and later revised, in part, as § 105.3 (21 CFR 105.3), stating that the term "special dietary use" applied to a food supplying a special dietary need that exists by reason of a physical, physiological, or other condition including convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, diabetes mellitus, or the need to control the intake of sodium. In 1978, FDA adopted regulations that defined the terms "low" and "reduced" for describing calorie content and set conditions for other label statements on special dietary foods used to reduce or maintain weight or in diabetic diets (43 FR 43278, September 22, 1978).

In the 1980s, FDA changed the focus of nutrient claims from providing guidance for the dietary management of certain diseases to providing information that is useful to the general population. In 1984, the agency adopted regulations (49 FR 15510, April 18, 1984) that defined how the terms "very low," "low," "free," or "reduced" may be used to describe the sodium content of food. In addition, in 1986, the agency proposed to define terms to describe the cholesterol content of foods (51 FR 42584, November 25, 1986).

This change in focus towards defining descriptors is in large part the result of recent scientific developments and recommendations that have emphasized the role of diet in the maintenance of health. For example, the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS) have jointly developed a set of recommendations known as "Dietary Guidelines for Americans" (Ref. 1). These recommendations, which were published in 1980 and revised in 1985 and 1990, are based on the view that the judicious selection of foods containing low or high levels of certain nutrients as part of an overall diet is prudent on the part of all consumers, not just those with special dietary needs.

In addition, two scientific consensus reports, "The Surgeon General's Report on Nutrition and Health" (1988) (Ref. 2) and the National Academy of Sciences' report "Diet and Health: Implications for Reducing Chronic Disease Risk" (1989) (Ref. 3), concluded that changes in current dietary patterns, namely reducing consumption of fat, saturated fatty acids, cholesterol, and sodium and increasing consumption of complex carbohydrates and fiber, could lead to reduced incidence of certain chronic diseases.

In the **Federal Register** of August 8, 1989 (54 FR 32610), FDA published an advance notice of proposed rulemaking (ANPRM) that announced a major initiative of DHHS to take a new look at food labeling as a tool for promoting sound nutrition for the nation's consumers. FDA asked for public comment on five areas of food labeling, including the use of descriptors such as "low" or "free" to characterize foods.

FDA received over 2,000 written comments in response to this notice, plus over 5,000 responses to a questionnaire that had been distributed by a consumer organization. Over 500 comments addressed issues related to specific descriptors. Four hundred and

fifty addressed the terms "light," "fresh," and "natural." Among those commenting, there was nearly universal agreement that these descriptors should be defined, and that FDA needed to proceed as quickly as possible to develop regulatory definitions for all descriptors that lacked definitions. Approximately 3,500 of the over 5,000 questionnaire responses also supported the need for additional descriptor definitions.

As part of this DHHS food labeling initiative, FDA also held four national public hearings, announced in the **Federal Register** of September 20, 1989 (54 FR 38806), to discuss nutrition labeling and other issues related to food labeling, such as descriptors. Some 200 people, including consumers, health professionals, trade associations and other industry representatives, and state and local health officials, testified at these hearings. In addition, 1,500 more persons participated in 50 local "consumer exchange" meetings conducted by FDA.

The comments revealed a common concern about the unregulated use of descriptors. Many comments stated that the proliferation of undefined terms had resulted in confusion for consumers and unfair competition for manufacturers. One comment stated that the terms were "meaningless in the way they are now used and are primarily used as marketing tools rather than as guides for the health conscious consumer." Food industry representatives requested flexibility in the use of descriptors, not only to allow simple content statements ("Contains X amount of sodium") but also to allow statements of nutrient reductions brought about by technological advances.

Comments also generally supported expanding existing definitions for descriptors to include a number of food components of public health significance such as fats and cholesterol. Although some comments addressed specific descriptive terms to be used on the label, few comments recommended nutrient or food component levels to qualify for descriptors. Some food industry representatives did, however, suggest criteria for "high" and "reduced" claims.

Comments from health professional organizations also supported the need for content claims to take into account the negative aspects of food in addition to the positive aspects, in order to not mislead consumers. Finally, several comments emphasized the need for FDA and USDA to be consistent in their definitions of descriptive terms.

On March 7, 1990, the Secretary, Dr. Louis W. Sullivan, announced that FDA would undertake a comprehensive, phased response to the comments on the ANPRM. In the **Federal Register** of July 19, 1990, FDA published its first set of proposals, including a tentative final rule that defined terms for use to describe the cholesterol content of foods (55 FR 29456) and a proposed rule (55 FR 29487, July 19, 1990) to require nutrition labeling on most foods that are meaningful sources of nutrients (hereinafter referred to as the mandatory nutrition labeling proposal). At the same time, FDA published a proposed rule (55 FR 29476, July 19, 1990) in which the agency updated the U.S. Recommended Daily Allowances (U.S. RDAs) used in food labeling and replaced the term "U.S. RDA" with "Reference Daily Intake" (RDI) (the RDI/DRV proposal). In the same proposal, the agency also introduced the term "Daily Reference Value" (DRV) and proposed DRVs for eight food components: total fat, saturated fatty acids, unsaturated fatty acids, cholesterol, carbohydrate, fiber, sodium, and potassium. These DRVs are based upon a reference diet of 2,350 calories, which is the population adjusted mean of the recommended energy allowances for persons 4 or more years of age (Ref. 4). Together the RDIs and DRVs are referred to as Daily Values. FDA also proposed (55 FR 29517, July 19, 1990) standardized serving sizes for categories of foods to assure reasonable serving sizes and to provide for comparison among similar products. FDA said that these serving sizes, if adopted, would ensure that claims such as "low cholesterol" were the result of the characteristics of the food and not of manipulation of the serving size. The agency stated that these standardized serving sizes will help to ensure that food label claims are not misleading to consumers.

In the fall of 1990, the Institute of Medicine (IOM) of the National Academy of Sciences, issued a report entitled "Nutrition Labeling Issues and Directions for the 1990s" (the IOM report) (Ref. 5). This report addressed, among other things, the use of descriptors on the principal display panel of food labels. The IOM report expressed concern that the unregulated use of these descriptors would nullify the efforts of consumers to make intelligent use of the factual information required on the nutrition label. The IOM report also stated that the absence of definitions for many descriptors would work to the disadvantage of manufacturers who are reluctant to use terms that distort or exaggerate nutritionally unimportant differences.

B. Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535). The 1990 amendments make the most significant changes in food labeling law since the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (the act). They strengthen the Secretary's food labeling initiative by clarifying the Secretary's (and by delegation, FDA,s) legal authority to require nutrition labeling on foods and by defining the circumstances under which claims may be made about the nutrients in foods.

Section 3 of the 1990 amendments among other things, added section 403(r)(1)(A) to the act. This provision states that a food is misbranded if it bears a claim in its label or labeling that either expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of nutrition labeling, unless such claim has been specifically defined (or otherwise exempted) by regulation.

In this document, FDA is proposing general principles and procedures to govern the use of nutrient content claims. The agency is also proposing definitions for descriptors except as they apply specifically to cholesterol, saturated fat, and total fat content. The use of descriptive terms for these nutrients, and the use of descriptive terms on standardized foods and on butter, is addressed in separate documents published elsewhere in this issue of the **Federal Register**.

In this document, the agency is also proposing procedures by which a person may petition FDA to revise these regulations, to provide for the use of new or similar descriptive terms, or to provide for the use of implied claims in brand names. It is also proposing to address certain descriptive terms that are used for purposes other than making nutrient content claims, namely "fresh," "natural," and "organic." The agency is proposing to define and provide for the proper use of "fresh," "freshly prepared," and "fresh frozen."

C. Organization of Regulations

To facilitate use of its regulations and to provide for the possibility of additional claims regulations, FDA is proposing to add Subpart D—Specific Requirements for Nutrient Content Claims to 21 CFR part 101. In so doing, FDA is proposing to redesignate current § 101.13 *Sodium labeling* as § 101.61 *Nutrient content claims for sodium content of foods* and to add a new

§ 101.13 *Nutrient content claims—general provisions.* This change will result in a more logical organization to the food labeling regulations. In addition, FDA is proposing to redesignate Subpart F as Subpart G and to add a new Subpart F—Specific Requirements for Descriptor Claims that are Neither Nutrient Content Claims nor Health Claims.

In response to section 3(b)(1)(A)(iii) of the 1990 amendments, the agency is organizing this preamble by descriptive term. However, to the extent that existing regulations are already in place or have been previously proposed, the agency is proposing to organize these regulations by nutrient. Claims for "light" or "lite" are codified separately.

II. General Principles for Nutrient Content Claims

A. Legal Basis

FDA is proposing to establish the conditions under which claims may be made about the level of a nutrient in a food (a nutrient content claim). FDA is also proposing to define various terms that may be used to make these claims. FDA, however, does not consider all terms used to describe a food as nutrient content claims. A term may describe some other attribute of a food such as freshness. Such claims would not be subject to requirements for § 101.13 *Nutrient content claims—general provisions.* FDA has authority to take these actions regarding nutrient content claims under sections 201(n), 403(a), 403(r), and 701(a) of the act (21 U.S.C. 321(n), 343(a), 343(r), and 371(a)). Those sections authorize the agency to adopt regulations that prohibit labeling that: (1) Is false or misleading in that it fails to reveal material facts with respect to consequences that may result from use of the food and (2) uses terms to characterize the level of any nutrient in a food that have not been defined by regulation by FDA.

Because the consensus reports cited above suggest that consumers adhere to certain dietary recommendations, and because comments to the 1989 ANPRM and testimony at FDA's public hearings on labeling show that consumers are concerned about, and want to adjust, their dietary intake of certain nutrients but are concerned with confusing and misleading label statements, it is important that these label statements not convey a misleading impression about the content of various nutrients in a food. Without clear definitions of the terms that describe the levels of these nutrients in food, manufacturers could use a term like "high in fiber" on products that vary widely in fiber content.

Inconsistent use of the same term on various products could lead to consumer confusion and nonuniformity in the marketplace. To ensure that consumers are not misled and are given reliable information, Congress found, and FDA agrees, that it is appropriate for the agency to establish specific definitions to standardize the terms used by manufacturers to describe the nutrient content of foods. FDA is proposing to do so in this document.

B. Scope

Under section 403(r)(1)(A) of the act, a claim that characterizes the level of a nutrient of the type required by nutrition labeling that is in a food may only be made in accordance with the regulations that FDA adopts under section 403(r)(2) of the act. FDA is incorporating this provision in proposed § 101.13(b). Among other things, such claims may only be made using terms that FDA has defined by regulation (21 U.S.C. 343(r)(2)(A)(i)) and must be made in conjunction with the appropriate labeling statements (21 U.S.C. 343(r)(2)(B)), unless they are subject to one of the exemptions in the act (21 U.S.C. 343(r)(2)(C), (D), and (E)). The remainder of this preamble and the accompanying proposed regulations fill in the details of these basic statutory requirements.

FDA is proposing in § 101.13 to prescribe the circumstances in which claims that characterize the level of a nutrient in a food may be made on a food label or in labeling (see 21 U.S.C. 343(r)(1)(A) and (r)(2)) In proposed § 101.13(a), FDA, reflecting the introductory language of section 403(r)(1) of the act, states that § 101.13 and the regulations in subpart D of part 101 apply to all foods that are intended for human consumption and that are offered for sale.

The regulation also states the types of claims that are covered. Proposed § 101.13(b), following section 403(r)(1)(A) of the act, limits the use of both express and implied nutrient content claims. The 1990 amendments do not elaborate about what constitutes an expressed or an implied claim. The legislative history, however, specifically the House report on the 1990 amendments (H. Rept. 101-538, 101st Cong., 2d sess. 19 (June 13, 1990)), states that an example of "an expressed claim covered by section 403(r)(1)(A) would be the statement 'low sodium'." Such an expressed claim makes a direct statement about the level of a nutrient, in this case sodium, in a food. Consequently, FDA is proposing in § 101.13(b)(1) that an expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food.

The House report also states that an example of an implied claim would be a statement that "implies that the product is low [or high] in some nutrient * * * but does not say so expressly." (*Id.*) The report cites two examples of implied claims: "lite," which according to the report implies that the food is low in some nutrient but does not say so expressly, and " 'high oat bran' which conveys an implied high fiber message." (*Id.*)

Although FDA is proposing a definition of "light" (or "lite") that is somewhat different than that portrayed in the House report, the agency considers that Congress' choice of the "high oat bran" claim as an example of an implied claim is significant. FDA notes that, based on this example, several other claims being used on the food label would constitute implied nutrient claims. For example, such claims as "contains no tropical oils," "contains no palm oil," and "made with 100 percent vegetable oil," convey an implied message that the product is low in, or free of, saturated fat. Therefore, FDA is proposing in § 101.13(b)(2) to define an implied nutrient content claim as any claim that describes the food, or an ingredient therein, in a manner that implies that a nutrient is absent or present in a certain amount or that may be useful to consumers in selecting foods that are helpful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy"). Significantly, if FDA adopts this definition, under the provisions of the statute, such implied claims would be prohibited until such time as they are defined by FDA by regulation.

FDA recognizes, however, that an argument can be made that statements such as "contains oat bran" are not intended to be nutrient content claims but are intended to advise consumers that oat bran is used as a significant ingredient in the product. Furthermore, a similar argument can be made that a statement that a particular ingredient constitutes 100 percent of the food (e.g., "100 percent corn oil" or "100 percent Columbian coffee) should not be considered an implied nutrient content claim when that statement is the statement of identity for the food. Moreover, FDA recognizes that this provision may raise questions about similar claims such as "contains no preservatives" or "contains no artificial flavors or colors." The agency believes that the latter claims cannot be

characterized as nutrient content claims because they do not relate in any way to nutrients of the type that are addressed in section 403(q) of the act. These claims are more appropriately characterized as ingredient claims. FDA requests comments on how to draw an appropriate line between implied nutrient content claims and ingredient claims.

In addition, because of the large variety of statements that can be considered to make implied claims about the level of a nutrient in a food or the usefulness of a food in achieving a diet that conforms to current dietary recommendations, and because of the resource constraints and strict timeframes under which this rulemaking is proceeding, FDA is not proposing to adopt regulations that authorize any implied claims at this time. However, the agency solicits comments concerning criteria for evaluating whether implied claims are appropriate and not misleading as well as information on specific implied claims.

If FDA receives sufficient information in comments, it will consider providing for specific implied claims in the final regulation. Alternatively, the agency may defer action on implied claims until after the rulemakings required by the 1990 amendments are complete. The agency would then consider individual implied claims through the petition process on a case-by-case basis. In this document, the agency is proposing procedural regulations for petitions on nutrient content claims, including those requesting definition of acceptable implied claims.

In § 101.13(b)(3), FDA is proposing to prohibit the use of nutrient content claims on food products that are specifically intended for infants and toddlers less than 2 years of age. The agency is proposing this prohibition for several reasons. Comments received in response to the 1986 proposal on cholesterol descriptors (51 FR 42584, November 25, 1986) stated that changing the diet of these children toward a more restrictive dietary pattern should await demonstration that such dietary restriction is needed and would support adequate growth and development. The agency agreed with these comments and proposed in the tentative final rule on cholesterol descriptors (55 FR 29456, July 19, 1990) to exclude the use of descriptors and quantitative cholesterol and fatty acid labeling on foods specifically intended for use by infants and toddlers. Furthermore, there is agreement among the American Academy of Pediatrics, the American Heart Association, the National Institutes of Health's Consensus Conference on Lower Blood Cholesterol and the National Cholesterol Education Program that fat and cholesterol should not be restricted in the diets of infants (Ref. 57). Relatively little attention has been given to the role of the pediatric diet in modifying the risk of other chronic diseases found in adults such as hypertension and obesity (Ref. 3). Thus, the agency lacks evidence that a more restrictive dietary pattern for other nutrients such as sodium or an increased intake for nutrients such as fiber are appropriate and recommended for infants and toddlers. Therefore, until the agency has information that such dietary patterns are appropriate for children and support adequate growth and development, FDA is proposing in § 101.13(a) that nutrient content claims may not be made on foods intended specifically for use by infants and toddlers less then 2 years of age.

The act specifically excludes statements that appear as part of nutrition information from the coverage of section 403(r)(1) of the act. This exclusion was included in the 1990 amendments to make it clear that the information required on the nutrition label, and the optional statements that are permitted as a part of nutrition labeling, are not claims under section 403(r)(1) of the act and are not subject to the disclosure requirements in section 403(r)(2) of the act (Congressional Record H5841 (July 30, 1990)). However, the legislative history of this provision specifically states that the identical information will be subject to the descriptor requirements if it is included in a statement in another portion of the label. (*Id.*) Consequently, FDA is proposing in § 101.13(c) that information that is required or permitted by § 101.9 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. Proposed § 101.13(c) also states, however, that if such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

C. Labeling Mechanics

The 1990 amendments do not include specific limits on the prominence of nutrient content claims. Although FDA recognizes the importance that certain nutrient content claims can have in encouraging sound dietary practices, it also recognizes that individual foods must be evaluated in the context of the total diet. Consequently, it is important not to overemphasize any one aspect of a single food. Therefore, FDA is proposing to require in § 101.13(f) that a nutrient content claim be, in type size and style, no larger than that of the statement of identity. The agency believes that this proposed requirement will ensure that descriptors are not given undue prominence. Under proposed § 101.13(f), descriptors that are a part of a statement of identity can be in the same type size and style as the other words in the statement of identity.

FDA is proposing this requirement under section 403(f) of the act as well as section 403(r) of the act. Section 403(f) of the act states that a food is misbranded if any statement required by or under the authority of the act is not placed on the label with such conspicuousness, as compared to other words, statements, designs, or devices, as to render it likely to be understood by the ordinary consumer. FDA believes that the requirement in proposed § 101.13(f) is necessary to ensure that importance of the information provided by the nutrient content claim, as well as that provided by the statement of identity, is fully understood by consumers. Because these two items will have at least equal prominence on the label or in labeling, the consumer will be able to judge that they both present important information that must be considered in structuring the total diet.

Section 403(r)(2)(B) of the act states that if a nutrient content claim is made, the label or labeling of the food shall contain, prominently and in immediate proximity to such claim, the following statement: "See _____ for nutrition information" (hereinafter referred to as the referral statement). Under section 403(r)(2)(B)(i) of the act, the blank must identify the panel on which the information described in the statement may be found. FDA is incorporating this requirement in proposed § 101.13(g).

Section 403(r)(2)(B) of the act requires that the referral statement must appear prominently, but it does not contain specific prominence requirements such as type size or style. However, section 403(r)(2)(A)(iii) through (v) of the act requires that statements that disclose the level of fat, saturated fat, or cholesterol, which must be presented in conjunction with certain nutrient content claims, "have appropriate prominence which shall be no less than one-half the size of the claim." The agency believes that for consistency, and because the referral statement and the statement disclosing the level of another nutrient must both be in immediate proximity to the claim, and therefore must be adjacent to one another, the type size of these statements should be the same. In

addition, FDA has long held that accompanying information should be in a size reasonably related to that of the information it modifies. This relative prominence, when codified, has been one-half the type size of the information modified (e.g., §§ 101.22(i)(2) and 102.5(b)(2)(ii)).

The agency is proposing one-sixteenth of an inch as the minimum type size for the referral statement. One-sixteenth of an inch is specified in § 101.2(c) as the minimum type size for most other mandatory information on the principal display panel or information panel, e.g., designation of ingredients, name and place of business, nutrition information, and warning and notice statements. Further, one-sixteenth of an inch is the minimum size required in § 101.105(i) for net quantity of contents statements. Consequently, the agency believes that the minimum type size for such information should be one-sixteenth of an inch.

In addition, the agency is proposing that the referral statement be "in easily legible boldface print or type in distinct contrast to other printed or graphic matter." Section 403(r)(2)(B) of the act states that the referral statement for nutrient content claims should be "prominent." In other instances where the act has suggested that information be prominent, FDA has proposed a similar requirement (see, e.g., proposed on percentage labeling of foods purporting to be beverages containing vegetable or fruit juice (56 FR 30452, July 2, 1991)). Therefore, to be consistent with previous actions and to ensure under section 403(f), that the referral statement is presented in a way that makes it likely to be read, FDA is proposing in § 101.13(a)(1) that the referral statement be presented in easily legible boldface print or type.

As stated above, the 1990 amendments require that the referral statement be in immediate proximity to the nutrient content claim. In addition, the related statements required by section 403(r)(2)(A)(iii) through (v) of the act are required to be in immediate proximity to such claims, and no distinction is made as to which statement must be closer to the actual claim. Because the related statements provide more specific information, FDA is proposing that they be presented before the referral statement.

Although there is no specific guidance given as to what constitutes immediate proximity, FDA has traditionally defined immediate proximity as immediately adjacent to, with no intervening material present. Section 101.2(e) of 21 CFR, for example, requires that there be no intervening material among the information that is required to appear on the information panel. By no intervening material, FDA means that there may be no printed matter, either pictorial or character between the two pieces of information. However, a claim may be made immediately preceding, or as part of, the statement of identity. Thus, for purposes of proposed § 101.13(g)(2), when the nutrient content claim immediately precedes or is part of the statement of identity, the statement of identity, or the non-claim part of the statement of identity, will not be considered intervening material. For example, if a product were labeled "Light cupcakes—contain ⅓ fewer calories than our regular cupcakes; see side panel for nutrition information," and no pictorial or written material intervened, the agency would consider that the related statements and the referral statement were in immediate proximity to the nutrient content claim of "light." The term "cupcakes" in this example would not be considered to be intervening material.

Section 3(b)(1)(A)(v) of the 1990 amendments states that the Secretary shall provide that if multiple claims subject to the nutrient content claim regulations are made on a single panel of the food label or page of a labeling brochure, a single statement may be made to satisfy the requirements for referral statements. To ensure that this referral statement is adequately prominent, the agency is proposing in § 101.13(g)(3) that the statement be adjacent to the claim that is printed in the largest type on the panel.

Although section 403(r)(2)(B) of the act requires that if a nutrient content claim is made, that referral statement be immediately adjacent to such claim, the agency believes that for those claims that appear more than one time on a panel, the referral statement need only be presented with the most prominent claim. To require referral statements for multiple claims on the same panel would unnecessarily burden the panel and dilute any other information presented on the panel. FDA is proposing to require that the referral statement be adjacent to the claim that is printed in the largest type because that claim is the one most likely to initially be seen by the consumer.

In addition, the agency believes that it is not necessary to include a referral statement if a claim is made on the panel containing nutrition information, because such claim would be made in view of the nutrition information cited in the referral statement. FDA is proposing to codify this provision in § 101.13(g)(2).

D. Disclosure Statements

Section 403(r)(2)(B)(ii) of the act states that if a food that bears a nutrient content claim "contains a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, the required referral statement shall also identify such nutrient." FDA is referring to this level as the "disclosure level."

The act goes even further with respect to health claims. In section 403(r)(3)(A)(ii), the act prohibits, except in special circumstances, health claims for a food if any nutrient is present in the food in an amount that increases the risk of disease or health-related condition. FDA will refer to this level as a "disqualifying level." The statutory language defining a disclosure level for a nutrient in conjunction with a nutrient content claim is the same as that for a disqualifying level for the nutrient for a health claim. Consequently, FDA is proposing the same levels for the individual nutrients for both types of claims.

In the proposed rule on health claims published elsewhere in this issue of the **Federal Register**, the agency discusses how it arrived at the various proposed disclosure/disqualifying levels. Briefly, in setting such levels, FDA considered that there are no generally recognized levels at which nutrients such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease. Therefore, if FDA were to attempt to set these levels on an individual food basis, it would not be possible to do so. However, sections 403(r)(2)(B)(ii) and 403(r)(3)(A)(ii) of the act require that the agency take into account the significance of the food in the total daily diet. For the general population, the intake of fat, saturated fat, cholesterol, and sodium in the total day's diet in excess of dietary recommendations increases the risk of diet-related disease. Therefore, because the agency's proposed DRVs for total fat, saturated fat, cholesterol, and sodium are based on recommended dietary intake levels, the agency tentatively decided to tie the disclosure/disqualifying levels to the DRVs.

To determine the appropriate disclosure/disqualifier levels, FDA used an approach based on the number of servings of food in a day and available information on food composition. As described in the health claims proposal, the agency has tentatively found that an appropriate disclosure/disqualifying

level for individual foods is between 10 and 20 percent of the DRV. The agency made this tentative finding by looking at the food supply. It noted that the nutrients fat, saturated fat, cholesterol, and sodium are present in roughly one half of the general USDA food categories. Therefore, if approximately 20 foods/beverages are consumed in a day, and half of the foods consumed contain the nutrient at a level of 10 percent of the DRV (on average), then the total daily intake of the nutrient would be 100 percent of the DRV. This level of intake would not constitute a risk for chronic disease. On the other hand, if the same number of foods are consumed, and half the foods contain on average 20 percent of the DRV, then the total daily intake of the nutrient would be 200 percent of the DRV, a level of intake that would increase the risk for diet-related disease. The agency then used food composition data to evaluate the effect of establishing various disclosure/disqualifying levels between 10 and 20 percent and tentatively concluded that a level of 15 percent of the DRV was most appropriate. If ½ of the foods consumed during a day contains on average this amount, the total daily intake of the nutrient would exceed the DRVs but without the risks inherent at higher levels. Yet, if this criterion is used, a significant number of foods would not be disqualified. Thus, FDA is proposing § 101.13(h) to establish disclosure/disqualifying levels for total fat, saturated fat, cholesterol, and sodium, and that these levels be 15 percent of the DRV per serving and per 100 grams (g) of food. These levels are 11.5 g for total fat, 4.0 g for saturated fat, 45 milligrams (mg) for cholesterol, and 360 mg for sodium.

The legislative history provides some guidance on how these disclosure statements about the presence of these nutrients should be made. It states that if FDA found, for example, that the fat in a food that bore a nutrient content claim was present at a level that increased the risk of disease or a health-related condition, then the referral statement would read, "See [nutrition panel] for information about fat and other nutrients." Congressional Record H5441 (July 30, 1990). Therefore, the agency is proposing in § 101.13(h) to require this information in the referral statement. Because the agency is proposing in § 101.13(g)(3) that if a single panel of a food label or labeling contains multiple nutrient content claims or a single claim repeated several times, a single referral statement may be made, and because § 101.13(h) only requires the disclosure statement as part of the referral statement, only one disclosure statement per panel would be required by the proposed regulation.

E. Disqualifying Levels for Nutrient Content Claims

Section 403(r)(2)(A)(vi) of the act provides that FDA can, by regulation, prohibit a nutrient content claim if the claim is misleading in light of the level of another nutrient in the food. FDA has tentatively made such a finding with regard to cholesterol claims and the presence of saturated fat. This finding is discussed in the companion document published elsewhere in this issue of the **Federal Register**. In that document, FDA is proposing to prohibit a claim for cholesterol content in foods containing saturated fat at levels above 2 g per serving.

F. Amount and Percentage of Nutrient Content Claims

Section 3(b)(1)(A)(iv) of the 1990 amendments states that the agency "* * * shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms [that FDA has defined]." In discussing this provision (which at that time was numbered as section 3(b)(1)(A)(iii)), the legislative history states:

> * * * [t]he Secretary is required, in the regulations, to define the circumstances under which statements disclosing the amount and percentage of nutrients in food will be permitted. Those statements must be consistent with the terms that the Secretary has defined under section 403(r)(2)(A)(i) [definition of descriptive terms] and they may not be misleading under section 403(a) in the current law.
>
> Thus, if the Secretary defined "low fat" as less than 1% fat for a particular category of food, the Secretary might conclude that the statement "Less Than 1% Fat" is consistent with the defined term. However, the Secretary might conclude that the statement "Less Than 2% Fat" is not consistent with the definition of "low" because it implies that the product is low in fat when it is not. Following a similar analogy, the Secretary might prohibit the statement "98% Fat Free" while permitting the statement "More Than 99% Fat Free" for a product where "low fat" has been defined as less than 1% fat.
> (Congressional Record H 5841-2 (July 30, 1990))

Like Congress, FDA is concerned that consumers may be easily misled by statements about the percent or amount of a nutrient in a product. The agency received many comments to the ANPRM asserting that statements such as "____ percent fat free" on foods are confusing and misleading. These comments suggest that many consumers do not understand this type of claim or similar claims that a product contains a specified amount of a nutrient such as "contains ____ mg sodium." Additional comments suggested that such claims be prohibited.

A statement that a food contains X percent of a nutrient implies that the food is useful in maintaining healthy dietary practices. If the level of the nutrient in the food was not in fact useful in structuring a healthy diet, the claim would be misleading. For example, claims that a food is "____ percent fat free" imply that the food has a very small amount of fat in it, and that the food is useful in structuring a diet that is low in fat. The impression that the claim gives is incorrect, however, if the food contains a significant amount of fat.

Similarly, since many consumers have a limited knowledge and understanding of the amounts of nutrients that are recommended for daily consumption, a statement declaring that the product contained a specified amount of a nutrient could be misleading. By its very presence, such a statement could give consumers who were unfamiliar with the dietary recommendations the false impression that the product would assist them in maintaining healthy dietary practices relative to the amount of the nutrient consumed when it, in fact, would not. Consistent with the statute, FDA is proposing not to permit the use of claims that state the percent or amount of a nutrient in those circumstances in which they would be misleading and thus would misbrand the product.

The agency believes that foods bearing such claims must be useful in maintaining healthy dietary practices for the claims not to be misleading. Accordingly, in § 101.13(i), the agency is proposing that foods bearing statements about the amount or percentage of a nutrient in a food must meet the definition for "low" in the case of fat, saturated fat, sodium, and calories and "high" for fiber, vitamins, and minerals, and other nutrients for which that term is defined. These definitions are discussed below, in the regulations for the particular nutrients.

G. Nutrition Labeling

Although the 1990 amendments establish that most foods will bear nutrition labeling, some foods are exempt from these requirements. In addition, there are provisions that permit some foods to bear an abbreviated form of nutrition information.

Under current § 101.9, nutrition labeling is required on all products that contain an added vitamin, mineral, or protein or whose label, labeling, or advertising includes any nutrition claim or information. The agency derived its authority to issue regulations to require this nutrition labeling on all foods bearing a claim for added vitamins, minerals, or protein from sections 201(n), 403(a)(1), and 701(a) of the act (21 U.S.C. 321(n), 343(a)(1), and 371(a)). Under section 201(n) of the act, the label or labeling of a food is misleading if it fails to reveal facts that are material in light of representations actually made in the label or labeling. Under section 403(a)(1) of the act, a food is misbranded if its label or labeling is false or misleading in any particular. Finally, under section 701(a) of the act, the agency has authority to issue regulations for the efficient enforcement of the act.

The agency is proposing in § 101.13(m) that a nutrient content claim may be used on the label or in labeling of a food provided that the food bears nutrition labeling that complies with the requirements in § 101.9 or, where applicable, § 101.36.

The applicability of current regulations to restaurant foods was discussed in rulemaking promulgating § 101.10 *Nutrition labeling of restaurant foods* (39 FR 42375, December 5, 1974 and 41 FR 51002, November 19, 1976). In the preamble to the proposed rule, the agency discussed its belief that nutrition education is of prime importance and stated that it will take every opportunity to foster the dissemination of such information to the consumer, including the use of nutrition labeling in restaurants. However, the agency acknowledged that if nutrition information provided in restaurants necessitates the expense of nutrition labeling, the restaurant "may choose not to provide any nutrition information in advertising or labeling, on the basis that the added cost of providing detailed information * * * might cause the project of providing nutrition information not to be worth the expense" (39 FR 42375). Therefore, to encourage the dissemination of nutrition information in the food service industry, FDA proposed to exempt ready-to-eat foods from the requirement of bearing nutrition labeling on food labels if the required nutrition labeling was displayed prominently on the premises by other means, e.g., counter cards or wall posters, where the information would be readily available to the consumer when he is making a menu selection.

Subsequent action on this proposal led to the issuance of a statement of policy in § 3.207 (recodified as 21 CFR 101.10 in the **Federal Register** of March 15, 1977 (42 FR 14302)) that if any advertising or labeling (other than labels) includes a claim or information about the total nutritional value of a combination of two or more foods (e.g., a combination consisting of a hamburger, french fries, and milkshake), then, as an alternative to providing nutrition information about each separate food on the food label, the restaurant may instead provide information about the total nutritional value of the combination of foods, provided that the statement of total nutritional value follows the nutrition labeling format and provided that the nutrition information is effectively displayed to the consumer both when he/she orders the food, and when he/she consumes the food.

As discussed in the supplementary nutrition labeling proposal published elsewhere in this issue of the **Federal Register**, the 1990 amendments specifically exclude restaurant foods and foods sold in other establishments in which food that is ready for human consumption is sold (hereafter "restaurant food") from the requirement for nutrition labeling. However, as stated above, the agency believes that it has the authority to issue regulations requiring restaurants that choose to make nutrient content claims to adhere to the requirements for such claims, including nutrition labeling.

FDA is not, at this time, making any specific provisions for the nutrition labeling of restaurant foods. FDA specifically seeks comment on how it should handle this issue. On one hand, many believe that it is important that consumers be given useful and meaningful nutrition information. On the other hand, many continue to be concerned, as FDA was in 1974, that the cost of compliance not be so high that restaurants will not be willing to offer and identify through nutrient content claims those foods that will assist consumers in selecting diets that provide health benefits. Therefore, the agency is requesting comments on whether and to what extent it has a basis for nutrition labeling when nutrient content claims are made on restaurant foods, or whether a requirement for such labeling would discourage restaurants from making nutrient content claims because of the cost associated with nutrition labeling.

If, based on comments received, FDA were to require nutrition labeling of restaurant foods, should the requirement apply only to large restaurant chains with fixed menu items? Additionally, should the content or format of nutrition labeling be different for the food service industry than for packaged foods? If so, how and why?

FDA recognized in its July 19, 1990 reproposal on mandatory nutrition labeling (55 FR 29504) that certain restaurant-type food service facilities cannot reasonably be expected to provide information concerning nutrient profiles, and that exemptive provisions should be established for such situations. The proposal advised that comments pointed out that nutrition labeling for foods served in restaurant-type facilities present significant feasibility problems in a number of situations. The comments made the following points: These facilities may not be able to develop consistent nutrient information on the foods that they sell because of frequent menu changes and variations in how the consumer wants the food prepared and served. Without nutrient consistency, frequent nutrient analyses would have to be performed to provide consumers with accurate nutrition labeling information. These analyses could become very burdensome. The cumulative costs of these analyses could place undue restrictions on some establishments. Firms could be inhibited from making frequent menu changes or forced to limit the options that consumers have in ordering a food.

Because of these problems, FDA proposed an exemption under section 201(n), 403(a), and 701(a) of the act for restaurant-type foods in the mandatory nutrition labeling proposal (see proposed § 101.9(h)(2), 55 FR 29516). Although the agency wanted to limit the exemptions to only those situations in which it is needed, FDA did not, and still does not, have sufficient indepth knowledge of the food service industry to develop adequate criteria to fairly impose such a limitation. The agency therefore requests comments on this issue.

A related question is what is to be done with § 101.10. Because § 101.10 was adopted under section 403(a) of the act, it is not subject to State enforcement under section 307 of the act. For this reason, and because § 101.10 has not been enforced by FDA, the agency believes that it is appropriate to make an affirmative statement about the continuing need for this provision. Thus, if FDA elects not to make restaurant labeling part of the Nutritional Labeling Education Act implementation, the agency will, in the final rule, delete § 101.10.

H. Analytical Methodology

The agency has proposed analytical methodology for measuring levels of nutrients in foods in the supplementary nutrition labeling proposal published elsewhere in this issue of the **Federal Register**. FDA is proposing in § 101.13(n) to use the analytical methodology specified in the final rule based on that proposal to determine compliance with the requirements for nutrient content claims.

I. Exemptions

The 1990 amendments provide certain exemptions from the requirements for nutrient content claims. These are discussed below.

1. Claims in a Brand Name

Section 403(r)(2)(C) of the act states:

Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).

Paragraph (a) that provision refers to is section 403(a) of the act which states that a food is misbranded if its labeling is false or misleading in any particular.

In discussing section 403(r)(2)(C), the House report states:

Section 403(r)(2)(C) states that section 403(r)(2)(A) does not apply to claims contained in a brand name that was in use before October 25, 1989 (the date the Subcommittee reported the bill). However, if the brand name contains a term that has been defined by the Secretary pursuant to section 403(r)(2)(A)(i), then it must comply with that definition. The disclosure provisions in section 403(r)(2)(B) will also apply to brand names. In addition, section 403(a) of that constitute false and misleading labeling, irrespective of whether the brand name was exempt under this provision.
(H. Rept. 101–538, *supra*, 20.)

Thus, manufacturers may continue to use brand names that include nutrient content claims that have not been defined by regulation so long as these claims appeared as part of a brand name before October 25, 1989 and are not false or misleading. Section 403(r)(2)(B) of the act, which requires the nutrition information referral statement, does apply to foods whose brand name includes such claims. Consequently, the labeling of products whose brand name includes such terms will have to bear an appropriate referral statement.

Accordingly, the agency is incorporating the provisions of section 403(r)(2)(C) of the act into its proposed regulations. Proposed § 101.13(o)(1) states that nutrient content claims not defined by regulation, appearing as part of a brand name that was in use prior to October 25, 1989, may be used on the label or in labeling of a food, provided they are not false or misleading under section 403(a) of the act.

2. "Diet" Soft Drinks

Section 403(r)(2)(D) of the act creates an exception from the requirement that a term may be used only in accordance with the definitions established by FDA for the use of the term "diet" on soft drinks, provided that its use meets certain conditions. First of all, the claim must be contained in the brand name of such soft drink. Secondly, the brand name must have been in use on the soft drink before October 25, 1989. Finally, the use of the term "diet" must have been in conformity with § 105.66. The act provides, however, that the claim remains subject to section 403(a) of the act, in that it would misbrand the food if it is false or misleading in any way.

Accordingly, the agency is proposing in § 101.13(o)(2) that if the claim of "diet" was used in the brand name of a soft drink before October 25, 1989, in compliance with the existing § 105.66, the claim may continue to be used. Any other uses of the term "diet" must be in compliance with amended § 105.66 and the other provisions of the part.

3. Vitamins and Minerals

Section 403(r)(2)(E) of the act states:

Subclauses (i) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.

Accordingly, the agency is proposing in § 101.13(o)(3) to permit the use of statements on the label or in labeling of a food that describe the percentage of a vitamin or mineral in relation to the RDI as defined in § 101.9, without specific regulations authorizing claims for each specific vitamin or mineral. The agency is proposing to permit such claims unless they are expressly prohibited by regulation under section 403(r)(2)(A)(vi) of the act.

4. Infant Formulas and Medical Foods

Section 403(r) of the act does not apply to infant formulas subject to section 412(h) of the act (see section 403(r)(5)(A) of the act) or to medical foods as defined in section 5(b) of the Orphan Drug Act. Section 412(h) applies to any infant formula that is represented and labeled for use by an infant who has an inborn error of metabolism or a low birth weight or who otherwise has an unusual medical or dietary problem. Under section 5(b)(3) of the Orphan Drug Act:

[t]he term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

FDA is presenting its views on what constitutes a medical food in its supplementary proposal on mandatory nutrition labeling, which was published elsewhere in this issue of the **Federal Register**.

Therefore, under section 403(r)(5)(A) of the act, nutrient content claims can be made on foods formulated to meet the unique medical requirements of certain individuals even though FDA has not defined the terms in those claims by regulation. The agency is proposing to reflect this fact in § 101.13(o)(4).

As discussed above, FDA has tentatively concluded that all nutrient content claims are inappropriate for use on the labels of food intended specifically for use by infants and toddlers less than 2 years of age. Therefore, if this proposal is adopted, nutrient content claims will not be permitted on most infant formulas. The agency recognizes, however, that the labels of certain formula products carry statements such as "with added iron" or "low iron." Such statements are already permitted under § 107.10(b)(4), issued under the authority of section 412 of the act.

5. Restaurant Foods

Section 403(r)(5)(B) of the act states:

Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

Section 403(r)(2)(A)(iii) through (v) of the act set forth certain labeling requirements and restrictions for foods bearing claims about cholesterol, saturated fat, and fiber. Section 403(r)(2)(B) of the act requires that the referral statement be on all foods that bear nutrient content claims. Although early versions of the bill that became the 1990 amendments exempted restaurant food from virtually all of the requirements for nutrient content claims, the statute, as it was passed, does not. As the legislative history states:

* * * Restaurants that use content descriptors in connection with the sale of food (for example, the use of the word "light" or "low. on a menu) must comply with the regulations issued by the Secretary under 403(r)(2)(A)(i). Restaurants would also be prohibited from stating the absence of a nutrient in food unless they complied with section 403(r)(2)(A)(ii). However, restaurants would be exempt from the disclosure requirements [listed above].
(Congressional Record H5841 (July 30, 1990).

Therefore, the agency is proposing in § 101.13(o)(5) that if a nutrient content claim is used for food that is served in restaurants or other establishments in which food is served for immediate human consumption, or for food that is sold for sale or use in such establishments, the claim must be used in a manner that is consistent with the definition that FDA has adopted. However, the agency is also proposing to provide, under section 403(r)(5)(B) of the act, that such claims are exempt from the requirements for disclosure statements in proposed §§ 101.13 (g) and (h), 101.54(d), 101.62(c), (d)(1)(ii)(C), (d)(2)(ii)(C), (d)(3), (d)(4)(ii)(C), and (d)(5)(ii)(C).

6. Standards of Identity

Section 403(r)(5)(C) of the act states that nutrient content claims that are made with respect to a food because the claim is required by a standard of identity issued under section 401 of the act shall not be subject to section 403(r)(2)(A)(i) or (2)(B) of the act. Thus, a nutrient content claim that is part of the common or usual name of a standardized food may continue to be used even if the use of the term in the standardized name is not consistent with the definition for the term that FDA adopts, or if FDA has not defined the term. Moreover, the label of the standardized food would not need to bear a statement referring consumers to the nutrition label.

It is clear, however, that Congress did not intend section 403(r)(5)(C) of the act to imply in any way that any new standards issued under the act would be exempt from the provisions for nutrient content claims in part 101. Rather, Congress intended that this exemption would apply only to nutrient content claims made in the names of existing standards of identity. The House Report states:

This exemption was necessary only because of the pre-existing standards for identity. To the extent that those standards provided definitions of content claims that are different from the definitions in the regulations issued by the Secretary under the bill, one basic purpose of the bill will be partially undermined. The Secretary has the authority to correct this problem by amending the portions of the standards of identity pertaining to food labels to conform with the regulations issued under section 403(r).
(H. Rept. 101-538, *supra*, 22.)

Therefore, the agency is proposing in § 101.13(o)(6) that nutrient content claims that are part of the name of a food that was subject to a standard of identity on November 8, 1990, the date of enactment of the 1990 amendments, are not subject to the requirements of § 101.13(b), (g), and (h) or to the definitions in subpart D of part 101. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposal on the use of nutrient content claims and terms that are defined in standards of identity to name new foods.

7. Use of Terms Defined in Response to Petitions

Sections 403(r)(4)(A) (ii) and (iii) of the act authorize the agency to permit the use of certain types of claims in response to a petition, without requiring that the agency grant such approval by regulation. The claims covered by these sections are those made by use of a term that is consistent with a nutrient content claim defined by the agency, i.e., a synonym, or by an implied claim made as part of a brand name. The act sets forth specific timeframes and procedures for FDA's handling of these petitions, which FDA is proposing to codify.

As discussed below in section IV, FDA intends to list any approved synonyms in the regulation defining the underlying nutrient content claim. The regulations will be updated in the annual issuance of the CFR. On the other hand, because brand name approvals apply to individual firms, the agency intends to retain a separate, publicly available list of approved implied nutrient content claims that may be made as part of a brand name.

The agency is proposing in § 101.13(o)(7) to recognize approved implied claims made as part of a brand name (e.g., "healthy") as exceptions to the general requirement in § 101.13(b) that terms used in a nutrient content claim be defined by regulation.

III. Definition of Terms

A. General Approach

1. Use of Reference Daily Intakes and Daily Reference Values in Formulating Definitions

In a proposed rule related to nutrition labeling (55 FR 29476, July 19, 1990), FDA updated and revised the U.S. RDAs used in food labeling and proposed to replace the term "U.S. RDA" with "RDI." In the same proposal, the agency also introduced the term "DRV" and proposed DRVs for eight food components. The proposed DRVs for total fat, saturated fatty acids, unsaturated fatty acids, carbohydrates, and fiber are based upon a diet of 2,350 calories, which is the population-adjusted mean of the recommended energy allowance for persons 4 or more years of age, as calculated based on the 10th edition of the "Recommended Dietary Allowances" (Ref. 4). The DRVs for sodium, potassium, and cholesterol are, however, independent of calories. Throughout this notice, the term "calories" is used instead of the more precise term "kilocalories" because of consumer familiarity with the former term.

With the exceptions of the term "sugars free" and terms related to caloric levels in foods, the agency has limited the proposed definitions to nutrients for which there are proposed DRVs or RDIs. This approach has the advantage of linking nutrient content claims to established reference values, thereby providing a consistent and quantitative basis for defining terms. Additionally, because these reference values were determined using established scientific reports, such as the "Recommended Dietary Allowances" (Ref. 4) as well as recognized consensus reports and dietary recommendations such as the "Surgeon General's Report on Nutrition and Health" (Ref. 2), "Diet and Health: Implications for Reducing Chronic Disease Risk" report (Ref. 3), and "Dietary Guidelines for Americans" (Ref. 1), claims are limited to essential nutrients and nutrients of public health significance.

2. Criteria for Definitions of Terms

a. Serving size to evaluate nutrient content claims. FDA proposed standardized serving sizes for categories of foods in a proposed rule (55 FR 29517, July 19, 1990) to assure reasonable serving sizes and to provide for comparison among similar products. FDA said that these serving sizes, if adopted, would ensure that claims, such as "low cholesterol," were the result of the characteristics of the food and not manipulation of the serving size. The agency stated that these standardized serving sizes would help to ensure that food label claims are not misleading to consumers.

In the 1990 serving size document, FDA proposed that for any container with more than one serving, the proposed standard serving size would be used to determine the appropriateness of a nutrient content claim. For containers identified as a

single-serving containing 100 percent or less of the standard serving size, the agency proposed to evaluate the label claims based on the standard serving size. However, for single-serving containers containing more than 100 percent but 150 percent or less of the standard serving, the agency proposed to evaluate the claim on the basis of the entire content of the package.

A majority of comments on FDA's proposal supported the proposed basis for evaluating the appropriateness of a nutrient content claim. However, many food industry and trade organization comments objected to the proposed evaluation criteria. Such comments generally stated that the standard serving size, not the package content, should be used to evaluate nutrient content claims on all types and sizes of packages. Manufacturers pointed out that under the 1990 proposal on serving size, the same food product that could be labeled as "low sodium" on the basis of the standard serving size might not qualify for a "low sodium" claim when packaged in a single-serving container containing between 100 percent and 150 percent of the standard serving. For example, an 8 fluid ounce (fl oz) container of skim milk containing 126 mg of sodium would meet the criteria for a "low sodium" claim, but a 10 fl oz container of the same milk containing 158 mg of sodium would not.

Because of the complexity of the issues with respect to serving size and the need to obtain additional public comment on the impact of the 1990 amendments and the IOM report (Ref. 5) on this subject, FDA announced a public meeting to discuss issues related to serving size determination (56 FR 8084, February 26, 1991). In the notice of the public meeting, FDA asked for comments about the role that serving size should play in defining nutrient content claims and asked for data to support any views presented. The public meeting was held on April 4, 1991, and provided opportunity for both oral and written comments.

In comments for this meeting, a manufacturer suggested that FDA establish reference serving sizes, and that both the reference serving size and the serving size declared on the label be used to evaluate the compliance with FDA criteria for nutrient content claims. The agency believes that this suggestion is a reasonable approach to regulating the use of nutrient content claims not only on single-serving containers but also on all other products when the serving size declared on the label differs from the reference standard (e.g., products in discrete units such as muffins). Therefore, in the agency's reproposal on serving sizes, published elsewhere in this issue of the **Federal Register**, FDA has set forth reference amounts customarily consumed per eating occasion (reference amounts) for 131 food product categories (§ 101.12(b)). In accordance with provisions of the 1990 amendments that require label serving sizes to be expressed in common household measures, proposed § 101.9(b)(2) in the same document provides procedures for manufacturers to use in converting the reference amounts, generally in metric measures, to label serving sizes most appropriate for their specific products.

In proposed § 101.12(g) of that document, FDA is proposing that, if the serving size declared on the product label differs from the reference amount listed in proposed § 101.12(b), both the reference amount and the serving size declared on the product label be used in determining whether the product meets FDA criteria for nutrient content claims as set forth in proposed subpart D of part 101.

Consistent with proposed § 101.12(g), FDA is proposing for nutrient content claims that all per serving criteria (e.g., 2 mg or less per serving for "cholesterol free" claims) will apply to the serving size declared on the product label and, where the label serving size and the reference amount differ, to the reference amount as well. Therefore, taking the preceding requirements and using skim milk as an example, the proposed reference amount customarily consumed for all beverages is 240 milliliters which is equivalent to 8 fl oz. When considering an 8 fl oz container, the reference amount and the label serving size are the same. Eight fl oz of milk contain 126 mg of sodium, and because the proposed definition for "low sodium" is 140 mg or less, the container could bear a "low sodium" claim.

However, when considering a 10 fl oz container, the label serving size is larger than the reference amount. Ten fl oz of skim milk contain 158 mg of sodium, an amount exceeding the definition for "low sodium." Therefore, while the amount of sodium in the reference amount of skim milk is within the definition, the amount of sodium in the labeled serving size is not. Hence, if this proposed rule is adopted, the 10 fl oz container could not bear a "low sodium" claim.

While acknowledging the different treatment resulting from this approach, FDA tentatively concludes that it would be misleading to allow claims based only on the reference amount since, particularly with single-serving containers, the consumer would be expected to consume the entire labeled serving size. Likewise, it would also be misleading to allow claims based only on the labeled serving size. If claims were defined in this way, manufacturers could manipulate serving sizes so that their products could bear a claim.

In proposed subpart D of part 101, the agency is specifically providing that the quantitative criteria must be met "per label serving size and per reference amount customarily consumed." Rather than complicating the discussions concerning proposed quantitative amounts in this preamble, however, FDA will abbreviate "per label serving size and per reference amount customarily consumed" as "per serving."

The agency had also considered as an alternative approach, defining nutrient content claims based solely on the amount of the nutrient in a specific amount of food, such as the amount of nutrient per 100 g of food. This approach has the advantage of presenting a nutrient content claim for a food in a way that is more consistent with labeling used internationally, and it may allow consumers a method to more readily compare very dissimilar foods. However, FDA does not believe that this approach alone is appropriate for the initial definition of descriptors. Foods vary greatly in weight or density and are consumed in various amounts depending upon their nature and use in the diet. The agency believes that content claims for certain nutrients, fat for example, could be misleading and not useful to consumers when applied equally to 100 g of nuts and to 100 g of spinach. Therefore, FDA decided to not propose the amount of nutrient per specified weight of food as the primary basis for evaluating nutrient content claims, but as discussed in the following section, the agency will consider a weight-based criterion to preclude claims attributable only to small serving sizes.

b. *Need for criterion based on a designated weight.* After reviewing comments received in response to the 1989 ANPRM as well as analyses of food composition, FDA has tentatively concluded that in some cases an additional criterion to the amount of nutrient per serving is needed to prevent claims from being misleading. The use of a criterion based on a serving is generally appropriate, but for a certain limited number of foods with small serving sizes, the use of the serving size criterion alone would allow claims on foods that are dense in a nutrient on a per weight basis but that have such small serving sizes that the food

qualifies for a content claim. For example, butter and some margarines contain 110–140 mg sodium per serving but contain as much as 900 mg per 100 g of food. The agency considers this situation to be problematic because some of these foods may be consumed frequently during the day and, thus, ultimately make significant contributions to the diet despite their purporting to be limited in a particular nutrient. Furthermore, such claims may be counterproductive relative to educating consumers about the nutrient quality of foods.

The use of an additional criterion based on the amount of a nutrient per specified weight of food is consistent with FDA practice. As provided in current § 105.66(c), the agency has used an additional criterion based on a designated weight of food (i.e., 1 g) for the term "low calorie." Recent analyses of available information on composition (modification of USDA's Nutrient Data Base, Standard Reference Release 9 (Ref. 6)) conducted by FDA indicate that for nutrients other than calories, there are foods that would meet a "low" criterion for amount per serving but still, on a weight basis, contain a substantial amount of the nutrient (Ref. 7). For example, assuming the use of a definition of "low fat" as less than or equal to 3 g per serving, a dessert topping that contains approximately 2 g of fat per serving would meet the definition of "low fat," but contains as much as 25 g of fat per 100 g of food.

Therefore, the agency is proposing to require that the definition of certain descriptors include an additional criterion based on the amount of nutrient per specified weight of food, specifically per 100 g of food. (For an instance in which the agency is not proposing to use this criterion, see the discussion of "low saturated fat" in the companion document on fat, saturated fat, and cholesterol claims.) while the agency has tentatively concluded that a weight-based criterion is not an appropriate criterion when used alone, in conjunction with the per serving criterion it helps to preclude the possibility of misleading claims attributable to small serving sizes alone.

Despite the agency's previous proposal to require an additional criterion based on percent dry weight for terms related to fat descriptors (55 FR 29456), FDA is not proposing to include percent dry weight as an additional criterion for any descriptor. Comments received by the agency in response to the 1989 ANPRM, at the public hearings on the ANPRM, and in response to the tentative final rule on cholesterol descriptors have persuaded FDA that the use of percent dry weight as an additional criterion would prevent the use of certain descriptors (e.g., "low fat") on foods such as salad dressings modified to be low in fat as well as on certain vegetables that surpass the criterion established using percent dry weight because of high water content. For instance, a radish contains 0.5 g of fat per serving and 0.5 g of fat per 100 g of food (Ref. 7). However, on the basis of percent dry weight it contains 10 g per 100 g of dry matter (Ref. 8). The agency, therefore, is not proposing to include a percent dry weight criterion in the definition of any nutrient content claim.

c. *Additional criteria.* FDA also is proposing to include additional elements in the definitions of certain specific claims in response to section 403 (r)(2)(A) of the act. For instance, the agency is proposing in the companion document on fat, saturated fat, and cholesterol descriptors to limit cholesterol content claims based on the amount of saturated fat present in the food (e.g., proposed § 101.62(d)(1)(i)(8)). These additional criteria will be discussed in conjunction with the individual claims.

3. Need for Consistency of Terms and Limited Number of Terms

In reviewing the requirements of the 1990 amendments, the agency has given considerable attention to the apparent need to develop a system of nutrient content claims that: (1) Is consistent in definitions, (2) is in keeping with public health goals, (3) can be used by consumers to implement dietary recommendations. Over the years, FDA has stressed the importance of consistent definitions and descriptive terms as a necessary requirement for effective education and for preventing misleading labeling (Ref. 9). The definition of more terms than is necessary to convey the qualities or characteristics of a food relative to dietary recommendations has the potential to increase the difficulty of educating the public about the meaning and interpretation of nutrient content claims and could result in food labels that are needlessly confusing to consumers. An approach that limits the number of defined terms is consistent with that advocated by a report of the Committee on the Nutritional Aspects of Food Standards, International Union of Nutritional Sciences (IUNS) (Ref. 10), which stated that caution should be exercised to constrain the number of descriptors that are considered desirable. The IUNS Committee questioned the wisdom of more detailed descriptors because of the difficulties of consumer understanding of a plethora of such terms.

Additionally, as suggested by the IOM report on nutrition labeling (Ref. 5), the use of consistent and targeted content claims increases consumers' confidence in the validity of the claim. Consumer discussions that occurred as part of focus group activities recently conducted by the agency (Ref. 11) revealed that the current plethora of terms has caused consumers to conclude that nutrient content claims are not so much targeted claims intended to be used in selecting foods to meet dietary recommendations as they are merely marketing techniques used by the manufacturer to get the consumer's attention and to sell a product. In these discussions, consumers stated that the frequent use and the number of terms currently appearing on food labels can result in "overload" and cause them to be skeptical of the validity of the statement.

Alternatively, some have argued that flexibility in the use of terms facilitates consumer understanding by attracting attention to the message being delivered. In addition, this argument suggests that more defined terms or flexibility to use various terms to convey nutritional information encourages competition among products and fosters nutritional improvements in products. The agency solicits comment on how it can balance those goals of consumer understanding and competition.

4. Synonyms

As discussed above, section 403(r)(2)(A)(i) of the act states that a nutrient content claim must be defined by regulation. In addition, section 3(b)(1)(A)(ix) of the 1990 amendments provides that those regulations may include similar terms commonly understood to have the same meaning. Although the agency does not have a comprehensive list of such terms that are actually in use, some synonymous terms have been suggested. Some have argued that the use of these terms defined by other label information, will be useful to industry as well as consumers.

In a letter of May 10, 1991 (Ref. 12), the Grocery Manufacturers of America, Inc. (GMA) submitted a list of synonyms that it considered to be illustrative of the type of synonyms that could be used. The GMA list is set forth below for comment.

No

free
meaningless
never a ____ (bit, trace, etc.)

none
not a ____ (bit, trace, etc.)
not any
zero

Very Low

dab	pinch
dash	slight
hardly any	smidgen
inconsequential	tinge
insignificant	tiny
meager	touch
minimum	trifling
negligible	trivial
next to nothing	very little

Low

few	short
little	small

Significant

added	goodness
consequential	important
enhanced	meaningful
enriched	sizeable
fortified	source
good source	supplemental

High

intense	major
loaded	rich
lots	

Very High

chief	predominant
excellent	preeminent
fantastic	super
finest	superior
great	terrific
outstanding	

On the other hand, as stated above, the IOM has raised concerns that the proliferation of synonymous terms on food labels will be confusing to consumers who may believe that there are differences among the terms. Accordingly, and because of agency resource constraints and the strict timeframes under which this rulemaking is being issued, FDA is only providing for similar terms for those descriptors that refer to absolute values such as "free" in these regulations. However, if information submitted in comments substantiates that authorizing a number of synonyms will be useful and not misleading, FDA will include a range of synonymous terms in the final regulations. In addition, petitions requesting permission to use specific synonymous terms may be submitted after the procedural regulations proposed in this document become effective.

B. Terms Describing the Level of a Nutrient

1. "Free"

a. *Backaround.* Nutrient content claims, that a nutrient is absent from a food, have historically been considered to have the most relevance for persons on strict therapeutic diets. The agency is of the opinion that the inclusion of such foods as part of a total daily diet would be useful to consumers attempting to limit their intake of certain nutrients in accordance with dietary recommendations. Furthermore, FDA believes that the ability to make claims describing a product as "free" of a particular nutrient would provide an incentive to manufacturers to make available alternative foods that will be helpful in meeting dietary recommendations. Finally, under section 3(b)(1)(A)(I) of the 1990 amendments, FDA is required to define the term "free," unless it finds that use of the term would be misleading.

The comments that FDA has received in response to the proposals that it has issued over the years to define the term "free," as well as in response to the 1989 ANPRM, have generally supported the use of this term in nutrient content claims. The IOM report on nutrition labeling, while not recommending a specific definition for this term, discussed its meaning in the overall context of nutrition labeling efforts and did not recommend against its inclusion as a nutrient content claim (Ref. 5). The IUNS Committee suggested that the term "free" was useful, and that the definition should be based on assuring the public that the food contributes truly insignificant amounts of the component to the diet (Ref. 10). Internationally, several countries including Canada have established definitions for nutrient free claims, including claims for calories and sodium.

The agency is therefore proposing to define "free" for the following nutrients: total fat, cholesterol, sodium, sugars, and calories. FDA is proposing definitions for "free" for these nutrients because limiting the amounts of these nutrients in the diets of many individuals is of public health importance (Refs. 2 and 3). The terms "fat free" and "cholesterol free" are defined in the companion proposal published elsewhere in this issue of the **Federal Register.**

b. *Statutory limitations on circumstances in which an absence ("free") claims may be made.* For a food to be labeled as a [*nutrient*] free [*product*], under section 403(r)(2)(A)(ii)(I) of the act, the nutrient must usually be present in the food or in a food that substitutes, as that term is defined by the Secretary (and by delegation, FDA), for the food. Under this provision, an appropriate absence claim would be "sodium free Italian bread" because Italian bread usually contains salt. In addition, beaten, frozen whole egg substitutes can be labeled as "cholesterol free." Although these products inherently contain no cholesterol, they have been formulated for use in cooking as a substitute for beaten whole eggs, which do contain cholesterol.

FDA recognizes, however, that there may be some confusion as to the circumstances in which one food mav be considered to substitute for another food. Therefore, in § 101.13(d), FDA is proposing to define when one food may be considered to substitute for another.

FDA is proposing that a substitute food is one that is used interchangeably with another food that it resembles in its physical characteristics (e.g., organoleptic properties and physical attributes) and in its performance characteristics (functional properties such as cooking and shelf life). Although FDA recognizes that substitute foods, such as substitutes for beaten whole eggs, may not be identical to the food for which they are a substitute, it believes that they should bear a substantial resemblance to that food and be able to be used like that food. (Substitutes for beaten whole eggs resemble beaten whole eggs and can be used in cooking like beaten eggs.) To the extent that a substitute food does not have the characteristics of the food for which it substitutes, FDA believes that that difference must be declared on the label or in the labeling of the substitute food, adjacent to the most prominent claim as defined in § 101.13(j)(2)(ii). FDA is proposing to require that this declaration be made in proposed § 101.13(d)(1).

For example, some foods with altered fat content cannot be used in cooking. The disclaimer would, therefore, state, adjacent to the most prominent claim, "Not for use in cooking." The agency tentatively concludes that information about such a difference is material under section 201(n) of the act because it bears on the consequences that may result from the use of the food, and that the substitute would be misbranded under section 403(a) of the act if the difference is not declared. To ensure that the disclaimer is presented with appropriate prominence, the agency is proposing in § 101.13(d)(2) that it be in easily legible print or type, no less than one half the size of the descriptive term (see section II.C. above).

In addition, the substitute food should not be nutritionally inferior, as defined in § 101.3(e)(4), to the food for which it substitutes. However, some foods, to meet the definition of the descriptive term for a particular nutrient, may be nutritionally inferior. Under § 101.3(e), these foods must be labeled as "imitation" foods. FDA believes that identifying imitation foods that meet the

descriptor definition may provide a benefit to the consumer, even though they are nutritionally inferior. Therefore, FDA tentatively concludes that such foods should be allowed to bear the appropriate nutrient content claim as long as they are appropriately labeled.

Section 403(r)(2)(A)(ii)(II) of the act states that absence (i.e., "free") claims may be made for foods if FDA allows such claims based on a finding that the claim would assist consumers in maintaining healthy diets, and the claim discloses that the nutrient is not usually present in the food.

FDA believes that highlighting that a food is free of a nutrient can help consumers maintain healthy dietary practices whether the food is inherently free of that nutrient or is processed to be that way. Furthermore, FDA surveys have shown that consumers want nutrient content claims and use them in making food selections, and that many respondents reported difficulty in understanding the quantitative information presented in nutrition labeling (Ref. 13). In addition, descriptive terms that highlight positive nutritional attributes (such as "fat free") help to educate consumers on the intrinsic properties of foods (Refs. 14 and 15). FDA believes that the definitions in this proposed rule respond to consumers' needs. Therefore, FDA has tentatively concluded that it is not necessary to limit absence or "free" claims to foods in which the nutrient is usually present or that substitute for foods that usually contain the nutrient.

However, the unqualified use of the term "free" on foods that are inherently free of a nutrient can be misleading because such terminology would imply that the food has been altered or specially processed or formulated to reduce the nutrient as compared to other foods of the same type. Accordingly, FDA is proposing for calories in § 101.60(b)(1)(ii) and for sodium in § 101.60(b)(1)(ii) to require that if a food is free of a nutrient without the benefit of special processing, alteration, formulation, or reformulation to lower the content of the nutrient, the relevant claim must refer to all foods of that type and not merely to the particular brand to which the labeling is attached. The agency is proposing a similar requirement for foods that are inherently fat or cholesterol free in the companion document published elsewhere in this issue of the **Federal Register**. For example, many fruits and vegetables would meet the definition for the term "fat free." If the agency adopts its proposed approach, a "fat free" claim on broccoli would have to be made as "broccoli, a fat-free food." FDA is proposing a similar rule if a food is inherently "low" in a nutrient.

This requirement is consistent with the general policy on nutrient content claims set forth in current § 105.66(c)(2) for low calorie foods, with that on "free" and "low" claims discussed in the preamble to the final rule on sodium claims (49 FR 15510 at 15517), and with that proposed in § 101.25 (a)(2)(i) and (a)(2)(ii) of the tentative final rule for both "free" and "low" cholesterol claims (55 FR 29456). The agency believes that this requirement is necessary to prevent the consumer from being misled by an implication that a particular food has been altered to lower its fat content, for example, when in fact, all foods of that type are naturally free of, or low in, fat. Therefore, it is proposing such a requirement in § 101.13(e)(2). Conversely, FDA is providing in proposed § 101.13(e)(1) that if a food has been specifically processed, altered, formulated, or reformulated to remove the nutrient from the food, it may reflect this fact by using the terms "free" or "low," as appropriate, before the name of the food.

FDA is aware that the effect of proposed § 101.13(e)(2) will be to allow to allow "free" or "low" claims on foods that do not usually contain, or are usually low in, the nutrient (e.g., "Brand A soft drink, a fat-free food"). However, for the reasons stated above, the agency believes that this course is the appropriate one. FDA specifically requests comments on this aspect of its proposal.

c. *How definitions of "free" for nutrients were derived.* In arriving at the proposed definitions for "free," the agency chose the level of the nutrient that is at or near the reliable limit of detection for the nutrient in food and that is dietetically trivial or physiologically inconsequential. This approach is consistent with that used by the agency in the past for defining "free." FDA established a policy of using "free" as a descriptor of physiologically insignificant components when it adopted the regulation for sodium descriptors (49 FR 15510, April 18, 1984). This approach is also consistent with the comments and recommendations submitted to the agency in response to the 1989 ANPRM.

The claim "(*nutrient*) free" is a representation that the food does not contain the nutrient. The agency believes that this representation can be made in good faith if the food inherently contains very small amounts of the nutrient because the amount present is physiologically insignificant. Such a representation cannot be made in good faith, however, if the manufacturer intentionally adds the nutrient to the food as an ingredient. In such circumstances, even though the nutrient might not be of dietary consequence, it is obvious when reading the ingredient statement that it has been added. The agency has received comments, including a letter from the state attorney general from Minnesota, writing on behalf of eight other state attorneys general, expressing the view that such labeling is misleading to consumers (Ref. 16). Thus, FDA tentatively concludes that representing the food as free of the nutrient when the nutrient is intentionally added, even at very small amounts, would cause confusion and be false and misleading under sections 201(n) and 403(a) of the act. To reflect this tentative conclusion, the agency is proposing to add an additional ingredient-based criterion to definitions for "free" for sugar and sodium, as discussed below and for fat, as discussed in the companion document on fat, saturated fat, and cholesterol that a product may not be labeled as free of a nutrient if that nutrient is added as an ingredient. However, some have suggested that this distinction creates a discrepancy between naturally occurring "insignificant" amounts and those that are added.

As an alternative approach, it would be possible to allow "free" claims even though the nutrient is added, if the label includes a disclosure statement in association with the claim acknowledging the addition of the nutrient. In order for the claim to be not misleading, such a disclosure statement would need to be prominent and immediately adjacent to the claim each time it is made. Such a disclosure might state, "An insignificant amount of fat has been added to this product as an ingredient." This approach was suggested by the Minnesota Attorney General, as an alternative if FDA determined that it was not feasible to prohibit nutrient free claims on products that contained a very small amount of a nutrient added as an ingredient (Ref. 16). The agency solicits comments on whether nutrient free claims should be allowed on products that contain a very small amount of the nutrient as an ingredient if such products provide an appropriate disclosure statement and, if so, what such a disclosure statement should be.

The agency points out that, although a product would not be allowed to call itself "free" of a nutrient if a manufacturer intentionally added the nutrient to the food as an ingredient,

under the regulations as proposed, the label could make other positive, true, nonmisleading statements about the product such as how little of the nutrient is actually in the product. For example, if a manufacturer found that it was necessary to add a very small amount of fat to a product to assure that the product was palatable to consumers, the label could make a statement reflecting the amount of fat in the product provided that that amount of that nutrient could meet the definition for "low fat." Such a statement might be: "contains less than ½ g of fat per serving," or if accurate, "99 percent fat free." This labeling is consistent with § 101.13(i) which states that, in addition to statements about the percent of a vitamin or mineral in a food relative to the RDI, the label or labeling of a product may contain a statement about the percent or amount of a nutrient that implies that the food is high or low in a nutrient if the food actually meets the definition for either "high" or "low" as defined for the nutrient that the label addresses.

In addition, the label or labeling of a product may bear a variety of other positive statements about the product such as the product is "low," or in the case of sodium, "very low," in the nutrient or that the amount of the nutrient in the food is reduced, if that is the case, or that there is less of the nutrient in the product than in some other product.

FDA is not proposing to include a criterion that is based on the amount of the nutrient per 100 g of food for the term "free." FDA considered the need to include this criterion and has tentatively concluded that because the level of each nutrient must be so low to qualify for a "free" claim as to be physiologically insignificant, even frequent consumption of such foods would not be sufficient to have any meaningful affect on the overall diet. For example, the proposed definition for "sodium free," discussed below is, an amount in a food equal to or less than 5 mg of sodium per serving. If a "sodium free" food were consumed as often as twenty times a day, the intake of sodium from "sodium free" foods would be no more than 100 mg of sodium, and it would likely be less. Given the proposed Daily Reference Value (DRV) for sodium of 2,400 mg per day, this intake of sodium would constitute less than 5 percent of the DRV and cannot be considered substantial or of physiological significance.

Additionally, consistent with the regulations on "free" claims that it has issued (current 21 CFR 101.13(a)(1)), FDA is proposing in the supplementary nutrition labeling proposal that foods meeting the criterion for "free" may declare the nutrient content as "zero" on the nutrition label. Such a declaration will prevent the confusion that would result if quantitative declarations other than zero were made on foods bearing nutrient-free claims. While some comments have suggested that the term "free" will mislead consumers into believing that a food so labeled is completely without the nutrient, the agency tentatively concludes that no harm will result because the foods that would be eligible to be labeled with this term contain a trivial amount of the nutrient compared to the total dietary intake of the nutrient for any particular individual.

d. *Synonyms for "free"*. FDA is proposing to allow the use of the terms "no," "zero," "trivial source of," "negligible source of," and "dietarily insignificant source of," as synonyms for the term "free." For example, a food that meets the criterion for "sodium free" could also be labeled with the terms "no sodium" or "zero sodium." As discussed above, the agency is concerned about the proliferation of synonymous terms because of the potential to confuse and mislead consumers. However, the agency does not believe that there is potential for consumers to misinterpret the terms "no" or "zero," and therefore the agency is proposing to provide for the use of these specific synonyms. The agency requests comments on whether consumers commonly understand the meaning of all these terms and whether they are synonymous.

e. *Specific definitions*—i. *"Sodium free" and terms related to salt.* In its 1984 regulation on sodium descriptors (21 CFR 101.13), FDA defined a "sodium free" food as one containing less than 5 mg of sodium per serving. FDA established this definition to ensure that a food that met it would contribute only a trivial amount of sodium to the total diet for all individuals (49 FR 15510). Furthermore, while the agency recognized that it would be almost impossible to consume a diet consisting of nothing but "sodium free" foods, it stated that availability of such foods would be helpful in balancing the sodium intake from foods that necessarily contain larger amounts of sodium. According to FDA's 1988 Diet and Health Survey (Ref. 17), sodium remains the most commonly mentioned component that consumers try to avoid in their diet. Moreover, the recent National Food Processors Association survey on food labeling (Ref. 18) reported that 88 percent of shoppers felt label information on sodium was either somewhat or very important.

The agency is proposing to redesignate existing § 101.13 (21 CFR 101.13) as § 101.61 and to retain in paragraph (b)(1) of that section, the definition of "sodium free," as less than 5 mg of sodium per serving. The agency believes that this definition is consistent with the concept of a dietetically trivial amount in foods and is unaware of any evidence that would suggest that this definition should be changed.

Some comments on the 1989 ANPRM suggested that an additional criterion, such as 5 mg per 100 g of food, be included in the "sodium free" definition to avoid categorizing foods as "sodium free" when the serving size is small and consumption may be frequent. However, as discussed above, FDA is not proposing a second criterion for the use with definitions for "sodium free." The intake of foods containing less than 5 mg sodium, even if frequent, is unlikely to contribute a meaningful amount of sodium to the overall diet.

As mentioned above, FDA believes that the label of a food that bears a "(*nutrient*) free" claim can be misleading if that nutrient is also declared as an ingredient in the ingredient list. Most consumers recognize that salt is a significant source of sodium in foods, and the agency is aware that the terms "salt" and "sodium" may be used interchangeably by many consumers. Yet some consumers may not have a clear understanding of the difference between these two terms. These terms are not the same. Sodium chloride, or common table salt, contains almost 40 percent sodium and is only one of several sources of sodium in the diet. Other common sources of sodium include baking powder (sodium aluminum sulfate), monosodium glutamate, and baking soda (sodium bicarbonate). There are numerous other sodium compounds commonly used as ingredients, but their use is at such low levels that they are correctly perceived as not contributing significantly to dietary intake of sodium, e.g., sodium citrate and sodium bisulfite.

The agency is proposing in § 101.61(b)(1)(ii) to include in the definition of "sodium free" that the food must not contain added salt (i.e., sodium chloride) or an added ingredient that contains sodium. This provision is based on the agency's view that, as discussed above, consumers would be confused by the presence of a "sodium free" claim on a food with, for example, sodium citrate declared in the ingredient list. This provision is consistent with proposed definitions for fat and sugar. While FDA

recognizes that the use of trivial amounts of sodium-containing compounds included for flavor or preservation purposes is not likely to have a meaningful impact on the overall sodium content of the diet, the agency is concerned that consumers will note the presence of these ingredients in the ingredient list and be confused as to the significance of the "sodium free" claim. FDA, however, specifically requests comments concerning the appropriateness of restricting ingredients in foods making sodium free claims and of the alternative approach of allowing the claim in the presence of an appropriate disclosure statement.

In the past, FDA has defined or provided conditions for the use of "salt free" and other terms containing the word "salt" § 101.13(b)), so as to prevent the terms from being misleading to consumers. The agency has said elsewhere in this document that statements about an ingredient that lead one to make an assumption about the level of a nutrient are implied nutrient content claims which are not being defined at this time. Salt is an ingredient, and thus claims concerning salt content could be considered to be implied nutrient content claims. However, FDA is tentatively proposing to retain the current provisions for the use of the term "salt" in a somewhat modified form in § 101.61(c).

The agency believes that because of the confusion between "salt" and "sodium," any food bearing the claim "salt free" must meet the definition of "sodium free." Therefore, the agency is proposing this requirement in § 101.61(c)(1).

In § 101.61(c)(2), FDA is proposing to define the terms "without added salt," "unsalted," and "no salt added," which are currently defined in § 101.13(b). These terms may be used only if no salt is added to the food during processing but is added to the food for which the food that bears the claim will substitute (e.g., peanuts). In addition, in response to a comment, the agency is proposing to require a declaration on the food label that the food is not sodium free, if that is in fact the case, to avoid misleading consumers when claims that a food is unsalted or contains no added salt are made.

This proposed declaration is consistent with current FDA regulations (21 CFR 105.66) concerning the use of the term "sugar free." The concern that consumers could interpret this term as an indication that a food is low in calories prompted the agency to require that any food not low or reduced in calories but making a statement about the absence of sugar must bear a statement that it is not a low calorie or reduced calorie food.

ii. *Sugars free.* Several comments received by the agency in response to the 1989 ANPRN and public hearings suggested a need for the agency to define descriptor terms for the absence of sugar or sugars. The ION report on nutrition labeling (Ref. 5) also recommended that FDA define descriptor to be used for the sugar content of foods.

(a) *Regulatory history: "Sugar" and "Sugars".* FDA has traditionally held that the term "sugar" in an ingredient list means "sucrose" and does not include other sugars. In 1974, FDA proposed to permit the term "sugar" to also include invert sugar (39 FR 20888). The agency withdrew that proposal on June 21, 1991 (56 FR 28592 at 28607) and at the same time denied a request to allow the term "sugar" in the ingredient list to include glucose and fructose (including high fructose corn syrup). "Sugar" is defined in 21 CFR 184.1854 (53 FR 44870, November 7, 1988). That regulation states that the terms "sucrose," "sugar," "cane sugar," and "beet sugar" are appropriate names for sucrose. Therefore, in the ingredient list, the term "sugar" is limited to sucrose.

FDA addressed the issue of the use of the terms "sugar free," "sugarless," and "no sugar" in its July 19, 1977 findings of fact and tentative order on label statements for special dietary foods (42 FR 37166). At that time, the agency stated that consumers may associate the absence of sugar with weight control claims and with foods that are low calorie or that have been altered to reduce calories significantly. The agency concluded that any food making a statement about the absence of sugar would have to bear a statement that the food is not low calorie or calorie reduced, unless the food is a low or reduced calorie food. The agency stated that without this disclosure, some consumers might think the food was offered for weight or calorie control.

Evidence had been introduced at the public hearing on special dietary food regulations to show that the "sugarless" claim is useful to identify foods like chewing gum, which is in sustained contact with the teeth, in which the use of a sweetener other than a fermentable or cariogenic carbohydrate may not promote tooth decay.

In the final rule on label statements for special dietary foods published in the **Federal Register** of September 22, 1978 (43 FR 43248), FDA required a statement that a food is not low calorie or calorie reduced (unless it is in fact, a low or reduced calorie food) when a "sugar free," "sugarless," or "no sugar" claim is made for the food. The agency also allowed for the use of alternative statements, such as "not for weight control" and "useful only in preventing tooth decay." The statements that the food is not low calorie or not useful for weight control were needed because the term "sugar free" meant only that the food was sucrose free. A "sugar free" food could contain other, fermentable carbohydrates.

More recently, in a 1981 report in entitled "Task Group Report on Nutrition Labeling of Sugars," a special task group comprised of representatives from FDA, USDA, and FTC developed guidelines for labeling of sugars in food products (Ref. 19). These guidelines were intended to serve as the criteria necessary to develop regulations for quantitative sugars labeling. The tri-agency task group concluded that quantitative label declarations for sugars should be based on the content (by weight) of total sugars, both added and naturally-occurring. They defined "total sugars" as the sum of all mono- and oligosaccharides through four saccharide units and their derivatives, such as sugar alcohols.

During the last several years, FDA has sent letters to food manufacturers that have set forth agency policy on the use of the term "sugar free." In a 1988 memorandum (Ref. 20) and memorandum of telephone conversation (Ref. 20a), the agency addressed the question of whether a "sugar free" claim would be considered appropriate for a food containing maltodextrin as an ingredient (e.g., a popsicle). FDA responded that, based on the recommendations of the tri-agency task group, a food product with a substantial amount of maltodextrin as an ingredient most likely would be considered misbranded if it bears a "sugar free" claim because while it may contain no added sucrose, it still contains significant amounts of indigenous sugars and sugars other than sucrose. FDA also responded (Ref. 21) to a question concerning the appropriateness of a "sugar free" claim on a product containing polydextrose by noting that at least 10 percent of polydextrose (by weight) qualifies as "sugar" and thus is subject to the same guidelines as specified for maltodextrin.

In mid-1989, FDA responded to a question about the appropriateness of a "sugar free" claim for a product sweetened with a nonnutritive sweetener but that contained lactose, polydextrose, sorbitol, and mannitol (Refs. 22 and 23). The agency pointed out that § 105.66(f)(1) states that "[C]onsumers may reasonably be

expected to regard terms that represent that the food contains no sugars or sweeteners, e.g., 'sugar free,' 'sugarless,' 'no sugar,' as indicating a product which is low in calories or significantly reduced in calories." Noting that the statement in § 105.66 says "no sugars or sweeteners," FDA concluded at the time that the absence of ingredients that, generically, are sugars or nutritive sweeteners is basic to a "sugar free" claim. Because lactose, polydextrose, and sugar alcohols are sugars or nutritive sweeteners, the agency could not conclude that the product was "sugar free."

Finally, in response to the 1990 amendments, FDA is publishing elsewhere in this issue of the **Federal Register** a supplementary proposal on nutrition labeling in which the agency is proposing a chemical definition for sugars and providing for the mandatory declaration of the sugars content of foods. FDA is proposing to define "sugars" as the sum of all free mono- and oligosaccharides (and their derivatives) that contain four or fewer saccharide units and to include sugar alcohols in that definition. However, FDA is proposing to permit a separate declaration of the amount of sugar alcohols on a voluntary basis. This definition of "sugars" is consistent with the guidelines developed by the tri-agency task group on sugars labeling (Ref. 19)

FDA is not, however, proposing a DRV for sugars because the leading consensus reports have not provided a quantitative recommendation for the intake of sugars.

Thus, in the ingredient label, the term "sugar" is limited to sucrose, and the agency is proposing to use the broader term "sugars" in the nutrition label.

(b) *Need for change.* In considering the appropriateness of defining the term "sugar free," the agency took into account the guidelines and regulations that it has developed on this term, the current and proposed definitions for "sugar" and "sugars," and the potential for the term "sugar free" to be misleading. The agency has received a comment indicating that this term, when used to refer to the absence of only sucrose, may be misleading to consumers, even though the nutrition labeling will list calorie content. Furthermore, the dietary guidelines issued jointly by DHHS and USDA stipulate that Americans should "use sugars only in moderation" and define "sugars" as table sugar (sucrose), brown sugar, raw sugars, glucose (dextrose), fructose, maltose, lactose, honey, syrup, corn sweeteners, high-fructose corn syrup, molasses, and fruit juice concentrate (Ref. 1).

The 1978 rule concerning the use of the term "sugar free" centered around sucrose or table sugar. However, more recent FDA regulatory policy, based primarily on the tri-agency report on sugars labeling, has specified clearly that the agency considers the term "sugar free" to be most appropriate for foods that do not contain sugars or nutritive sweeteners, although FDA has not addressed this issue specifically for food products such as chewing gum sweetened with sugar alcohols which may be useful in not promoting dental caries. As stated above, the proposed definition for "sugars" for nutrition label purposes includes not only mono- and oligosaccharides but also sugar alcohols (56 FR 28592)

Given the consumer interest in the sugars content of food, the fact that current dietary guidelines recommend that consumers "consume sugars in moderation" (Ref. 1), and the agency's longstanding practice of providing for the use of a descriptive term intended to indicate the absence of sugar in some form, FDA is tentatively proposing to define the claim "sugars free" in § 101.60(c). FDA is defining this term to mean the absence of total sugars rather than the absence of sugar (i .e., sucrose).

The agency considers it important for nutrient content claims to be consistent with the nutrition label, which serves as a source of specific information for consumers concerning the nutritional value of the food. As stated above, the agency has proposed to require that the nutrition label contain information on the sugars content. FDA is concerned that there would be potential for confusion if the nutrient content claim were to use the term "sugar," and the nutrition label were to specify information using the term "sugars." Such a discrepancy could make it more difficult to implement education efforts pertaining to label information.

The need for consistency is supported by the IOM report on nutrition labeling (Ref. 5). The report highlights the importance of the content claims on the principal display panel being supported by the quantitative values listed in the nutrition information panel. Furthermore, "sugars free" is consistent with the terminology used in government dietary recommendations, specifically "Nutrition and Your Health, Dietary Guidelines for Americans" (Ref. 1), which advise that sugars should be consumed in moderation.

The agency acknowledges that it has been a common practice to use the term "sugar free" rather than "sugars free," but FDA believes that the term "sugars free" is more appropriate for the reasons stated above. The agency believes that anticipated education efforts to assist consumers in interpreting the nutrition label (including the term "sugars") will improve consumer understanding of the term "sugars free." Furthermore, even if consumers continue to interpret the term "sugars free" as synonymous with sucrose free (i.e., "sugar free"), consumers will not be misled or harmed because a "sugars free" food will in fact be sucrose free.

(c) *Definition.* FDA is proposing to define "sugars free" as less than 0.5 g of sugars (i.e., all free mono- and oligosaccharides and their derivatives that contain four or fewer saccharide units as well as sugar alcohols) per serving. In defining the term, the agency considered both the amount that would be trivial from a dietary intake perspective as well as that level that could be reliably detected using available laboratory methodologies. In the supplemental nutritional labeling proposal, FDA proposed that analytical values for sugars content that are less than 0.5 g per serving could be declared as zero on the nutrition label. On this basis, FDA is proposing in § 101.60(c)(1)(i) to define "sugars free" as containing less than 0.5 g sugars per serving.

In the past, FDA has not provided a definition for the term "sugars free" relative to its use in managing or planning diabetic diets, although the agency has provided for the use of certain declarative statements so as to avoid confusion among persons with diabetes (§ 105.67). Recently, the American Diabetes Association (ADA) issued a policy on the use of caloric sweeteners in recipes and foods intended for use by diabetics (Ref. 24). The new policy is more liberal than previous policy concerning the inclusion of caloric sweeteners in diabetic diets. The permitted intake of sucrose, honey, molasses, and other caloric sweeteners is 1 teaspoon per serving size. This amount of sweetener is equal to approximately 4 g of sugar per serving.

The proposed definition for "sugars free" is less than or equal to 0.5 g per serving, well below the 4 g amount suggested by ADA. Thus, the use of the term is not contradictory to current recommended diabetes management practices. However, the agency wishes to emphasize that definitions of nutrient content claims do not specifically address issues related to diabetes management, and that diabetes management should not be based solely on the consumption of "sugars free"

foods. Rather, diet planning for diabetics should encompass the entire diet and be supervised by a trained professional.

The agency believes that the amount of sugars allowed in a food bearing a "sugars free" claim is so small that even frequent consumption of such a food will not result in an intake of sugars that would affect the overall diet in any meaningful way. Therefore, FDA is not proposing an additional criterion based on the weight of the food.

However, the agency is proposing a criterion in the definition of "sugars free" to prevent the use of the term on the labels of products to which a sugar has been deliberately added (proposed § 101.60(c)(1)(i)). Despite the fact that these foods can meet the criterion of "sugars free," confusion could occur if the ingredient list for a food bearing the term included any sugars deliberately added. Therefore, the proposal states that to bear a "sugars free" claim, no ingredient in the food can be an added sugar. As stated in previous sections, the agency solicits comment on the appropriateness of this policy.

Finally, FDA continues to believe that any food that bears a statement about the absence of sugars should bear a statement indicating that the food is not low calorie or calorie reduced unless the food meets the requirements for a low or reduced calorie food. Without this disclosure, some consumers might think the food was offered for weight or calorie control. As discussed above, this requirement is already established in § 105.66(f) and will be recodified as § 101.60 (c)(1)(iii)(A) and (c)(1)(iii)(B).

(d) *Sugar alcohols.* The agency acknowledges that this approach for defining "sugars free" would preclude the use of the term on certain products such as chewing gums that contain sugar alcohols (also known as polyols) as nutritive sweeteners and have for some time stated on the label the potential benefit of their product in not promoting tooth decay.

The agency is concerned that these products serve a useful purpose in that they offer an alternative to chewing gums that contain sucrose. FDA also believes that there is some benefit to the consumer in label statements that identify these gums by noting the difference in the two types of products. Accordingly, the agency believes that gums containing no sucrose may continue to be able to bear the terms "sugar free," "sugarless," and "no sugar" along with the other statements currently required in § 105.66(f). The agency is therefore proposing in § 101.13(o)(8) to permit these products to continue to bear sugar free claims provided that the label also bear, when the food is not low or reduced calorie, a statement such as "Not a reduced calorie food," "Not a low calorie food," "Not for weight control," or "Useful Only in Not Promoting Tooth Decay." As has been required in § 105.66(f), this term should be immediately adjacent to the claim each time it is used.

However, the determination of the usefulness in not promoting tooth decay of gums sweetened with sugar alcohols was based on data that are now over 20 years old. The agency intends to reevaluate this determination in light of new data and current scientific criteria. The agency solicits comments specifically on whether the terms "sugar free," "sugarless," and "no sugar" on chewing gum would be confusing in light of the total sugars declaration in the nutrition label and on whether those terms may be useful in spite of any such confusion. In addition, the agency specifically solicits data on the effects of consumption of these sugar alcohols and on any other types of products that should be included in the exemption in proposed § 101.13(o) (8).

(e) *Synonyms.* In § 105.66(f), the agency provided for the use of the term "sugarless" as well as "sugar free" and "no sugar." However, as specified earlier in the introductory section, the agency is proposing to allow five terms as synonyms for "sugars free." The agency is proposing these terms in § 101.60(c). However, the agency is proposing not to provide for use of "sugarless" for several reasons. To be consistent and thus synonymous with "sugars free," the term defined would have to be "sugarsless." The agency believes that the synonyms defined are sufficient to advise consumers of the absence of sugars in a food, and that there is no need to define additional terms at this time.

(f) *Unsweetened, no added sweeteners.* In the September 22, 1978 final rule on label statements for special dietary foods (43 FR 43248), FDA also addressed the terms "unsweetened" and "no added sweeteners." The agency concluded they were factual statements about the organoleptic properties of the foods. FDA is not aware of any reason to change this view. Therefore, unlike the term "sugar free," these terms, when used for foods with apparent inherent sugars content (such as juices), are not subject to the requirements of section 403(r) of the act for nutrient content claims. FDA is reflecting this fact in proposed § 101.60(c)(3).

FDA is unaware of any evidence to indicate that the use of these terms has been misleading to consumers. The agency advises that it will use the definition of sweeteners in proposed § 101.4(b)(21) in determining the appropriateness of the terms "unsweetened" and "no added sweeteners" on a food label. FDA included this definition in its proposal on ingredient declaration in the **Federal Register** of June 21, 1991 (56 FR 28592). The agency considers that the final rule on that proposal will provide an adequate basis for these terms.

(g) *No added sugars.* While FDA has not issued regulations for the use of the terms "no added sugars," "without added sugars," or "no sugars added," the agency has provided advice concerning their use. In a 1979 letter to the Sugars Association (Ref. 26), FDA stated that the terms "no sugar added" and "no sucrose added," when unqualified, may reasonably be interpreted by consumers to mean that these foods are low or reduced in calories. The agency also stated that such claims should be supplemented either by statements that disclose the presence of, or the usefulness of, the alternative sweetener or by other explanatory statements as appropriate to minimize the likelihood of consumer confusion.

In a 1984 letter to representatives of a food manufacturing firm (Ref. 27), FDA reiterated its earlier position concerning the term "no sucrose," stating that its unqualified use may be misleading, and that the agency had long felt that food labeling claims that highlight either the presence or absence of a particular sweetening substance, unless appropriately qualified by additional statements that are understandable to the ordinary consumer, have the potential to mislead and confuse. The letter also pointed out that the statements "no sucrose added" and "no sugar added," without further qualification, may reasonably be interpreted by consumers to mean that these foods are low or reduced in calories. It continued that therefore, such claims should be supplemented either by statements that disclose the presence of, or the usefulness of, the alternative sweetener or by other explanatory statements. FDA specifically stated that it did not object to a factual statement that a food is "sweetened with fructose (etc.) instead of sugar."

In 1985 (Ref. 28), FDA stated that it believed that the statement "No sugar—Honey Sweetened" was acceptable because "no sugar" implied no table sugar. In 1987 FDA responded to a request for clarification from a food manufacturer (Ref. 29) by stating that the term "no sugar added" may be used on the labels of fruit spread provided

that each time the statement appears, it is accompanied by a qualifying statement explaining the manner in which the product is sweetened, for example "sweetened with concentrated grape juice." On January 3, 1990, FDA sent a notice of adverse findings to a food manufacturing firm (Ref. 30) that included a statement that a label claim of "no sugar added" was false and misleading when applied to a product that contains sugar from sugar cane juice.

Thus, in providing advice on the use of the terms "no added sugar," "no sugar added," and "without added sugar," the agency has generally considered the intent of these claims to be limited to claiming the absence of so-called table sugar, that is, sucrose. FDA has expressed concern that consumers may expect such products to be low or reduced in calories and has therefore stated that statements as to whether the food is low calorie or reduced calorie content, as well as to the presence or use of alternative sweeteners, should accompany the claim.

Thus, for terms such as "no added sugar," as for "sugar free," FDA considered whether to continue to limit their application only to sucrose. Currently, a variety of added nutritive sweeteners are used in foods, and these sweeteners often contain sugars other than sucrose. Dietary guidelines (Ref. 1) stipulate that Americans should "consume sugars only in moderation" and indicate that sugars other than sucrose should be consumed in moderation.

Therefore, given current dietary recommendations, FDA has tentatively concluded that the use of a descriptive term that implies that the product has been made without adding sugars would be more helpful to consumers in implementing such recommendations than would a term that is limited only to sucrose (i.e., "sugar"). However, the agency believes that to avoid misleading consumers, such terms should be limited to foods that would be expected to contain added sugars. Claims concerning the absence of added sugars on products that would not normally contain added sugars, for example canned tuna or potato chips, are likely to mislead consumers into thinking that a particular brand may be more desirable when compared to other brands of the same product. Based on all of these factors, the agency is proposing to provide for "no added sugars" claims, to define them in terms of the other proposed definitions pertaining to sugars, and to specify provisions for their proper use.

The agency is proposing in § 101.60(c)(2) that claims for the absence of added sugars apply only to those foods to which sugars have not been added during processing or packaging. This provision is consistent with the provisions proposed above with respect to the addition of salt to foods. Also, consistent with earlier provisions, the agency is proposing to require that products bearing a "no added sugars" claim bear a statement that the food is not low calorie or calorie reduced, if applicable. Furthermore, the agency believes that it would be misleading to claim "no added sugars" if an ingredient that contains added sugars, for example jam, is added to the product. The agency also believes that it would be misleading to claim "no added sugars" if the sugars content of the product has been increased by the manufacturer using a means such as adding enzymes to the product. Consumers would expect that a product bearing a claim for "no added sugars" would contain only sugars naturally present in ingredients, when in fact the manufacturer would have deliberately "added" to the sugars content of the product via the addition of enzymes.

The agency is proposing in § 101.60(c)(2) to permit the use of the terms "no added sugars," "without added sugars," or "no sugars added." These claims will be permitted only if:

(1) No amount of sugars (as defined for nutrition labeling purposes in § 101.9) is added during processing or packaging;

(2) The product does not contain ingredients that contain added sugars, such as jam, jelly, and concentrated fruit juice;

(3) The sugars content has not been increased above the amount naturally present in the ingredients of the food by some means such as the use of enzymes;

(4) The food that it resembles and for which it substitutes normally contains added sugars; and

(5) The product bears a statement indicating that the food is not low calorie or calorie reduced (unless the food meets the requirements for a low or reduced calorie food) and directing consumers' attention to the nutrition panel for further information on sugars and calorie content.

iii. "*Calorie free*". The agency has recognized that people who are interested in controlling their weight can be aided if the level of calories in a food is brought to their attention, particularly when the calorie level is low (42 FR 37166). Accordingly, FDA responded to the need for descriptive terms for claims concerning the caloric content of foods by defining "low calorie" and "reduced calorie" (43 FR 43248). However, the agency has not proposed a definition for "calorie free." Comments received by the agency in response to the 1989 ANPRM and at the public hearings stated that the term "no calories" or "calorie free" should be defined by the agency.

While FDA has not defined the term "calorie free," current § 105.66(e) provides for the term "diet" for use when a food is represented as being useful in reducing caloric intake or reducing or maintaining body weight. The term has often been used on foods that are virtually free of calories, such as specially formulated soft drinks. However, under § 105.66(e) (1), a "diet" food is not necessarily a food free of calories because "diet" may be used with products that are low or reduced in calories.

FDA is proposing to define "calorie free" because the ability to call attention to products free of calories will provide useful guidance to consumers who are seeking to control their caloric intake. The agency, however, notes that such a claim may be applicable to relatively few foods in the food supply and therefore, requests comments on the appropriateness of providing such a definition.

The agency is proposing in § 101.60(b)(1)(i) to define the term "calorie free" as less than 5 calories per serving. The proposed nutrition labeling regulation which is publishing elsewhere in this issue of the **Federal Register** provides for the declaration of the calorie content of a food as zero when caloric levels are less than 5 calories per serving. The agency believes that this level of calories can be considered trivial and of no physiological significance. Even frequent consumption of such "calorie free" foods would not result in a caloric intake great enough to affect in any meaningful way on the overall intake of calories. For example, if "calorie free" foods were consumed 20 times a day, the usual number of servings a person consumes, the intake of calories from such foods would be no more than 100 calories. As a point of reference, the population adjusted mean intake of calories per day is 2,350. Additionally, as discussed above, FDA is proposing five terms as synonyms for "calorie free."

2. "Low"

a. *Background.* Nutrient content claims that describe the level of a nutrient as "low" are among the most common claims on labels but are not consistently defined or used (Refs. 5 and

10). FDA's first efforts to define the term "low" were made regarding calories, particularly so that the term could be used to assist in weight control. On September 22, 1978 (43 FR 43248), FDA issued a final rule that established a definition for "low calorie." In 1984 (49 FR 15510), FDA issued a rule defining "low sodium," and on November 25, 1986 (51 FR 42584), FDA proposed a definition for "low cholesterol" which was expanded upon in the tentative final rule on July 19, 1990 (55 FR 29456). The agency also has developed guidelines for use of the term "low fat" in experimental shelf-labeling programs (Ref. 31).

Current dietary recommendations (Refs. 1, 2, and 3) make clear the continued usefulness of identifying or calling attention to foods low in the nutrients of which consumers have been advised to limit their intake including fat, saturated fat, cholesterol, sodium, and calories. Comments from a variety of consumer and professional organizations strongly support the use of the term.

Definitions for "low" can also be found internationally. Canadian regulations and guidelines specify conditions for the use of the term to describe fat, cholesterol, sodium, and calorie content (Ref. 32), and a Codex Alimentarius standard for foods for special dietary uses defines "low sodium" (Ref. 33). Further, Codex guidelines that would define "low" for a number of other nutrients are in development, as is a European Community directive on labeling claims that includes claims relating to low content.

The agency is proposing to define "low" for the following nutrients: total fat, saturated fat, cholesterol, sodium, and calories. The definitions for "low fat," "low saturated fat," and "low cholesterol," and the basis for those definitions, are presented in the companion document published elsewhere in this issue of the **Federal Register**. FDA is not proposing definitions for low content claims for other nutrients because low levels of these other nutrients in foods are not of public health importance according to major consensus documents such as the "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 3) and The Surgeon General's Report on Nutrition and Health (Ref. 2).

While the agency has defined "sugars free," FDA does not believe that it is appropriate to define "low sugars." Unlike the claim "sugars free," which is based on the absence of sugars in a food, a definition for a "low" level of sugars (or any other nutrient) in foods should relate to the total amount recommended for daily consumption. Because the available consensus documents do not provide recommendations for daily intake of sugars, FDA is not proposing a reference value for this nutrient. The agency has thus tentatively concluded that without quantified recommendations for sugars intake, a definition for low levels of sugars in food cannot be specified.

b. *How definitions of "low" for nutrients were derived.* In the **Federal Register** of July 19, 1977 (42 FR 37166), FDA provided a basis for the definition of "low." Although the definition was specific to calories, the principle can be applied to other nutrients. The agency stated that "low" should designate foods of distinctly low nutrient value, but the level for "low" should not be restricted to foods that can be "eaten freely in numerous servings." Thus, FDA's view in 1977 was, and the agency continues to believe, that the designation "low" should not necessarily mean that the nutrient is present in the food in an inconsequential amount as with "free," but rather that the selection of a food bearing the term "low" should assist consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit certain nutrients. The agency believes that to meet current dietary guidelines, it should not be necessary for persons to limit their diets solely to foods "low" in the nutrients that the guidelines recommend limiting. Rather, FDA expects that educational efforts will stress the importance of a total daily diet that is comprised of a mixture of foods, some of which may be "low" in a particular nutrient and some of which may not.

In establishing the proposed definitions for "low," FDA has tentatively concluded that there should be a single definition of what is low for each nutrient that would be applicable to all foods, rather than several definitions for use with specific categories of foods. As discussed in the companion document on claims for fat, saturated fat, and cholesterol content (published elsewhere in this issue of the **Federal Register**), FDA received a comment that requested that the agency define "low fat" differently for different foods, that is, that FDA vary the quantitative definition of "low" according to food category and designate as "low" those foods that are relatively low compared to other foods in the food category. The agency rejects this approach.

The use of different criteria for different food categories has several disadvantages that affect both consumers and the food industry. When different criteria are used for different categories of foods, consumers cannot use the descriptors to compare products across categories and will likely find it difficult to use the descriptors for substituting one food for another in their diets.

Although an argument can be made that different criteria for different foods would permit consumers to identify the products with the lowest (or highest) nutrient level in a category, the agency believes that such a system would have a high potential for misleading the consumers about the nutrient content of foods. The product that has the lowest nutrient content in a category is not necessarily low in the nutrient. Also, with different criteria for different food categories, it would be possible that some foods that did not qualify to use the descriptor would have a lower content of the nutrient than foods in other categories that did qualify.

Furthermore, in this document, FDA is proposing to provide for the use of relative claims on the labels of food products, claims that are intended to alert consumers that a particular product, when compared to a similar product, is lower or higher in certain nutrients. FDA believes that this approach is more appropriate for consumers to identify favorable or desirable products within a food category.

FDA has received many comments asking for increased consistency among nutrient content claims to aid consumers in recalling and using the defined terms. In addition, the IOM report recommended that "low sodium," for example, should have the same meaning whether it is applied to soup, frozen peas, or meat (Ref. 5). Accordingly, the agency concludes that establishing different cutoff levels for each nutrient content claim for different food categories would greatly increase the complexity of using such claims to plan diets that meet dietary recommendations. Therefore, the agency is proposing a single definition for "low" for each nutrient across the entire food supply.

FDA believes that the most logical starting point for the definition of "low" is the level that FDA has defined as the measurable amount of the nutrient in a serving of a food. In § 101.3(e)(4)(ii), FDA has defined this amount as 2 percent or more of the reference value (i.e., U.S. RDA), the level at which all of the nutrients in question can be measured in all or nearly all foods.

The reference value for the nutrients for which FDA is proposing to define the

claim "low" is the DRV rather than the U.S. RDA, but all the nutrients in question have proposed DRVs. Two percent of the proposed DRV, then, is an amount that can be considered to be low relative to overall recommended intakes.

Looking at this definition from a different perspective, FDA has generally estimated the number of servings of foods and beverages to be 16 to 20 per day. The Minnesota Nutrition Coordinating Center has estimated the average number of servings of foods and beverages to be 20 per day (Ref. 34). If the nutrient were contained in all foods, and 2 percent of the DRV was adopted as the basis of the proposed definition for "low," persons who selected only foods designated as "low" in the nutrient would have a daily intake of the nutrient that would be no more than 40 percent of the proposed DRV (i.e., 2 percent times 20 servings). Thus, 2 percent of the DRV as a definition for "low" provides for a quantitatively low amount in food that is sufficiently restrictive to allow consumers to select a variety of foods, including some that are "low" in a nutrient and some that are not "low," and still meet current dietary recommendations.

On the other hand, the agency believes that 2 percent of the DRV can be overly restrictive as a definition for "low" for those nutrients that are not contributed by all food categories or that are found in relatively few foods. FDA believes that in defining the term "low," the amount per serving for nutrients that are not found in all categories of foods can be larger than for nutrients that are ubiquitous in the food supply. For example, assume that nutrient X is spread across 20 foods/beverages in a day, while the intake of nutrient Y is contributed by only 10 foods/ beverages in a day, that is one-half as many as contribute to the intake of nutrient X. If the definition of "low" for nutrient X is established as 2 percent of the DRV, the consumption of only foods "low" in nutrient X results in an intake of 40 percent of the DRV, that is 2 percent times 20 foods/beverages. If the definition for "low" for nutrient Y is set at 4 percent (i.e., twice than 2 percent) the consumption of only foods "low" in nutrient Y also results in an intake of only 40 percent of the DRV because only 10 foods containing the nutrient are eaten in a day (i.e., 4 percent times 10 foods/beverages in a day). If the definition of 2 percent of the DRV for "low" had been applied to nutrient Y, then the intake of nutrient Y would be only half the intake of nutrient X. Thus, such a limit on nutrient Y would be overly restrictive.

However, this general approach cannot be precisely refined because there are only limited data available to determine the number of foods eaten in a day that may be expected to contribute the various nutrients. Furthermore, distributions of nutrients among food categories may not reflect the patterns of consumption of consumers. FDA is thus tentatively proposing to apply a rough and simplistic "rule of thumb" for adjusting the 2 percent DRV definition for "low" for those nutrients that appear to be less than ubiquitously distributed among foods and therefore are assumed to be consumed less frequently than nutrients that are present in virtually all foods consumed during the day.

The agency used the FDA Regulatory Food Composition Data Base (Ref. 6) to examine the availability of nutrients from foods in 18 USDA-defined food categories (for example, vegetables; fruits; cereal grains and pasta; milk, cheese and eggs; meat, poultry and fish; legumes; nuts; and fats and oils) (Ref. 35). For this analysis, FDA considered that a nutrient is found in a food category if over half of the foods in the category contain 2 percent or more of the proposed RDI or DRV for the nutrient in question. The agency further considered a nutrient to be:

(1) Ubiquitously distributed if it was found in more than 75 percent of the food categories;

(2) Moderately distributed if it was found in 51 to 75 percent of the food categories; and

(3) Not widely distributed if it was found in 50 percent or fewer of the food categories.

After gathering the results of this review, the agency applied factors to adjust the "low" definition for a nutrient (i.e., 2 percent of the DRV) depending on the nutrient's estimated distribution across food categories. However, because of the variable nature of diets selected by individuals, precise factors could not be developed, so the agency applied general factors.

If the nutrient is available from approximately 50 to 75 percent of food categories, FDA believes that it is reasonable to expect that it may be available from perhaps as few as half of the foods/beverages consumed. In other words, assuming that as many as 20 foods/beverages are consumed in a day (Ref. 34), it is reasonable to expect that a nutrient that is moderately distributed in the food supply is available from perhaps as few as 10 of the foods/beverages. In this case, the agency has used a factor of 2 times 2 percent or 4 percent of the DRV (i.e., doubling) in arriving at the definition of low. If the nutrient is found in half or less of the foods consumed, that is, if it is not widely distributed, FDA believes that it is reasonable to find that the nutrient will be consumed in seven or fewer foods a day. In this case, a factor 3 times 2 percent, or 6 percent, of the DRV, is reasonable. If the nutrient is ubiquitous across food categories, FDA is not proposing to adjust the definition of "low."

As described below, in arriving at the definitions for "low," FDA evaluated each nutrient in light of this general rule of thumb, past policy, other available data and information, and current public health recommendations.

c. *Criterion based on weight.* As discussed above in section III.A.2.b. of this document, the agency believes that in addition to a criterion based on the amount of a nutrient per serving, a criterion based on the amount of nutrient per quantity of food is needed to control claims on nutrient-dense foods with small standard serving sizes. Without a limitation on the amount of nutrient per 100 g of food, declarations for "low" levels of a nutrient could be misleading. Analyses of FDA's Regulatory Food Composition Data Base (Ref. 6) suggest that there are a number of foods that would meet the "low" criterion for amount per serving but that would still contain a substantial amount of the nutrient on a weight basis (Ref. 7). For example, as stated above, certain margarines or spreads contain about 130 mg of sodium per serving but contain over 900 mg per 100 g. In this circumstance, a small serving size would result in a nutrient-dense food qualifying for a "low" content claim if only the per serving criterion is used.

A criterion based on weight is currently provided in § 105.66(c) for the term "low calorie." That regulation stipulates that a "low calorie" food must not provide more than 0.4 calories per g of food. Similarly, FDA is proposing to include a second criterion based on the amount of the nutrient per 100 g of food in the definition for "low" for all but one of five nutrients identified above.

d. *Foods inherently "low" in a nutrient.* Consistent with the agency's conclusion pertaining to foods inherently "free" of a nutrient, the agency believes that the use of terms such as "low sodium" or "low fat" on foods that are inherently low in that nutrient can be misleading (see proposed § 101.13(e)(2)). Accordingly, FDA is proposing for calories in § 101.60(b)(2)(ii) and for sodium in

§ 101.61 (b)(4)(iii) to require that for claims of low nutrient content on foods that meet the definition for "low calories" or "low sodium" without benefit of special processing, alteration, formulation, or reformation to decrease the nutrient content, that the label refer to all foods of that type and not merely to the particular brand to which the labeling attaches. For example, applesauce would inherently meet the definition for "low sodium." Therefore, if the agency adopts these proposed provisions, a jar of applesauce could be labeled with a statement such as "applesauce, a low sodium food." The agency is proposing in § 101.61(b) (2) (iii) a similar requirement for "very low sodium foods." These requirements are consistent with the general policy on "free" nutrient content claims discussed above.

The agency is proposing a similar requirement for "low fat," "low saturated fat," and "low cholesterol" claims in the companion document published elsewhere in this issue of the **Federal Register**.

e. *Synonyms.* FDA is proposing as synonyms for "low" the terms "little or (few)," "small amounts of," and "low source of." The agency is proposing these synonyms to provide flexibility for industry. FDA requests comments on whether consumers commonly understand these terms to have the same meaning as "low."

f. *Specific definitions.*— i. *"Low sodium and very low sodium".* In defining sodium claims for the current regulation on sodium labeling (21 CFR 101.13), FDA considered the number of servings of food that the average American consumes each day (49 FR 15534, April 18, 1984). Based on 20 servings per day as a reasonable average number of servings for adults and a criterion of 140 mg of sodium per serving, the agency estimated that the consumption of 20 "low sodium" foods would contribute about 2,800 mg of sodium per day. FDA stated that it was likely that persons on "mildly restricted" diets would consume a number of sodium free foods or foods containing very low levels of sodium, thereby providing some flexibility in the diet to allow for the consumption of sodium from other sources such as drinking water or table salt. In the 1984 final rule, FDA also cited evidence that more than 50 percent of the foods in the analysis that it did at the time fell below 140 mg per serving, suggesting that the term would have a reasonably broad application in the food supply.

Thus, in 1984, FDA defined "low sodium" as less than or equal to 140 mg sodium per serving. FDA had originally proposed that the term "low sodium" be defined as 35 mg or less per serving (47 FR 26580). However, comments on the proposed definition persuaded the agency that 35 mg or less of sodium was a level too low to be broadly useful to the general public. The agency therefore modified its definition of this term. However, the agency added the term "very low sodium" and defined it as less than or equal to 35 mg sodium per serving. In the 1984 final rule, FDA concluded that "very low sodium foods" would be useful to individuals in the population wishing to reduce their total sodium intake to a more moderate level and would be especially useful to individuals on medically restricted diets.

Thus, the descriptive terms for sodium have been defined and used for approximately 8 years, and the agency believes that consumers have become familiar with the terms "low sodium" and "very low sodium." In general, comments received in response to the 1989 ANPRM and at the public hearings did not indicate a need to change the definitions for these terms. Several comments supported keeping the existing criteria. For these reasons, the agency is proposing to retain 35 mg or less per serving as the first criterion for the definition of "very low sodium" and 140 mg or less per serving as the first criterion for the definition of "low sodium."

The agency is aware that this definition for "low sodium" is not consistent with the general basis on which FDA is proposing to define "low" claims. With the exception of all fruits and raw vegetables, sodium is present in or added to many categories of foods in the food supply. Therefore, if sodium were considered to be ubiquitous in the food supply, the general rule of thumb could result in an initial definition for "low sodium" of 2 percent of the DRV or 48 mg of sodium per serving. Clearly, 48 mg of sodium per serving is considerably lower than 140 mg of sodium per serving. Even if the agency were to conclude that sodium cannot be considered to be ubiquitous, and consequently the value representing 2 percent of the DRV for sodium was doubled, the criterion would still be only 96 mg or less sodium per serving.

The agency considered defining the term "low sodium" as 96 mg or less per serving (i.e., that amount reflective of approximately 4 percent of the DRV for sodium), and not defining "very low sodium." Such an action would be consistent with the most recent dietary recommendations and with the agency's general goal of limiting the number of descriptor terms. However, such an action would be contrary to the majority of comments received by the agency in response to the 1989 ANPRM concerning the level for "low sodium." Therefore, FDA is proposing to retain the definition for "low sodium" as 140 mg or less per serving and to define "very low sodium" as 35 mg or less per serving.

The agency specifically requests comments concerning these definitions. FDA is interested in comments concerning: The appropriateness of the definitions given recent consensus reports and dietary recommendations such as the NAS Diet and Health report; whether substantially increased public health benefits could be realized by using a criterion lower than 140 mg per serving for defining sodium; and the utility of retaining both the "low sodium" and "very low sodium" terms.

FDA is proposing a second criterion for defining "low sodium" as 140 mg or less sodium per 100 g and "very low sodium" as 35 mg or less sodium per 100 g. The per 100 g criterion is needed to control claims on sodium-dense foods with small serving sizes because, as explained above, these foods may be consumed frequently, resulting in a substantial total daily intake of sodium. Because the claim would be misleading to consumers unless both the per serving and per 100 g criteria are met, the agency is proposing that both must be satisfied to meet the definition. Examples of foods for which the proposed sodium descriptors could not be used because they do not meet both criteria for "low" include olives with 105 mg sodium per serving but 750 mg per 100 g and butter/spreads with about 120 mg sodium per serving but over 800 mg per 100 g. In the case of "very low," the foods excluded as a result of the second criterion include canned beef gravy with 28 mg of sodium per serving but 50 mg per 100 g. (However, canned beef gravy would be able to bear a "low sodium" claim.)

Accordingly, the agency is proposing in § 101.61(b)(2)(ii) that the term "very low sodium" may be used on the label and labeling of foods that contain 35 mg or less of sodium per serving and per 100 g, and in § 101.61(b)(4)(ii) that the term "low sodium" may be used on the label and in labeling of foods that contain 140 mg or less of sodium per serving and per 100 g.

ii. *"Low calorie".* Obesity is a major health problem in the U.S., and dietary recommendations consistently stress the need to maintain a healthy weight. FDA believes that people can be helped to control their weight if foods that are low in calories are brought to their attention (42 FR 37166, July 19, 1977).

In 1978, FDA established in 21 CFR 105.66 a definition for "low calorie" (43 FR 43248, September 22, 1978). In the preamble to its tentative rule (42 FR 37166, July 19, 1977), FDA accepted the concept that the designation "low calorie" should apply to foods of distinctly low caloric value in a single serving. However, as stated above, the agency rejected the view that low calorie foods are only those that are so low in caloric value that they can be eaten freely, without adding significantly to the caloric content of the total diet. The agency stated that the proposed definition of "low calorie" would require that consumers apply reasonable judgment in selecting "low calorie" foods as part of an overall dietary pattern. FDA said that consumers could determine from nutrition labeling how much of a particular food they could consume per day without adding significantly to their total caloric intake. The agency stated that this approach was appropriate because caloric requirements vary considerably from person to person.

In 1978, FDA defined, in § 105.66(c)(1)(i), "low calorie" as 40 calories or less per serving (43 FR 43248, September 22, 1978). The agency stated that this definition would include only foods of distinctly low caloric value while at the same time allowing a reasonable number of foods to be labeled as "low" in calories, as supported by analyses of available data bases. FDA also provided for a second criterion for the definition of "low calorie" of 0.4 calories or less per g of food (i.e., 40 calories per 100 g) (§ 105.66(c)(1)(i)). The agency stated that this level was appropriate because available data indicated that foods generally considered the most useful types of low calorie foods (e.g., most soups, juices, fruits, and vegetables containing 40 calories or less per serving) also satisfy this second, density-based criterion.

In response to the 1989 ANPRM and recent public hearings, the agency received numerous comments from a variety of consumer and professional organizations strongly supporting the use of the term "low calorie." In the time since the 1978 rule, public health policy and dietary recommendations relative to caloric intake have not changed appreciably, although there is evidence that the problem of obesity may have increased (Ref. 3). The concepts articulated in the 1977 rule remain appropriate for current dietary recommendations and, in the opinion of the agency, remain appropriate as a basis for defining "low calorie."

While a DRV for calories has not been established, FDA used a reference caloric intake of 2,350 calories in establishing the DRVs for other nutrients. This reference level is the population-adjusted mean of the recommended energy allowance for persons four or more years of age, as indicated in the 10th Edition of the "Recommended Dietary Allowances" (Ref. 4). The agency used this reference caloric intake in reviewing the current definition for "low calorie." Calories are ubiquitous across food categories (Ref. 35), and therefore using the general approach described above, 2 percent of 2,350 calories (i.e., 47 calories) would be a reasonable starting point for the definition of "low calorie." Because the current definition of 40 calories per serving is sufficiently close to this calculated amount of 47 calories per serving, FDA tentatively concludes that it is not necessary to alter the long-established criterion of 40 calories per serving. Therefore, FDA is proposing in § 101.60(b)(2)(i) to retain the definition of a "low calorie" food as a food containing 40 calories or less per serving.

The agency continues to believe that the inclusion of a weight-based criterion in the definition of "low calorie" is appropriate and prevents claims from being misleading to consumers. However, as originally stated in the **Federal Register** of September 22, 1978 (43 FR 43248 at 43250), the agency believes that although sugar substitutes would not meet the weight-based criterion, they should continue to be excluded from this criterion.

Sugar substitutes contain calories. In fact, many contain more than 40 calories per 100 g. However, they have considerably less weight per degree of sweetness than sugars. Consequently a considerably smaller amount of sugar substitute than sugar may be used and still provide the same degree of sweetness. Because sugar substitutes are used on a sweetness rather than a weight basis, FDA believes that a weight based criterion is not appropriate for these foods. Such a criterion would mean that sugar substitutes could not make low calorie claims even though they are frequently used as ingredients in low calorie foods. By continuing to not require sugar substitutes to meet the 40 calories per 100 g requirement, sugar substitutes can continue to be labeled as "low calorie." Therefore, FDA is proposing in § 101.60(b)(2)(i) for the term "low calorie" to provide that, in addition to containing no more than 40 calories per serving, such foods, except for sugar substitutes, must contain no more than 40 calories per 100 g of food.

3. "High" and "Source"

a. *Background.* The agency considered several approaches for defining terms useful in making nutrient content claims to emphasize the presence of a nutrient. Earlier, in response to the increased use of descriptive terms as part of shelf-labeling programs in supermarkets, the agency had suggested definitions for the terms "source," "good source," and "excellent source" (Ref. 9). The agency defined these terms as providing 10 percent or more, 25 percent or more, and 40 percent or more of the U.S. RDA, respectively, per serving of food, and in the case of dietary fiber, 2 g or more, 5 g or more, and 8 g or more, respectively, per serving of food.

The report from the IOM Committee on nutrition labeling (Ref. 5) favored a system in which vitamins and minerals, when listed on the label, would be described qualitatively using words rather than quantitatively using numbers or percentages of the U.S. RDA. However, the committee did not specifically address the need for criteria for nutrient content claims.

While FDA is proposing to retain quantitative listings of nutrients in the nutrition label, the agency believes that there is merit in the IOM Committee's recommendations concerning the use of certain descriptive terms, especially when used for nutrient content claims intended to emphasize the presence of a nutrient.

The IOM Committee suggested definitions for the terms "contain," "good source of," and "very good source of." However, it commented that the term "excellent source" would provide an unintended incentive for unnecessary vitamin and mineral fortification. In addition, the IOM Committee's review of the vitamin and mineral content of a variety of foods indicated that very few foods would be eligible to use the term "excellent source" as currently defined by FDA, even though many of the foods are recognized as important sources of specific nutrients. The IOM Committee further pointed out that most vitamins and minerals do not occur naturally at high levels in any one food. The IOM Committee's report stated that an adequate diet must be assembled from a variety of different foods, and it emphasized that such a varied diet was the type of dietary pattern that food labeling should encourage. The IOM Committee recommended that FDA definitions of descriptive terms should be based on more "modest" definitions than the 40 percent of U.S. RDA

currently used to define the term "excellent source."

The agency agrees that consumers should be encouraged to consume a wide variety of foods. The agency also believes that the criteria for descriptive terms should be consistent with the levels of nutrients occurring naturally in foods, and that definitions for terms should allow for a reasonable number of foods to make the claim. For these reasons, the agency does not believe that descriptive terms such as "high" can be considered useful to consumers if they can identify only very few foods or only specially formulated foods. Such criteria could discourage the consumption of a wide variety of foods. Furthermore, the use of criteria that take into account the amounts of nutrients occurring naturally in foods is in line with the recommendations provided in "Nutrition and Your Health: Dietary Guidelines for Americans" issued jointly by DHHS and USDA (Ref. 1). Those recommendations emphasize the need to select a diet from a wide variety of foods and to obtain specific nutrients from a variety of foods rather than from a few highly fortified foods or supplements.

b. *How definitions of "high" and "source" were derived for nutrients.* As directed by the 1990 amendments (section 3(b)(1)(A)(iii)(VI)), FDA is proposing to define the term "high" for use in nutrient content claims. The agency is proposing in § 101.54(b)(1) that the term "high" may be used when a serving of the food contains 20 percent or more of the proposed RDI or the proposed DRV. The agency is also proposing in § 101.54(c)(1) that the term "source" unmodified by an adjective may be used to describe a food when a serving of the food contains 10 to 19 percent of the RDI or the DRV.

The use of 20 percent or more of the proposed reference value as a standard for the presence of upper levels of a nutrient (i.e., "high") is generally consistent with the IOM Committee recommendation for "very good source" for vitamins and minerals. The IOM Committee stated that a criterion of more than 20 percent of the reference value would encompass a sufficient number of items in the food supply to ensure that the use of the criterion would encourage consumers to select a varied diet (Ref. 5).

In evaluating the appropriateness of the criterion of 20 percent or more of the RDI or DRV as the basis for the definition of "high," FDA used its Regulatory Food Composition Data Base to examine the types of foods that contain nutrients at levels that meet or surpass 20 percent of the proposed reference value (Ref. 36). Sixteen nutrients with RDIs and one with a DRV (i.e., potassium) were considered in this analysis. Other nutrients with RDIs or DRVs were excluded either because the agency is not proposing to define "high" for these nutrients (e.g., fat), or because the nutrients values in the data base were absent or insufficient (i.e., missing values for more than 25 percent of the foods). For the majority of the 17 nutrients considered, at least 10 percent of the foods in the data base contain 20 percent or more of the RDI or DRV (i.e., the proposed definition for "high"). For these nutrients there was at least one and often more than one food category that contained a substantial number of foods containing 20 percent or more of the RDI or DRV.

Those nutrients for which fewer than 10 percent of the foods in the data base contain 20 percent or more of the RDI or DRV were calcium, magnesium, copper, manganese, potassium, pantothenic acid, and vitamin A. However, even with these nutrients (with the exception of potassium), there was a substantial number of foods in at least one food category that would qualify for "high" claim if the proposed definition were used. Thus, based on this evaluation, the agency agrees with the IOM Committee's conclusion that this criterion would permit a sufficient number of food items to allow consumers to use the claim in selecting a varied diet. Therefore, the agency tentatively concludes that a criterion of 20 percent or more the RDI or DRV provides an appropriate basis for upper-level content claims and can readily be used by consumers to implement current dietary guidelines.

While the IOM Committee has suggested the use of the term "very good source" for levels above 20 percent of the label reference value, the agency is proposing to define this level as "high" to be consistent with the 1990 amendments. Additionally, while the IOM Committee suggested a definition of more than 20 percent of the reference value, FDA has tentatively concluded that a definition of 20 percent or more is more consistent with the agency's approach of defining the term "low" in that the definition includes the integer. The inclusion of the integer makes little practical difference in terms of the types and numbers of foods omitted or included (Ref. 37).

As discussed previously, the agency is concerned that the use of many descriptive terms could overburden consumers and result in consumer confusion or frustration. The agency believes, for example, that allowing the terms "rich" and "high" to describe two different levels of a beneficial ingredient, would be confusing and misleading to consumers who could reasonably be expected to have difficulty distinguishing "rich" from "high."

While the 1990 amendments specify that FDA should define the term "high," the statute does not preclude the agency from defining other appropriate terms for making nutrient content claims to emphasize the presence of a nutrient. The agency is concerned that the use of only the term "high" will encourage persons to focus their attention solely on foods "high" in nutrients, when, in fact, a healthy diet can include a range of foods that are not necessarily "high" in a particular nutrient. Therefore, to expand the number of foods to which consumers' attention may be drawn and from which consumers are encouraged to select and still be likely to meet dietary recommendations, FDA is proposing to define the term "source" unmodified by an adjective.

FDA believes that it is appropriate and beneficial to consumers to allow the use of this term, which characterizes a mid-range of nutrient content. In defining the term "source," FDA intends to allow food manufacturers and retailers to make a nutrient content claim for a food that provides a significant amount of the nutrient in a serving of the food but for which the nutrient level cannot be described as "high." FDA believes that this information will be helpful to consumers in selecting a healthy and nutritious diet.

The agency is proposing that for a food to be considered to be a "source" of a nutrient, the food must contain 10 to 19 percent of the proposed RDI or DRV per serving. FDA believes that a criterion of 10 to 19 percent is consistent with the criterion 11 to 20 percent of the RDI or DRV suggested by the IOM Committee for the term "good source of," a term intended to reflect a mid-range of nutrient content. The proposed definition of "source" is also consistent with the agency's suggestion that, for the purposes of grocery store shelf-labeling, the term "source" could be used when a serving of the food contains 10 percent or more of the U.S. RDA of the featured substance (Ref. 31). Consequently, the term "source," used to denote that a food contains at least 10 percent of the RDI or DRV of a nutrient, has been introduced to, and used by, consumers in grocery-store shelf-labeling and is likely to be familiar to them.

FDA is not proposing to define the term "contains," such as "contains vitamin C" or "contains fiber." While the IOM Committee has proposed the

use of the term "contains," this recommendation was made in the context of describing, on the nutrition label, the levels of nutrients in a food in lieu of use of percentages of the U.S. RDA. The IOM Committee's system of terminology, therefore, represented a descriptive scheme that graded the levels of nutrients from upper to lower levels.

The agency is concerned that consumers would not be able to distinguish easily between "source" and "contains" when used as nutrient content claims, and that consumers would find these terms confusing. More importantly, the agency believes that for the purposes of nutrient content claims, the use of "high" and "source" provides appropriate opportunities to call attention to the positive aspects of the nutrient content of foods, and that these terms adequately reflect levels of nutrients in foods that can be especially useful to consumers in planning overall diets. Furthermore, the agency has long held that levels of nutrients of less than 10 percent of the US RDA could not be used as content claims because current nutrition labeling regulations prohibit claims that a food is a significant source of a nutrient when the nutrient is present in the food at a level of less than 10 percent of the US RDA per serving. FDA is unaware of evidence suggesting that the policy should be changed and therefore is not proposing a descriptive term for nutrient levels of less than 10 percent of the RDI or DRV per serving.

FDA recognizes that limiting defined descriptors to "high" and "source" for the purpose of emphasizing the positive aspects of the presence of a nutrient is a change from previous agency guidance which permitted the use of the terms "excellent source," "good source," and "source," and that Canadian guidelines also permit a variety of such terms (Ref. 38). The agency, however, has tentatively concluded that limiting the number of descriptors will assist consumer understanding of, as well as confidence in, nutrient content claims by providing for consistent, clear, and limited messages concerning the presence (or absence) of nutrients in foods. The agency requests comments concerning its approach and whether an additional term describing an upper level amount of a nutrient (such as "very high") is necessary and appropriate.

However, the agency is proposing to include synonyms for the two defined terms. FDA is proposing to allow the use of "rich in" and "a major source of" as synonyms for "high." It is also proposing to allow the terms "good source of" and "important source of" as synonyms for "source." FDA is including these synonyms to provide some flexibility in the use of these terms.

FDA recognizes, however, that this aspect of the proposal may be controversial. Concerns about the use of synonyms for terms like "high" and "source" have been raised by IOM and the IUNS Committee (Ref. 10). The IUNS Committee questioned the wisdom of more detailed descriptors because of the difficulties for the consumer in understanding a plethora of such terms (Ref. 10). FDA requests comments on this issue and on consumer understanding of the terms that it has proposed as synonyms for "high" and "source."

c. *"High" and "source" not defined for total carbohydrate and unsaturated fatty acids.* FDA has tentatively concluded that definitions for "high" and "source" for the nutrients total carbohydrate, including complex carbohydrates, and unsaturated fatty acids would be misleading. Therefore, FDA is proposing to exclude these nutrients from the coverage of these terms (proposed § 101.54(a)).

In proposing declarations of nutrient content as part of the nutrition label, FDA is proposing to define total carbohydrate as consisting of both complex carbohydrates and sugars. Available consensus reports and current dietary recommendations generally encourage the increased consumption of complex carbohydrates, while suggesting that sugars intake be limited (Refs. 1, 2, and 3). Therefore, a nutrient content claim such as "high in carbohydrate," or "source of carbohydrate," provides misleading dietary advice. At best, the claim is ambiguous in that it does not allow for the distinction between high levels of complex carbohydrates and high levels of sugars.

Furthermore, the agency does not believe that allowing more specific claims relative to levels of carbohydrate in foods, such as "high in complex carbohydrates," can be supported based on recommendations provided in the major consensus reports (Refs. 2 and 3) concerning complex carbohydrate and sugars intake because quantitative recommendations for these nutrients are not provided. Additionally, while the agency has tentatively proposed to require declarations of complex carbohydrates and sugars content on the nutrition label in response to the 1990 amendments, the agency has expressed concern about the appropriateness of including these nutrients. The inclusion of complex carbohydrates and sugars within the mandatory nutrition label may be misleading to consumers because it may suggest that these nutrients have greater public health significance than has been established by existing diet and health studies. In particular, the identification of a specific benefit for complex carbohydrates is confounded by the fact that diets high in complex carbohydrates are usually mixed diets that contain significant amounts of cereal grains, fruits, and vegetables, which are high in fiber, vitamins, and minerals and low in fat (Ref. 2). Thus, the extent to which complex carbohydrates provide a health benefit separate from that provided by the fiber, vitamins, minerals, and reduced level of fat is unclear.

Nutrient content claims concerning "high" amounts of unsaturated fatty acids in foods are problematic for several reasons. Unsaturated fats are comprised of various mono- and polysaturated fatty acids. Different types of unsaturated fatty acids are known to have different effects on health. Some have been shown to lower serum cholesterol levels when substituted for saturated fatty acids (Ref. 3). On the other hand, there is a growing body of evidence suggesting that *trans* isomers of unsaturated fatty acids may be associated with increases in serum cholesterol levels (Ref. 3). The agency has expressed concern about the appropriate definition of unsaturated fatty acids in its supplementary proposal on nutrition labeling. FDA is proposing to provide for voluntary declarations for the amount of unsaturated fatty acids in a food, which would be based on the sum of all polyunsaturated and monounsaturated fatty acids (i.e., both *cis* and *trans* isomers). If claims for "high" unsaturated fatty acids were permitted, *trans* isomers would be included in the level of unsaturated fatty acids reflected in such claims. However, FDA has acknowledged the controversy concerning the inclusion of *trans* isomers in the definition of unsaturated fatty acids. The agency is specifically asking for comments on the appropriateness of including these isomers in the definition for unsaturated fatty acids, given currently available research and public health goals, in the supplementary proposal on mandatory nutrition labeling.

Furthermore, high levels of intake of unsaturated fatty acids, particularly high polysaturated fatty acid intakes, may increase risk of certain cancers (Ref. 2). The NAS report "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 3) recommended that intakes of polyunsaturated fatty

acids not exceed 10 percent of total calories, and that intake be maintained at the current U.S. level, i.e., approximately 7 percent of total calories. Claims for "high unsaturated fatty acids," however, could promote increased intakes of polyunsaturated fats.

Therefore, FDA has tentatively decided not to define the claim "high" for unsaturated fatty acids here. FDA believes that such claims are potentially misleading because there is some evidence suggesting that certain components of unsaturated fatty acids may be associated with the increased risk of certain cancers because current dietary recommendations advise against increases in at least one component of unsaturated fatty acids, and because the current science base has suggested that the benefits of polyunsaturated fatty acids derive not from increased intake but rather from their substitution for saturated fatty acids.

d. *Special requirements for fiber claims for foods not low in fat.* Consistent with section 403(r)(2)(A)(v) of the 1990 amendments, FDA is proposing to require that unless a food meets the definition for "low fat" (i.e., contains 3 g or less of fat per serving and per 100 g of food), as proposed in § 101.62(b)(2) of the companion document on claims for fat, saturated fat, and cholesterol content, the claims "high fiber" or "source of fiber" shall be accompanied by a declaration of the amount of total fat in a serving of the food. Therefore, FDA is proposing in § 101.54(d) that if a claim is made that a food is high in fiber, or is a source of fiber, and the food is not low in total fat as defined in § 101.62(b)(2), then the label must disclose the level of total fat per labeled serving in the referral statement (e.g., "Contains [*X g*] of total fat per serving. See [*nutrition panel*] for nutrition information").

C. Relative Claims

1. Introduction

Among the terms the agency is required by the 1990 amendments to define, unless they are found to be misleading, are "light" (or "lite"), "reduced," and "less" (section 3(b)(1)(A)(iii)(III), (b)(1)(A)(iii)(IV), and (b)(1)(A)(iii)(V), respectively). Claims that include these terms are intended to help guide consumers to foods that may be useful in meeting current dietary recommendations. In addition, these terms provide a basis for comparing the level of a nutrient in one food to its level in another food. The agency refers to these claims as "relative claims" to distinguish them from the "absolute" nutrient content claims using, for example, "low" or "high." However, the term "light" has been used not only as a comparative term to indicate that there is less of a nutrient in this particular food compared to another food, but it has also been used to directly describe a characteristic of the food itself without direct comparisons to another food.

The agency is also proposing to define the circumstances under which the terms "fewer" and "more" may be used. Together with "less," FDA considers "fewer" and "more" to be a subset of relative claims referred to as "comparative claims."

Although there is a certain amount of overlap in the proposed definitions of these terms, the agency is really defining them to create a continuum for "light" claims, to "reduced," and finally to "less," with decreasing rigor in the requirements for use of the terms. FDA's tentative view is that such an approach will limit consumer confusion with respect to the meaning of these terms. However, FDA recognizes that, as an alternative, the terms could be used subject to a single set of definitional requirements, with full disclosure, as part of the claim, of the reference food, the percent the nutrient has been decreased, and the quantitative amount of the nutrient in the labeled food and the reference food. This alternative approach is discussed below in section IV.

2. General Requirements

The general requirements for relative claims, including comparative claims, are set forth in proposed § 101.13(j).

a. *Reference foods.* Relative claims compare the amount or percentage of a nutrient in one product to the level of that nutrient in another food. The agency uses the term "reference food" to denominate the food to which the labeled product is compared. Because a relative claim may be made with respect to a variety of reference foods, FDA believes that for such a claim to be complete and not misleading, the claim must be accompanied by a statement that compares the food for which the claim is made to a specified reference food. This information is important because the amount of a nutrient in a food product, potato chips for example, may vary widely. Some brands or formulations may be relatively low in a nutrient, such as fat, while others are relatively high. Consequently, the declared percentage reduction in a nutrient in a food making a claim will vary depending on the food to which the comparison is made. Conversely, two products showing the same percentage reduction in a nutrient, 25 percent for example, may vary considerably in the absolute amount of the reduction, depending on the product to which each altered food is compared.

The agency believes that a food bearing a relative claim, but not the identity of the reference food, would be misbranded under section 403(a) and 201(n) of the act because a fact material to understanding the significance of the claim would not be revealed. Information about the nature of the modification of the product, which would be essential in judging the usefulness of the product, would not be declared. The agency believes, therefore, that the identity of the food that serves as the basis for the relative claim must be stated on the label.

To ensure that the comparisons made are appropriate, FDA is proposing criteria for selecting reference foods. FDA first developed these criteria in response to comments on its proposal on cholesterol content claims (51 FR 42584, November 25, 1986). These criteria were discussed in the subsequent tentative final rule (55 FR 29456, July 19, 1990). In that document, the agency tentatively concluded that appropriate reference points for "reduced" and comparative claims would be: (1) An industry wide norm, (2) the manufacturer's regular product, or (3) a similar product or class of products as found in a current valid composite data base.

Although FDA is proposing to retain these general points of comparison, the agency considers it necessary to alter the application of these references to accommodate the expanded scope of the descriptors found in this document.

The agency is now proposing an industry-wide norm as a reference point for all relative claims in § 101.13(j)(1)(i). An industry-wide norm takes into account all foods in a particular product class. Consequently, it provides the broadest base and the least opportunity for abuse of any of the reference foods. As defined in the cholesterol tentative final rule, an "industrywide norm" is an average value that is determined by calculating the weighted average of the nutrient in question on a unit or tonnage basis according to the national market share of all foods of the type for which the claim is being made. This concept utilizes national market share information that is readily available to both industry and government. The agency believes that by calculating the industry-wide norm on a unit or weight basis rather than on the basis of dollar sales, the price variability between various brands of similar products (generic or store brand versus national

brands, for example) will not affect the result.

As an example of the calculation for "industry-wide norm," if brand A has a market share of 75 percent and contains 100 mg of cholesterol per 10-ounce (oz) serving, and brand B has a market share of 25 percent and contains 200 mg of cholesterol per 10-oz serving, then the industry-wide norm is 125 mg of cholesterol per 10-oz serving.

FDA is proposing in § 101.13(j)(1)(ii) that reduced and comparative claims may also be made using "a manufacturer's regular product." In the cholesterol tentative final rule, FDA defined this food as a food actually offered for sale to the public on a regular basis for a substantial period of time in the same geographical area, by the same business entity or by one entitled to use its trade name. This criterion will prevent misleading comparisons by precluding a manufacturer from specially formulating a product that is particularly high in a nutrient for limited distribution, for the sole purpose of providing a favorable basis of comparison for another product. A manufacturer's regular product provides a reference to a known specific food and consequently provides a meaningful basis for "reduced" and comparative claims which compare one product directly to another.

Finally, FDA is proposing in § 101.13(j)(1)(iii), for comparative claims only, that a food may also be compared to a similar product or class of products whose compositions are published in a current, valid composite data base, such as the revised sections of USDA's Agriculture Handbook No. 8: "Composition of Foods, Raw, Processed, Prepared" (Ref. 39). By including valid data bases as a basis of comparison, the agency would permit comparative statements based on comparisons of foods within a product class. A product class would include foods for similar dietary uses, i.e., foods that are used interchangeably and have similar product characteristics. For example, this reference point would allow a potato-based snack food to make comparisons with potato chips or with corn chips and a waffle to be compared with a pancake or french toast. This approach would also allow certain new types of products that have a nutritional advantage over existing foods to make a comparative statement. Such a comparative statement might read, for example, "potato puffs, contains 25 percent less fat than potato chips." Because a valid data base, such as USDA's Agriculture Handbook No. 8, (Ref. 39) includes a wide variety of foods within a product category, the agency believes that this reference is inappropriate for "reduced" or "light" claims.

b. *Need for information to accompany claim.* The agency believes that even though terms used in relative claims will be defined by regulation, the claims may be misleading unless they are accompanied by certain material facts that are necessary if consumers are to understand the change that has been made in the food. The agency considers that in the presence of a relative claim: (1) The percent of change in the nutrient level, and (2) the amounts of the nutrient in the labeled food and the reference food are material facts under sections 403(a) and 201(n) of the act.

As will be discussed in detail later, the agency is proposing to permit relative claims on foods based on nutrient differences of 25 percent and above for diminished levels of a nutrient and 10 percent or more of the DRV or RDI for increased levels of a nutrient. Consequently, information about the percent difference in the level of the nutrient between the food and the reference food is necessary for the consumer to evaluate the claim.

Even if a product declares the percent reduction in a particular nutrient compared to the reference food (or the percent more of the DRV or RDI compared to the reference food for "more" claims), the amount of that nutrient in the product relative to the reference food is also necessary information. Information on the amount of nutrient present is necessary for consumers because it provides an additional basis on which they can evaluate the significance of the change, and because it helps them in composing a diet to meet nutritional requirements.

FDA is proposing that statements about the relative amount of a nutrient in the labeled food compared to the reference food state the amount of the nutrient in each food, i.e., "This cheesecake contains 150 calories per serving compared to 200 calories per serving of our regular brand."

As discussed in section II.C. of this document on referral statements, the agency believes that required accompanying information should be in type size no less than one-half the size of the claim. Therefore, consistent with current regulations and proposed requirements for referral statements, the agency is proposing that the required information accompanying a claim about the relative amount of a nutrient be in type no less than one-half the size of the type of the claim but in no case less than one-sixteenth of an inch. One sixteenth of an inch, as discussed above, is the minimum size normally permitted (per § 101.2(c)) for information required on the principal display, or information panel of food labeling.

The agency recognizes that the information that it is proposing to require accompany a relative claim is considerable, but it considers this information necessary to ensure that the claim is not misleading. On the other hand, FDA also recognizes that a requirement that this information be included each time a relative claim is made would overburden the label to the point that the usability of the required information could be diminished. Therefore, the agency believes that the quantitative information required to accompany the claim should be required with only the most prominent declaration of the claim on the food.

Accordingly, based on the foregoing discussion, the agency is proposing in § 101.13(j)(2) that for foods bearing relative claims, the label must bear immediately adjacent to a relative claim in the most prominent location on the label, and in type no less than one-half the size of the type in the claim but in no case less than one-sixteenth of an inch, the following information: (1) The identity of the reference food, (2) the percentage by which the amount of the nutrient in the food differs from the amount in the reference food, and (3) quantitative information comparing the amount of the subject nutrient in the food per labeled serving with that in the reference food (§ 101.13(j)(2)(i)).

The agency is also proposing that the determination of which use of the claim is in the most prominent location will be made based on the following factors, considered in order: (1) A claim on the principal display panel adjacent to the statement of identity, (2) a claim elsewhere on the principal display panel, (3) a claim on the information panel, or (4) a claim elsewhere on the label or labeling (proposed § 101.13(j)(2)(ii)). These factors are based on the fact that the statement of identity is the most critical information on the package, and that the principal display panel, followed by the information panel, are the most important label panels. In addition, these requirements are reiterated in the appropriate paragraphs for relative claims for the individual nutrients e.g., in § 101.54(e)(1)(iii) for "more" claims, § 101.56(b)(3) for "light" claims, § 101.60(b)(4)(ii) and (b)(5)(ii) for calorie claims, and § 101.61(b)(6)(ii) and (b)(7)(ii) for sodium claims.

c. *Absolute difference in nutrient levels for relative claims with*

decreased levels of nutrients. The agency is concerned that relative claims that highlight a decrease in the amount of a nutrient will be made on products that normally contain only a small amount of that nutrient. In such products, a large percentage reduction would produce only a small change in the actual amount of the nutrient present. For instance, a food containing only 50 calories per serving could be reformulated to contain 35 calories per serving and thereby qualify to use a relative claim when, in fact, the difference of 15 calories cannot be considered of nutritional significance. A claim for such a nutrient content difference would be misleading.

Therefore, the agency believes that an additional criterion that specifies a minimum reduction in the amount of the nutrient is necessary to ensure that manufacturers do not make changes based on inconsequential changes in their products.

Currently, no guideline or definition that can be used for determining the amount of a nutrient in food that can be considered consequential or nutritionally meaningful is available. However, FDA believes that the definition for a "low" claim on a per serving basis should be used as such an amount. The agency considers this level to be appropriate because the amount specified as "low" is not inconsequential relative to the overall intake of the nutrient. A person who chose a diet exclusively of foods that qualified for a "low" claim for a particular nutrient would be expected to consume as much as 50 percent of the recommended levels for that nutrient. Yet, because the definition of "low" is tied to the measurable amount of the nutrient, it is clearly a small amount.

Accordingly, FDA is proposing in § 101.13(j)(2)(iii) that a relative claim for a decreased level of a nutrient may be made on the label or in labeling of a food only if the nutrient content for that nutrient differs from that of the reference food by at least the amount specified in the definition of "low" for that nutrient. Consequently, to bear a relative claim for decreased levels of calories, for example, a food would have to have a decrease from the reference food of more than 40 calories per serving.

3. Reduced

a. *Background.* FDA has recognized the potential dietary benefits of foods that have been fabricated or altered to reduce their nutrient content. FDA regulations, proposed regulations, and guidelines provide for the use of the term "reduced" for content of sodium (21 CFR 101.13(a)(4)), fat (Refs. 3 and 31), cholesterol (55 FR 29456, July 19, 1990), and calories (21 CFR 105.66.(d)). Canadian regulations provide for the use of the term "reduced" for altered foods, specifically for the content of calories (Ref. 32) and carbohydrates (Ref. 33).

In response to the 1989 ANPRM and the public hearings, FDA received a variety of comments concerning the term "reduced." Many supported the use of the term, although a few comments suggested that the term was redundant to the agency's provision for comparative statements, and that the term could be misleading to consumers who would interpret the claim to be synonymous with "low." Several comments stated that there is a need to limit the descriptor to a "significant standard of reduction" or a difference of "nutritional significance" to consumers. Other comments argued that, in defining this term, it is necessary to avoid using unreasonably restrictive criteria that could not be met technologically. These comments stated that such criteria would not provide incentives for alterations in food products. However, the comments generally supported the use of levels such as the 33.3 percent for calories, the 50 percent for fat, and the 75 percent for sodium that FDA has established as the reduction levels. Some comments stated that for consumer ease of understanding, and to provide for industry incentives to reduce nutrients in foods, general use of 33.3 percent for all nutrients was desirable. Other comments supported the use of a 50 percent reduction for all nutrients.

The agency believes that consumers associate the term "reduced" with a beneficial reformulation of the food product, and many comments support this belief. Furthermore, given the considerable increase in public awareness and concern about diet and health, the term is viewed by industry and by public health professionals as being particularly effective in causing consumers to select one product over another. Therefore, FDA agrees that the term should be defined, and that the definition of the term should be limited to reformulations that reflect considerable decreases in the level of the nutrient and that have the potential to result in a significant impact on dietary intake of the nutrient. Moreover, as stated above, section 3(b)(1)(A)(iii)(IV) requires that FDA define this term.

In defining the term "reduced," FDA acknowledges the possibility that consumers could interpret the term to be synonymous with the term "low" but believes that consumer education efforts can help to alleviate the potential confusion. Moreover, the possibility of misinterpretation does not outweigh the potential benefits of encouraging the availability and consumption of foods containing reduced levels of certain nutrients. Furthermore, as described above, the agency is proposing to require declaration of quantitative comparisons both in terms of percent reductions and absolute amount reductions. These proposed provisions should decrease the possibility of consumer misinterpretation of the term "reduced."

FDA is proposing to define "reduced" for the following nutrients: total fat, saturated fat, cholesterol, sodium, and calories. The rationale for defining "reduced fat," "reduced saturated fat," and "reduced cholesterol," and the proposed definitions for these terms, are set forth in the companion document on claims about these nutrients published elsewhere in this issue of the **Federal Register**. FDA tentatively concludes that reduced claims for nutrients other than these five are not appropriate because the reduction of other nutrients in the diet is not identified as being of public health importance in the major consensus reports currently available (Refs. 2 and 3).

b. *How definitions of "reduced" for nutrients were derived.* To justify a "reduced claim" and the consequent emphasis on the fact that a reduction in a nutrient has occurred, FDA believes that there should be a substantial reduction in the amount of nutrient present in the food, which in turn could result in a substantial reduction in the amount of the nutrient in diets of individuals. While there is general agreement that the availability of foods reduced in specific nutrients is beneficial from a public health perspective (Refs. 5 and 46), there are no scientific data available to indicate precisely the extent to which reductions of these nutrients in available foods are needed, nor the extent to which such reductions could affect the diets of individuals. Nonetheless, FDA has developed a general approach to the use of this claim.

In defining "reduced," and what would constitute a substantial reduction in the level of a nutrient in a food, an important consideration is the distribution of the nutrient in the food supply. If a nutrient is provided by all general categories of foods, such as fruits, vegetables, grain products, and dairy products, the nutrient can be considered to be ubiquitous in the food supply. The extent of reduction necessary to justify a "reduced" claim for nutrients that are ubiquitous is likely

to be different than that necessary for nutrients that are found in only some or a few food categories. If the dietary reduction of a nutrient can be spread out over all or most food categories, smaller reductions on a food-by-food basis would be needed to achieve a substantial dietary impact than would be needed if the nutrient is present in only some food categories.

A second important consideration in defining "reduced" is the need to provide a consistent definition for this term for all nutrients, so that consumer education efforts can be more easily implemented. Comments have suggested that consumers will more readily recall the meaning of the term "reduced" if it is limited to one level of reduction, such as one-third or one-half. The agency agrees that consistency in definition is desirable.

Therefore, in developing the general criteria for the use of the term "reduced," the agency considered the level of reduction that would result in a substantial reduction in the nutrient content of foods as well as the need for consistency of terms. In addition, FDA considered two other factors. In response to comments, FDA considered the technological feasibility of reducing levels of nutrients in foods. Finally, in developing these definitions, the agency reviewed the quantitative differences between current levels of intake for these nutrients and recommended levels of intake.

FDA is proposing to define the term "reduced" as a difference of 50 percent for all specified nutrients except calories. The agency has tentatively decided that there are no compelling reasons to change the current definition for "reduced calorie" of a 33.3 percent reduction in calories (§ 105.66(d)(1)(i)). For the other four nutrients, reductions of 50 percent are feasible, even in the case of total fat. Current technology has demonstrated that for many foods, including dairy products, a reduction in total fat of 50 percent or more is achievable (Ref. 40).

In addition to a percentage reduction, FDA is proposing to include an absolute reduction criterion in the definitions for "reduced" for particular nutrients. To bear a "reduced" claim, the food must contain a level of the nutrient that is reduced from that in the reference food by an amount that exceeds the per serving criterion for "low" for that nutrient. FDA explained the basis for its reliance on that criterion in section III.C.2.c. of this document, above.

c. *Reference foods for "reduced" claims.* As discussed above (section III.C.2.a. of this document), FDA is proposing in § 101.13(j)(1) two reference points against which a food can be compared to develop a "reduced" claim that is not false or misleading: (1) An industry-wide norm and (2) a manufacturer's regular product.

The agency believes that these reference points are appropriate for "reduced" claims because they reflect points of comparison that are accurately and consistently quantifiable and that thus can provide a meaningful basis of comparison. An industry wide norm represents a reference point calculated on the basis of all foods of the particular type for which the claim is being made. Likewise, the manufacturer's regular brand, which has been available for sale to the public on a regular basis for a substantial period of time and in the same geographic area by the same business entity or one entitled to use its trade name, provides the consumer with a valued reference point to which they should be familiar.

The agency, however, does not consider the third reference point, i.e., a similar product or class of similar products in a current valid composite data base, to be an appropriate point of reference for comparing "reduced" foods. Such a reference point reflects a much wider variety of products than the other two. The agency believes that "reduced" comparisons should be made to a product or type of product that is most like the product bearing the claim. For example, if a product is labeled as "reduced fat imitation bacon bits," it is claiming that it contains reduced fat when compared to other imitation bacon bits. If such a claim could be made on the basis of a data base of products similar to imitation bacon bits, the data base would likely include a range of products, including bacon. The imitation bacon bits could have reduced fat when compared to the data base but not necessarily any less fat than other imitation bacon bit products. In such circumstances, the claim would clearly be misleading. Thus, FDA believes that comparison to a data base of similar products is not an appropriate basis for a "reduced" claim.

Moreover, particularly as a data base ages, the values in the base may no longer represent the nutrient composition of foods that are on the market. If, for example, all manufacturers have lowered the amount of fat in their products, it would not be appropriate for an individual manufacturer to make a "reduced" claim against the higher value represented by the older average value. By requiring that the comparison be made against an "industry-wide norm" or the manufacturer's regular product, the agency believes that this problem is minimized.

d. *Specific definitions*—i. *Reduced sodium.* FDA is proposing to define "reduced sodium" in § 101.61(b)(6)(i) as a reduction of at least 50 percent and a minimum reduction of more than 140 mg per serving. This definition is different than the current FDA regulation (21 CFR 101.13(a)(4)), which provides that for a food to be labeled "reduced sodium," its level of sodium must be reduced by 75 percent. No weight based criterion is specified in the current regulation.

In its 1984 rule on sodium descriptors (49 FR 15510), FDA stated that it intended the "reduced sodium" descriptor to be reserved for those products in which there has been a very substantial reduction in the level of sodium, and that the feasibility of a 75 percent reduction in sodium had been demonstrated for a few products such as cheese and soups. The agency stated that it did not consider a 75 percent reduction to be too severe, unrealistic, or technologically infeasible.

Few data are available to determine the extent to which foods have been reformulated to meet the current criterion for "reduced sodium." A review of data in FDA's 1988 Food Labeling and Packaging Survey (FLAPS) data base revealed that of the 1,265 foods in the data base, none had "reduced sodium" in their brand name or elsewhere on the label (Ref. 41). Information from a market survey for the period of January to June 1989 (Ref. 42) reveals that about two dozen products from over 222,000 products were recorded as having "reduced sodium" or "reduced salt" in their brand name.

While the results of those surveys may suggest that the current criterion may be too difficult to meet, a firm conclusion cannot be drawn because these surveys are selective and not comprehensive. However, the agency recognizes that a 75 percent reduction in sodium may be too difficult to achieve to provide incentive to the food industry to develop and promote reduced sodium foods. The agency therefore believes that some reduction in this criterion would be appropriate.

One reason to consider a 50 percent reduction as a more appropriate criterion for "reduced sodium" is the desirability of harmonizing the criteria used to define the term "reduced" among the various nutrients. As discussed above, consistency of definition will facilitate education efforts and potentially decrease the level of confusion concerning the overall use of the term. In the companion

document concerning fat, saturated fat, and cholesterol descriptors, FDA is proposing a 50 percent reduction as the definition for "reduced fat," "reduced saturated fat," and "reduced cholesterol."

Furthermore, evidence from FDA's Regulatory Food Composition Data Base (Ref. 35) suggests that while sodium is not ubiquitous in the food supply, it is present in many foods. As a result, there are a large number of potential candidates for a "reduced sodium" claim. While a 50 percent reduction is obviously smaller than a 75 percent reduction, if more manufacturers make reduced sodium foods as a result of this decrease in the criterion, the 50 percent reduction criterion may ultimately be as effective, or more effective, in lowering sodium intake than would be a 75 percent reduction in fewer foods.

Additionally, the agency has estimated that a general reduction of 50 percent in sodium intake is needed to meet current dietary recommendations (Ref. 43). While such an estimate cannot form the basis for defining precisely the necessary level of reduction of a nutrient needed, in the case of sodium it supports that a 50 percent reduction in individual foods is not inconsistent with current public health goals in that the proposed level of reduction in foods corresponds to the apparent need for reduction in the general diet.

FDA is therefore proposing in § 101.61(b)(6) to amend the current regulation for reduced sodium foods (§ 101.13(a)(4)) by establishing 50 percent for "reduced sodium" as a minimum reduction. The agency specifically asks for comments concerning this proposed criterion, its public health impact, and nutritional significance, as well as the extent to which the benefits of consistency among definitions and increased availability of sodium reduced foods should be considered.

The agency is also proposing in § 101.61(b)(6) to limit the use of the term "reduced sodium" to those foods for which the total reduction in sodium levels exceeds 140 mg per serving. As discussed above, this second criterion will prevent "reduced sodium" claims on foods that have undergone inconsequential reductions in sodium levels.

ii. *Reduced calorie.* FDA is proposing in § 101.60(b)(4)(i) to define the term "reduced calorie" as a level of reduction of at least 33⅓ percent and a minimum reduction of 40 calories per serving. This proposed definition is consistent with current agency regulations concerning the use of this term (§ 105.66(d)) but differs from the other current proposed levels of reduction for sodium, total fat, saturated fat, and cholesterol, all of which are proposed to be defined as a reduction of at least a 50 percent for the designated nutrient.

FDA first defined the term "reduced calorie" in 1978 (43 FR 43248). At that time, concerns about the term centered on ensuring that it applied to foods that have special value for reducing or maintaining body weight or caloric intake. The agency had tentatively defined "reduced calorie" as one that had at least a one-third reduction in calories (42 FR 37166). Comments received by the agency generally suggested that a lower number, such as a 25 percent reduction, be used. However, the agency adopted the 33⅓ percent reduction because it is feasible for many foods to achieve such a reduction, and because the agency felt that consumers expect a substantial reduction when "reduced" is used. FDA acknowledged that not all foods could be calorically altered but stated that it was important to have a reasonably large reduction in those that can be altered and that are offered for sale primarily on the basis of their caloric reduction.

Comments received by FDA in response to the 1989 ANPRM and public hearings generally supported the use of the term "reduced calorie." No comments expressed concern that the current level used to define this term was inappropriate. One comment, however, suggested that all terms for "reduced" should be defined as a 25 percent reduction, and one comment suggested that the level of reduction for all relevant nutrients should be one-third.

In arriving at a definition for "reduced calorie," FDA considered that the ubiquity of calories across all food categories suggested that the reduction in calories in each food necessary to achieve an overall reduction of public health significance could be less than that necessary for nutrients such as cholesterol or fat. Additionally, the agency considered the public health recommendations relative to weight control, which stress the desirability of only moderate reductions in calories coupled with an increase in exercise or energy (calorie) expenditure (Refs. 2 and 3).

Diets with a moderate reduction in calories are the most advisable for general use because they present less risk that the intake of essential nutrients will be inadequate when the caloric intake is controlled. A one-third reduction criterion allows a greater variety of nutritious foods to bear claims of usefulness in reducing or maintaining caloric intake or body weight, and variety is important in maintaining the motivation to adhere to a calorie control program. Finally, the agency considered that the current definition of "reduced calorie" has been used for a considerable time without apparent difficulty for manufacturers or consumers.

For these reasons, the agency continues to believe that the percentage reduction specified in its current definition of "reduced calorie" in 21 CFR 105.66(d) is appropriate and that there is no compelling reason to change this criterion. Thus, FDA is proposing to recodify this provision as § 101.60(b)(4). Additionally, as discussed above in section III.C.2.c. of this document, the agency is also proposing that declarations concerning reductions in calories be limited to those foods in which there has been a reduction of more than 40 calories per serving.

4. "Light" or "Lite"

a. *Reduced calorie/reduced fat products.* The 1990 amendments, in section 3(b)(1)(A)(iii)(III), instruct the agency to define the term "light" or "lite." (For purposes of this notice, the term "light" will be used to mean either "light" or "lite.")

The term "light," as it has been used for a number of years, connotes a wide variety of meanings such as low or reduced calorie; reduced in fat, sugar, or sodium; light in weight, texture, or color; and thin or less viscous. However, surveys (Refs. 44 and 45) conducted in 1982 and early 1990 found that consumers (70 percent in 1982 and 69 percent in 1990) believe that the term "light" means that the caloric level has been altered in some manner. The similarities in the consumer responses in these two surveys demonstrate considerable stability in consumer perception of the term "light," even though the extent and variety of uses of this term in food labeling have increased many-fold since 1982.

In addition to being a relative claim that compares a food to another food, the term "light" has been used to directly describe the food itself. Without specifying a reference food, the term "light" has been used to imply that the food bearing the term is somehow better nutritionally than other similar but unspecified foods not bearing the term. In this way it has been used more like the absolute claim "low."

The legislative history reflects this use of "light." It states that "an example of an implied claim * * * would be the statement "lite," which implies that the product is low in some nutrient

(typically calories or fat), but does not say so expressly." (H. Rept. 101-538, *supra*, 19.) When "light" has been used as an implied claim, the consumer has generally not been given any explicit product-to-product comparisons to support the claim. The use of "light" without such comparisons results in a direct statement about the food, suggesting that the food itself was somehow more healthful.

Thus, it is not surprising that "light" appears to have great appeal to consumers. In a 1990 Gallup Poll (Ref. 45) many consumers said that they consume "light" products. Sixty-five percent said they consume "light" cheese, yogurt, and sour cream, and 46 percent said they consume "light" ice cream and frozen desserts. Because a majority of consumers associate "light" with a reduction in calories even though there are other meanings for the term, the potential for misuse of the term is created. For example, the use of the term "light" on a food oil may lead consumers to believe that the product has been reduced in calories or fat, when the term is actually being applied to the food to refer to its color.

Because the term "light" appears to be meaningful to a majority of consumers, and because of the potential for misuse of the term, the agency believes that use of the term must be limited to foods that, compared to other products in their class, contribute substantially to the reduction of calories and fat in the diet. Although FDA currently has no regulations governing the use of "light," the agency believes that its definition should be based primarily on consumers' perception that the word "light" means "reduced" in calories. As discussed above, the agency is proposing to retain the definition of "reduced calorie," currently in § 105.66 (⅓ reduction in the number of calories compared to a reference food) in proposed § 101.60(b)(4)(i). Therefore, the agency is proposing in § 101.56(b)(1) that the terms "light" or "lite" may be used without further qualification to describe a food provided that the food has been specifically formulated or processed to reduce its calorie content by 33⅓ percent or more from the reference food that it resembles and for which it substitutes.

Recently, however, FDA has also allowed the term "light" to be included as part of the name of dairy products that are altered to have, in addition to one-third fewer calories, at least 50 percent less fat, but to otherwise possess the same nutritional properties, as the food for which they substitute. The agency has issued a number of temporary marketing permits allowing manufacturers to test market modified standardized foods on this basis (e.g., "lite sour cream"—55 FR 12736, April 5, 1990; "light ice cream"—55 FR 3772, February 5, 1990 and "light egg nog"—55 FR 46998, November 8, 1990.)

Because manufacturers of high fat products, such as sour cream and egg nog, have petitioned FDA to use the term "light" to describe the altered versions of their products, and because other normally high fat products, such as cheese foods, are currently using the term "light," the agency believes that it is necessary to establish criteria for use of the word "light" on altered products that substitute for foods that normally contain relatively high amounts of fat.

The agency believes, however, that it would be misleading to permit the term "light" to be used on a product that normally contains relatively high levels of fat and in which the fat has been reduced but not the calories. As the research discussed above shows, consumers expect a "light" product to primarily be reduced in calories. Therefore, FDA is proposing that for a food in which fat contributes 50 percent or more of the calories to bear the term "light," it must be reduced both in calories and in fat by the percentage of nutrients that would allow the food, for both calories and for fat, to bear the term "reduced" (i.e., 33⅓ and 50 percent respectively). The agency selected 50 percent of calories from fat as the point at which the fat content contributes so significantly to the calorie level in the food (i.e., half) that the fat level must be reduced along with the calorie level to justify a "light" claim.

Consequently, the agency is proposing in § 101.56(b)(2) that a food that derives more that 50 percent of its calories from fat may use the term "light" or "lite" provided that, in addition to the caloric content being reduced by 33⅓ percent, its fat content is reduced by 50 percent or more compared to the reference food that it resembles or for which it substitutes.

It has been suggested as an alternative, rather than to prohibit a "light" claim on a product containing more than half of its calories from fat that has not been reduced also by 50 percent in fat, that such product should bear some type of statement informing the consumer that the product was not reduced in fat. Such a statement might be "Contains X percent fat," or "Contains X percent calories from fat." Would it be misleading to call such a product "light" without the defined fat reduction? The agency requests comments about this approach and about what statement might be required. For the claim to not be misleading, such a disclosure statement would need to be prominent and immediately adjacent to the claim each time it is made.

As with "reduced" foods, so as not to allow nutrient content claims for reductions in foods that are inconsequential, the agency believes that a minimum reduction in calories and, where appropriate, fat should be required to justify an unqualified "light" claim. Consistent with the proposed requirements for "reduced calorie" and "reduced fat" claims, the agency believes that these minimum reductions should be more than 40 calories and 3 g of fat. The agency is proposing this minimum reduction in § 101.56 (b)(1) and (b)(2).

Also, as with "reduced" foods, the agency considered what types of products would be appropriate as reference foods for "light" claims. Because a "light" claim is really two "reduced" claims, it would seem possible to make "light" claims on the basis of the same reference foods as "reduced" claims. However, FDA's experience with foods presently on the market that bear "light" claims has led it to tentatively conclude that for "light" claims, comparisons to a single food in the product class (i.e., the manufacturer's own brand) may be misleading. This is particularly the case if the reference food differs significantly from the norm for the product class and contains the nutrient at a level that is at the high end of the range for the product class.

An example of a food with respect to which a comparison with a manufacturer's own brand could be misleading is chocolate chip cookies. An informal label survey (Ref. 58) revealed a wide variety of fat and calorie levels on a per serving basis for an equally wide variety of chocolate chip cookies. In fact, using the criteria from the serving size proposal published elsewhere in this issue of the **Federal Register**, even two chocolate chip cookies from the same manufacturer were found to differ widely in their fat and calorie content. A serving of one variety of chocolate chip cookies (two ½ ounce cookies) contained 100 calories and 4 g of fat, while the same size serving of another variety contained 180 calories and 10 g of fat. Clearly comparison with either cookie could result in vastly different claims. Consequently, the agency believes that the manufacturer's own brand may be misleading as a reference food for "light" products, and the agency is not

proposing the manufacturer's own brand as an appropriate reference food.

Therefore, because of the potential for abuse of this term, FDA is proposing that the reference food for "light" claims be only an industry wide norm as defined in § 101.13(j)(1)(i). The agency, however, solicits comments on this issue.

b. *"Light" sodium products.* Some product labels have used the term "light" to describe the salt or sodium content of the food. Because this use of the term results in "light" being used on foods that have not been reduced in calories, the agency considers that this use could be misleading. Therefore, FDA believes that the term "light" should not be used on products solely in reference to their sodium content. Accordingly, the agency is proposing in § 101.56(c) that a product other than a salt substitute that is low, reduced, or otherwise altered in sodium content cannot use the term "light" solely because of this alteration but rather must use, as appropriate, the terms "reduced sodium" or "low sodium."

Although the agency is proposing that the primary basis for the definition of "light" should be a reduction in calories, and that all other unqualified uses of the term are not permitted, the agency believes that the definition for "light" as used with salt substitutes can be viewed differently. Salt substitutes are offered for sale as products that contain virtually no calories. Because a salt substitute clearly contains no calories, a "light" claim would not imply that such a product has been reduced in calories and would not be misleading. In addition, salt substitutes that use the term "light" have been on the market for a number of years, and consumers have become familiar with, and understand, the concept of "light" salt as being reduced in sodium. Therefore, the agency is proposing to permit "light" to be used on salt substitutes that contain at least 50 percent less sodium than table salt. This proposed use of the term is consistent with the approach used for defining "reduced sodium." Accordingly, the agency proposes in § 101.56(d) that the term "light" may be used to describe a salt substitute if the sodium content of the product has been reduced by at least 50 percent compared to table salt.

However, because these salt substitutes may contain significant amounts of sodium, the resulting product may not meet the definition for a low sodium food. The agency therefore invites comments on the use of "light" for these products.

c. *Other uses of the word "light."* As stated previously, the use of the word "light" on food labels generally means reduced calories. However, in some cases it has been used to convey other meanings. The agency believes that the unqualified use of the term may mislead consumers into believing that a food is reduced in calories when this term is actually used to refer to properties of the food other than calories. Consequently, the agency believes that unqualified use of the term "light" when not referring to calories (or sodium in the limited circumstances discussed above) should be prohibited.

If the term is meant by the manufacturer to refer to an organoleptic or other quality, such as texture, color, flavor, weight, or density, all of which may be a logical basis for the use of the term "light," FDA believes that that fact must be clearly and plainly conveyed on the label. For example, the label may state "light in color," "light in texture," or use other terms that clearly convey the nature of the product. In addition, so as not to give undue prominence to the term "light" in relation to the term it modifies, FDA is proposing that this qualifying information be in the same type size, style, color, and prominence as, and in immediate proximity to, the word "light."

Therefore, the agency is proposing in § 101.56(e) that the term "light" may not be used to refer to a food that is not reduced ln calories by ⅓ and, if applicable, in fat by 50 percent, unless: (1) It describes some physical or organoleptic attribute of the food, such as color or texture, and the qualifying information (e.g., light in color, light in texture), so stated, clearly conveys the nature of the product, and (2) the qualifying information is in the same type size, style, color and prominence as the word "light" and in immediate proximity thereto.

The agency recognizes that there are some long standing uses of the term "light" to characterize the particular nature of the product or distinguish it from a similar product with slightly different attributes. Examples of such products are light corn syrup as opposed to dark corn syrup, light brown sugar as opposed to dark brown sugar, and light molasses as opposed to dark molasses. Such light products are generally recognized to be both lighter in color and in flavor (i.e., less intense or more delicate) than their darker counterpart. The agency considers that the long standing use of the term "light" on these few products, whose special "light" characteristics are commonly understood, is sufficient reason to permit their continued use.

Therefore, FDA is proposing in § 101.56(f) that in those rare cases where the word "light" has come, through common use, to be part of the statement of identity, the agency will not require that statements of identity for such products be further characterized. If this provision is adopted, light brown sugar will not be required to be labeled "light color brown sugar" or otherwise meet the requirements for nutrient content claims. The agency is proposing in § 101.52(f) that if a manufacturer can demonstrate that the word "light" has been associated, through common use, with a particular food (e.g., "light brown sugar," "light corn syrup," or "light molasses)" to the point where it has become part of the statement of identity, such use of the term "light" will not be considered a nutrient content claim subject to the requirement as specified in part 101.

FDA specifically asks for comments as to whether the approach to the term "light" outlined in this document is adequate to eliminate the misuse of this term.

5. Comparative Claims

a. *Less or fewer.* The agency recognizes that there are some foods that can achieve meaningful reductions in the level of certain nutrients but for which reductions of ⅓ of calories or 50 percent or greater for nutrients are not feasible. While these foods cannot bear a "reduced" claim, the agency believes that such foods should be permitted to be labeled with comparative statements using the term "less" or, because it is grammatically correct, "fewer" in the case of calories, that specify the extent to which the nutrient has been reduced. For example, the label of a pound cake could bear the statement, "25 percent fewer calories than our regular pound cake—this pound cake contains 150 calories compared to 200 calories per serving in our regular brand." The agency believes that the use of comparative claims provides manufacturers with an incentive to lower the nutrient content of a food even though it may not be technologically possible to achieve nutrient levels that are sufficiently low to allow the product to be labeled as "reduced."

To ensure, however, that the reductions are nutritionally meaningful, and that consumers are not misled by claims for reductions that are inconsequential, the agency believes that a comparative statement should be permitted on the label or in labeling of a food only if the food has been formulated or processed so that it contains a decrease in the level of the nutrient that is 25 percent or more compared to the reference food. This

requirement is consistent with the agency's current policy for comparative claims for sodium (49 FR 15521, April 18, 1984) and the tentative final regulation for cholesterol (55 FR 29456).

The proposed 25 percent reduction requirement is based on agency findings in those notices that products in which there has been a 25 percent or greater reduction in the amount of a nutrient will serve a useful role in the diet of those individuals who are attempting to limit their consumption of that nutrient. In addition, the agency made the finding in the 1984 sodium notice that because of variations in nutrient content within a food or class of food, any less of a reduction, such as the 10 percent that was originally proposed for sodium, would not always assure that the altered product contained less of the nutrient than the regular product. Improvements in food technology or other factors may make it practicable for manufacturers to measure reductions in nutrient content of less than 25 percent. The agency solicits comments, including data, on whether 25 percent is necessary as a minimum reduction requirement for all foods, or whether a lower level is possible. However, FDA acknowledges that permitting comparative claims for foods with a percentage reduction of less than 25 percent may serve to facilitate consumers' efforts to improve these diets if such claims are reliable, and the absolute reduction referred to by the comparative claim is nutritionally significant. This alternative will also be discussed in the supplemental NPRM referenced in section IV above.

Currently, Canadian guidelines and regulations provide for comparisons when differences are at least 25 percent (Ref. 38). This criterion is also consistent with USDA guidelines that permit comparative fat claims for meat and poultry products when fat is reduced by 25 percent or more (Ref. 46).

In addition, so that the reductions are nutritionally consequential, as with "reduced," the agency is proposing that the minimum reduction for comparative claims be more than the value of "low" for that nutrient. Although the reduction in the amount of a nutrient is less for a comparative claim than for a "reduced" claim, it is still important that the reduction be of nutritional consequence. There is no basis to find that a decrease in the level of a nutrient smaller than the amount necessary to justify a "low" claim would be consequential. Therefore, FDA is proposing to require the same minimum quantitative decrease in a nutrient for a "less" claim as for a "reduced" claim.

i. *Sodium.* In the preamble to the final rule on sodium descriptors (49 FR 15510 at 15521), the agency stated that a minimum sodium reduction of 25 percent was necessary for a product to make a comparative statement about sodium. This guidance was not codified in the regulation, but it did serve as the basis, as discussed above, for sodium claims using the term "less." The agency sees no reason why the requirements for use of the term "less" in describing the level of sodium in a product should be any different than those proposed for the other nutrients. The proposed definition for "reduced sodium" is in accord with the definitions for "reduced" for all other nutrients except calories. Moreover, such an approach is in line with the agency's goal of making the definitions for the various terms as consistent as possible to help prevent consumer confusion.

As discussed above, the agency is also proposing that the minimum amount by which a nutrient must be reduced for a food to bear the term "less" should be more than the value of "low" sodium, i.e., 140 mg per serving.

Therefore, the agency in proposing in § 101.61(b)(7) that a comparative claim using the term "less" may be used to describe the sodium content of a food provided that: (1) the food has been formulated or processed to reduce its sodium content by 25 percent or more with a minimum reduction of more than 140 mg per serving from the reference food that it resembles and for which it substitutes as specified in § 101.13(j)(1)(i), (j)(1)(ii), or (j)(1)(iii); and (2) the food meets the requirements of § 101.13(j)(2).

ii. *Calories.* The agency believes that comparative statements should be permitted when the level of calories in a food is reduced by 25 percent compared to a reference food, even though there is only an 8 percentage point difference between the levels at which a "reduced calorie" claim and a comparative statement may be made. Permitting comparative claims will allow claims to be made about the decrease in calorie levels in foods that cannot meet the "reduced" criterion because of technological or other reasons. The agency believes that it is important to provide for comparative labeling for these foods because of the nutritional benefit that such foods can contribute to the diet. If a person who generally consumed a diet containing a normal amount of calories, i.e., 2,350, were to consume a diet consisting solely of foods decreased in calories by 25 percent, he or she could achieve a significant weight loss.

In addition, as discussed above, in order to prevent comparative claims being made for calorie reductions that are inconsequential, the agency believes that, as with all other nutrients, a minimum quantitative reduction should be established. This criterion, if adopted, will ensure that the reduction is nutritionally consequential. Consistent with the requirements for the various nutrients, the agency believes that this value should be more than 40 calories (the level set for "low" calories) per serving.

Therefore, the agency is proposing in 101.60(b)(5) that a comparative claim using the term "fewer" may be used to describe the caloric content of a food provided that: (1) The food contains at least 25 percent fewer calories, with a minimum reduction of more than 40 calories per serving from the reference food that it resembles and for which it substitutes as specified in § 101.13(j)(1)(i), (j)(1)(ii), or (j)(1)(iii); and (2) the food meets the requirement of § 101.13(j)(2).

However, because there is only an 8 percentage point difference between the lower level of calories for "light" and "reduced" (33⅓ percent) versus comparative claims (25 percent), the agency solicits comments on the usefulness of allowing comparative claims in addition to "reduced" and "light" claims for calories.

iii. *Sugars.* Although the terms low or reduced sugars have not been defined, the agency believes that a term that highlights a difference in the amount of sugars in a product relative to another food would assist consumers in following the dietary guidelines relative to sugar. The agency believes that the term "less" may be useful in providing this information.

The agency can see no reason to define a comparative value for "less" to be used with sugars that is different from the value for "less" for the nutrients previously defined. Therefore, the agency is proposing in § 101.60(c)(4) that a comparative claim using the term "less" may be used to describe the sugars content of a food relative to the amount of sugars in another food provided that the food contains at least 25 percent less sugars than the food to which it is compared.

However, because the agency has not established a DRV for sugars, it does not have a basis for defining an insignificant amount of sugars to be used as a second criterion. The agency believes that, as for other claims using the term "less," a second criterion establishing a minimum quantitative reduction is necessary and

solicits comments on how such a second criterion might be derived.

The agency, advises however, that regardless of whether any comments provide a suitable basis for a second criterion, that it intends to establish such a criterion to insure that claims of less sugars are not misleading because the decrease in the amount of sugars is nutritionally insignificant.

b. *More.* Although the 1990 amendments do not require that FDA define the term "more," the agency recognizes that there may be instances when a manufacturer could make a statement on the label or in labeling that a food product contains more of a desirable nutrient than is in a reference food. Such claims may be made for food products containing nutrients such as dietary fiber, potassium, protein, vitamins, and minerals. In addition, claims using the term "more" may be useful in certain limited circumstances to describe the level of complex carbohydrates and unsaturated fatty acids.

FDA considers that such claims are currently governed by § 101.9(c)(7)(v), which states, in part, that: "No claim may be made that a food is nutritionally superior to another food unless it contains at least 10 percent more of the U.S. RDA of the claimed nutrient per serving (portion)." In its proposal of July 19, 1990, on mandatory nutrition labeling, the agency retained and expanded this regulatory provision, in proposed § 101.9(c)(11)(iv) (55 FR 29515), to read: "No claim may be made that a food is nutritionally superior to another food unless it contains at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for complex carbohydrates, fiber, unsaturated fatty acids, or potassium or at least 25 percent less on a weight basis for fat, saturated fatty acids, cholesterol, and sodium per serving (portion)." In the supplemental proposal on nutrition labeling, FDA is proposing to delete the above provision from the nutrition labeling regulations because the issue of descriptors used on food labels or in labeling is being dealt with in the present document. The agency feels that the paragraph in question is more appropriately regarded as a general principle governing comparative claims than one relating to nutrition labeling.

After careful consideration, FDA is proposing to retain its existing approach that a food must contain at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or potassium before a comparative claim using the term "more" would be permitted. The agency is proposing to retain the level of 10 percent more of RDI or DRV for a number of reasons.

First, the difference must be on the basis of the RDI or DRV, rather than on a weight basis, for the relative difference to have dietary significance. For example, consider a product containing 100 mg of calcium. On a weight basis, it would have 10 percent more calcium than a product containing 90 mg and 25 percent more than a product containing 80 mg. However, in terms of the proposed RDI for calcium (900 mg), the three products contain 11, 10, and 9 percent of the RDI, respectively. These differences are dietarily insignificant.

Secondly, there must be at least a 10 percent difference relative to the RDI or DRV before consumers can be assured that there is truly a difference in the foods being compared. This finding is consistent with the agency's proposed definition of "source" discussed elsewhere in this document. A nutrient must be present in a food at a level of at least 10 percent of the RDI or DRV before that food can be designated as a source of the nutrient. Consequently, the agency believes that a nutrient must be present at a level of at least 10 percent more of the RDI or DRV than in the reference food before the food can be designated as a better source of the nutrient. Because of natural variability of nutrients in food, there is a real possibility that the foods being compared would have virtually no difference in nutrient content if values of less than 10 percent of the RDI or DRV were compared. This percent of the DRV or RDI functions similarly to both the first and second criteria for other relative claims because it ensures that the comparison is always meaningful and significant.

Thirdly, the agency considered requiring at least a 25 percent difference relative to the RDI and DRV in the reference foods before permitting comparative claims using the term "more". This level would be somewhat analogous, and symmetrical, with the proposed requirement for comparative claims using the term "less." However, FDA has tentatively rejected this approach because of the agency's concern that a level higher than 10 percent of the DRV or RDI would result in inappropriate fortification of foods in an attempt to make superiority claims.

The agency's policy on appropriate fortification of foods is stated in § 104.20 (21 CFR 104.20). The fundamental objective of that policy is to establish a uniform set of principles that serve as a model for the rational addition of nutrients to foods. In that policy, FDA clearly states its concern that random fortification of foods could result in deceptive or misleading claims for foods. However, to the extent that food does not conflict with § 104.20, the agency believes that a statement using the term "more" can be used to compare the amount of certain specified nutrients in one food to the amount of such nutrients in similar foods.

Therefore, the agency is proposing in § 101.54(e)(1) that a comparative claim using the term "more" may be used to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a food provided: (1) That the food contains at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or for potassium than the reference food that it resembles and for which it substitutes; (2) where the claim is based on a nutrient that has been added to the food, that fortification is in conformity with the policy on fortification in § 104.20; and (3) that it meets the requirements of § 101.13(j)(2) except that the percentage (or fraction) that the nutrient varies compared to the reference food should be expressed as a percent of the Daily Value (e.g., "Contains 10 percent more of the Daily Value for fiber than our regular wheat bread. Fiber content has been increased from 1 g to 3.5 g per serving.") Moreover, FDA believes that it is consistent with section 403(r)(2)(A)(v) of the act to require that if a "more" claim is made for fiber, the level of fat be disclosed on the label unless the food meets the definition of "low fat." This type of claim, like a "high" claim, emphasizes the amount of fiber in the food. Therefore, FDA is including "more" claims in the coverage of proposed § 101.54(d).

As discussed earlier, the agency does not believe that claims for specific amounts of carbohydrates (such as "high in complex carbohydrates") can be supported based on dietary recommendations in the major consensus reports because quantitative recommendations for carbohydrate consumption are not included. However, FDA believes that label statements using the term "more" to characterize the relative difference in carbohydrate content of two food products would be useful to consumers, provided that the claim is based only on the difference in complex carbohydrates as defined in § 101.9(c)(6)(i) of the supplementary proposal on mandatory nutrition labeling and not on the levels of other carbohydrates. The agency believes that this is appropriate because the major consensus reports (Refs. 1, 2, 3, and 5) advocate using sugars in moderation but recommend increasing consumption of

foods that contribute complex carbohydrates to the diet. A statement comparing carbohydrate contents of foods that can be used interchangeably in the diet would be useful to consumers in constructing a diet that adheres to the various dietary recommendations.

However, the agency believes that a statement concerning the percent increase in carbohydrate relative to the Daily Value contained in one product as compared to another is misleading because the DRV for carbohydrate is based on total carbohydrate, and under the proposal, the increased content that forms the basis of the claim must be provided by complex carbohydrates only. There is no DRV for complex carbohydrates. Further, mention of the Daily Value may suggest to consumers that this food component has greater public health significance than has been established by existing diet and health studies. Therefore, the agency is proposing in § 101.54(e)(2) that a comparative claim using the term "more" may be used to describe the difference in the level of complex carbohydrates, in two foods, provided that the food that bears the claim contains at least 4 percent more of the DRV for carbohydrates (i.e., 13 g) and that the difference in the level of carbohydrates between foods consists of only complex carbohydrates as defined § 101.9(c)(6)(i).

The agency is proposing 4 percent of the DRV as the criterion for this claim because 10 percent of the DRV for carbohydrates is 32 g, an amount of complex carbohydrate that would be unreasonable to expect to be found in excess of what is present in a reference food. For instance, most ready-to-eat cereals, which are a good source of complex carbohydrates, contain less than 18 g of complex carbohydrates. In fact, the agency is aware that a 4 percent differential may be difficult to reach. However, a lower value, e.g., 2 percent, is associated with definitions for low levels of nutrients and does not seem appropriate. FDA recognizes that the definition it is proposing from past requirements for claims of superiority and requests comments on the public health validity of the change.

In addition, the agency has received several requests urging that it permit claims comparing the amounts of unsaturated fat in products. The guidance provided in the consensus documents (Refs. 1, 2, 3, and 5) is that total fat and saturated fat consumption should be reduced, and that unsaturated fat should not be increased above current consumption levels. Furthermore, some recent data (Refs. 47 and 48) suggest that "trans" fatty acids, which are unsaturated fatty acids, act like saturated fatty acids relative to their effect on blood cholesterol. Additionally, high levels of intake of unsaturated fatty acids, particularly polyunsaturated fatty acids, may increase risk of certain cancers (Ref. 2). For these reasons, as discussed earlier, the agency has tentatively concluded that claims for "high" in unsaturated fatty acids are potentially misleading.

However, FDA believes that label statements using the term "more" to characterize the relative amount of unsaturated fatty acid in two food products would be useful to consumers, provided that the total fat level in the product bearing the claim is not increased above the total fat level in the product of comparison and provided that the level of *trans* fatty acids in the product bearing the claim does not exceed 1 percent of the total fat content. The agency believes that this proposed action is appropriate because the major consensus reports, such as the NAS report "Diet and Health," advocate substituting unsaturated fatty acids for saturated fatty acids as a means of achieving greater health benefit from the diet. However, because all major consensus reports place considerable emphasis on reducing total fat intake, the agency considers it misleading for a product to claim to have more unsaturated fatty acids if the product has more total fat than the food being used for comparison. In addition, because of the recent data suggesting that *trans* fatty acids may act like saturated fat in raising serum cholesterol, the agency believes that it would be misleading for products containing measurable amounts of *trans* fatty acids to bear claims of "more" unsaturated fatty acids. The agency is proposing a limit on *trans* fatty acids of 1 percent of the total fat because the analytical techniques for measuring *trans* fatty acids below that level are not reliable. Further, the agency believes that a reference to the DRV for unsaturated fatty acids on the panel containing the unsaturated fatty acid claims would be misleading because it would imply to consumers that it is a dietary goal for unsaturated fatty acids that should be attained, when in fact it is the consumption of total fat that should be moderated.

For these reasons, the agency is proposing that a food bearing a "more unsaturated fat. claim must contain at least 4 percent more of the DRV for unsaturated fatty acids (i.e., 2 g) than the reference food. The DRV for unsaturated fatty acids, like that for complex carbohydrates, is sufficiently large that the agency has tentatively concluded that it is unreasonable to require a differential of more than 4 percent of the DRV for unsaturated fat to make a claim of "more." Again, comments, including data are requested on the proposed definition of the claim.

Therefore, the agency is proposing in § 101.54(e)(3) that a claim for more unsaturated fatty acids only be permitted on those foods that contain at least 4 percent more of the DRV for unsaturated fat, do not contain more than the reference food, and in which the level of *trans* fatty acids does not exceed 1 percent of total fat. The agency requests specific comment on this issue.

6. Modified

The declarations discussed above for making relative claims do not include terminology that is suitable for use in a statement of identity with a comparative claim in the way that .reduced" and "light. may be used. For example, "25 percent Less Fat Cheese Cake" is awkward.

Consequently, the agency believes that an appropriate term should be proposed for use with comparative claims. Although the agency recognizes that numerous terms may be adequate to convey this information, given the need, as discussed above, for a term that consumers can recognize and understand, FDA is proposing that the term "modified" be used. FDA has chosen this term because it is applicable to both positive and negative alterations in nutrient content, i.e., comparative statements using either terms "more" or "less."

Under proposed § 101.13(k), the term "modified" may be used in the statement of identity of a food that bears a comparative claim that complies with the requirements in Part 101, followed immediately by the name of the nutrient whose content has been altered, e.g., "Modified fat cheese cake." This statement of identity must then be immediately followed by the comparative statement such as "Contains 35 percent less fat than ____," and all other information required in 101.13(j) for comparative claims. This information is necessary because it presents information that is material in light of the "modified" representation. Consumers must be advised of the nutrient modified, the extent of the modification of that nutrient, and the factual basis on which the extent of modification has been calculated. Without this information, the food would be misbranded under sections 201(a) and 403(a) of the act.

D. Use of Descriptors With Meal-type Products

The agency received many comments to the ANPRM and during the public hearings requesting that it define and allow for the use of descriptors for meal-type products. FDA is aware that nutrient content claims are frequently used on such products even though the agency has not developed definitions specific to that use. In its proposed rule on cholesterol descriptors (51 FR 42584 at 42591), FDA acknowledged that it is not reasonable to expect nutrient content claims on meal-type products to meet the same criteria as those used for individual food items. At that time, FDA proposed as a guideline that a meal containing less than 100 mg of cholesterol could be described as a "low cholesterol meal." However, in its tentative final rule on cholesterol descriptors (55 FR 29456), the agency withdrew from this position because there was no clear definition of the term "meal" and asked for further comment.

The GMA submitted a letter to the agency (Ref. 12) in which they suggested that a "meal-type product" be defined as a food that: (1) Makes a significant contribution to the diet by providing at least 200 calories per serving or weighing at least 6 oz per serving; (2) contains ingredients from 2 or more food groups; and (3) is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Under GMA's proposed definition, such representations may be made either by statements or by photographs or vignettes.

FDA finds merit in this 3-part definition and, lacking any other equally-comprehensive definition, is proposing in § 101.13(1) to adopt it with the qualification that the product must contain two of four specified food groups. However, the agency recognizes that, with this definition, there may be a tendency to assume that a level of 200 calories is appropriate for all meals consumed in one day. This assumption would suggest that three meals and a snack provide only 800 calories per day. The agency, however, assumes that some of the meals would contain more than 200 calories, especially if the product contained only two food groups. Such meals might then consist of a 200 calorie 7 ounce main dish and a fruit or vegetable, starch, or dairy product. If these types of products meet this assumption, it will ensure that a minimum daily intake would be greater than 1,000 calories.

The agency requests specific comments on the appropriateness of this definition of a "meal-type product" as well as on the appropriateness of specific amounts (e.g., 200 calories and 6 oz) and specific product types (e.g., "main dish") used as a basis for this definition.

1. Definition of "Free"

FDA is not proposing separate definitions for "free" for meal-type products. The term "free" is an absolute term implying absence of a nutrient. Therefore, whenever a food is labeled "free," whether it is an individual food item or a meal-type product, it would be misleading unless it met the definition for "free" for the particular nutrient that is the subject of the claim.

2. Definition of "Low" and "Very Low"

GMA suggested that for meal-type products, the nutrient descriptor "low" should be defined on the basis of the amount of the nutrient per 100 g of the meal-type product and suggested specific levels for calories (105 calories per 100 g), total fat (3.5 g or less per 100 g), saturated fat (1.2 g or less per 100 g), cholesterol (20 mg or less per 100 g), and sodium (200 mg or less per 100 g) (Ref. 12). FDA has considered these levels in conjunction with its proposed values for nutrient content claims for individual foods (foods as sold separately, not as part of a meal), discussed earlier in this document. With the exception of calories, the suggested values are similar, or identical, on a 100 g basis to the definitions for the various nutrients proposed for individual foods in this document and in the companion proposal on fats, saturated fat, and cholesterol published elsewhere in this issue of the **Federal Register**.

The agency finds merit in defining nutrient content claims for meal-type products on the basis of the amount of the nutrient per 100 g. This approach alleviates the necessity to accommodate variations in serving size for the various types of meals. A review of such products on the market shows that it would allow nutrient content claims on meal-type products that can be used in a diet that is consistent with dietary recommendations set forth in the Dietary Guidelines for Americans (Ref. 1).

FDA believes that it will be beneficial if the agency used the same quantitative amounts except calories per 100 g as the definitions of "low" that it is proposing for individual foods in this and the companion document on fat, saturated fat, and cholesterol claims. Such consistency will assist consumers and health professionals to be able to recall and use these amounts.

Accordingly, FDA is proposing in § 101.61(b)(5) that a "low sodium" claim may be made for a meal-type product that contains 140 mg or less sodium per 100 g of product. The agency is proposing similar definitions for fat, saturated fat, and cholesterol claims in the companion document.

In the case of low calorie claims, FDA is proposing that an individual low calorie food be defined as containing 40 calories or less per serving and per 100 g of food. The agency recognizes that if it applied this criterion on a 100 g basis to meal-type products, the use of "low calorie" claims on meal-type products would essentially be precluded (e.g., a 10 oz meal would have to contain 113 calories or less to bear a "low calorie" claim). Obviously, such a definition would be unrealistic for two reasons: (1) It is unlikely that a reasonably sized balanced meal could be created that contained so few calories and still made a significant contribution to the daily food intake of an individual; and (2) such a meal is consistent with a 400–500 calorie daily diet (i.e., 113 calories X 4 eating occasions), and such very low calorie diets should be followed only under the strict supervision of a physician. Therefore, FDA is not proposing that 40 calories per 100 g be part of the definition for a low calorie meal.

GMA has suggested that a meal-type product be allowed to make a "low calorie" claim if it contains 105 calories or fewer per 100 g of product. This value would allow a 10 oz "low calorie" meal type product to contain 298 calories. This value appears appropriate for the wide diversity of meal-type products (i.e., meals or meal components intended for breakfast, lunch, or dinner which are offered either as a whole meal (three or more components) or as part of a meal (main dish, entree, or pizza). A value of 105 calories for a low calorie meal-type product would allow many FDA-regulated products within this wide variety of meals or portions of meals to make low calorie claims. The U.S.D.A. has conducted a preliminary evaluation of this value for meal-type products containing meat and poultry and found that approximately 40 percent of such products with a brand name that might imply a "low calorie" claim (e.g., "lean") would not be classified as "low calorie" using the 105 calorie per 100 g criterion (Ref. 12a). As stated previously, the agency assumes that, particularly in the case of entrees and main dishes, meal-type products will not be consumed as the single component of a meal but will be supplemented with a fruit or vegetable, starch (e.g., bread or rolls), or

beverage (e.g., milk or juice) to provide a balanced meal. Consequently, the agency believes that this definition for meal-type products is in line with a 1,200 calorie per day diet.

FDA notes that calorie restricted diets often contain 1,200 calories, frequently broken down into three meals and a snack each day (Ref. 49). Under this scenario, meals would be expected to contain approximately 300 to 350 calories (i.e., 900 to 1,050 calories per day as meals and 150 to 300 calories per day as a snack). Accordingly, FDA has tentatively concluded that 105 calories per 100 g is a reasonable definition for a "low calorie" meal-type product and is proposing this value in § 101.60(b)(3). Nevertheless, the agency requests comments on whether consumers would actually consume meal-type products alone, and whether they depend on these products for the major portion of their caloric intake throughout the day. If so, comments are requested on whether the criterion of 105 calories per 100 g of product for low calorie meal type products is too low.

The agency also is concerned, however, about the application of this definition to meals that are atypically large in size within this class of foods. For example, a 16 oz dinner could have 475 calories and meet the definition for "low calorie." Accordingly, FDA is considering the application of upper limits for each nutrient for meal-type products. Comments are requested on the need for such limits and, if needed, where such limits should be drawn and why.

Finally, the agency has proposed a definition of 35 mg of sodium per serving and per 100 g for "very low sodium" in individual foods in § 101.61(b)(3). The agency is uncertain as to whether there needs to be a comparable value for meal-type products, since it could prove very difficult to create a very low sodium meal. Such a definition might be virtually meaningless. On the other hand, FDA does not wish to preclude the use of a definition which might be of value in assisting consumers to choose products that have minimum amounts of sodium if such products are feasible. The agency has tentatively concluded that a definition for "very low sodium" meal-type products would serve some purpose and is consequently proposing such a definition. However, the agency seeks comments on the usefulness and necessity of this definition.

3. Relative Terms

Inasmuch as the primary criterion for the use of relative claims (i.e., "reduced," "light," and comparative claims) is a percent reduction, FDA does not believe that it is necessary to propose different criteria for meal-type products. While acknowledging the difficulty in reducing the calorie, fat, and cholesterol content of meal-type products, FDA believes that the consumer expects significant differences in products bearing these claims and would be best served by adherence to the proposed definitions for individual foods.

The second criterion for the use of relative terms on individual foods is a minimum reduction in amount of nutrient equivalent to the value established for "low" for that nutrient per 100 g. Again, FDA believes that the criterion for individual foods would be appropriate for meal-type products. This requirement will allow the proposed regulations for relative claims on individual foods to apply equally to meal-type products.

a. *Reduced.* The agency is, however, concerned about providing for the use of the term "reduced" with meal-type products because of the difficulty in establishing an appropriate reference food. The proposed definition for "reduced" for individual foods is based on a comparison of a product to another product of the same type, e.g., one cupcake to another. A comparison of meal-type products could be of a broiled fish fillet to a piece of fried, breaded fish. Such a comparison would equate two products that, although they had the same basic ingredient, i.e., fish, were distinct in their method of preparation, additional ingredients, taste, and appearance. Such a comparison would be inappropriate for a "reduced" claim because it would be comparing products that were insufficiently similar to make a valid comparison. The agency is of the opinion that there is an insufficient basis on which to establish a reference criterion, and consequently there is no basis on which to establish a definition for "reduced" meal-type products. Therefore, the agency is not proposing to provide for the use of "reduced" claims on meal-type products.

b. *Comparative claims.* Comparative claims, however, by their very nature provide for comparisons of foods within a product category, provided the basis of comparison is adequately stated in the claim, e.g., comparison of a snack food to another snack food. Comparative claims, using the terms "less," "fewer," and "more," would be appropriate for comparing similar meal-type products such as broiled fish to fried, breaded fish because both of these somewhat dissimilar products would be in the same product category. Therefore, the agency is proposing to incorporate the provisions for comparative claims for meal-type products into the comparative claims provisions in the various nutrient sections.

c. *"Light".* FDA is proposing a more narrow reference food criterion for "light" claims on individual foods than for "reduced" claims. It follows, then, that since the agency is proposing not to permit "reduced" claims on meal-type products, it would do likewise for "light" claims. However, the agency recognizes that there might be some basis to find that an alternative course is appropriate.

The agency believes that the term "light" could be useful to consumers in selecting meal-type products by highlighting products that contain fewer calories than would be expected in a normal meal. Because there is no identified set of reference foods to which "light" meal products could be compared, the agency has considered using a different criterion for the definition of "light" meal-type products. The agency is considering allowing use of the term "light" on meal-type products that meet the criteria for "low calorie" meals. At 105 calories per 100 g or approximately 300 calories per 10 oz portion, the criterion for "low" calorie meals is very nearly one fourth of the intake in a calorie restricted diet of 1,200 calories a day (Ref. 49). The agency believes that such products would meet the consumer's expectations that the food is low or reduced in calories.

In addition, FDA is also considering a second criterion that "light" meal-type products not contain fat, saturated fatty acids, sodium, or cholesterol at a level that exceeds one-fourth of the DRV of the nutrient. This criterion would ensure that light meal-type products would not only be low in calories but would also not contribute amounts of these nutrients that would cause total daily intake to exceed recommended values.

These criteria for the term "light" on meal-type products would permit some meal-type products to bear "light" claims and would ensure that such claims are not misleading. The agency solicits comments on the need to provide for use of "light" on meal-type products and on possible guidelines for selection of reference foods. Comments are also requested regarding this definition "light" meal-type products, including the criterion relative to other nutrients and on possible guidelines for selection of reference foods. If the comments warrant, the agency many propose appropriate definitions and requirements for use of the term "light" for meal-type products.

4. "Source" and "High" Claims

As with the definition for "low" for meal-type products, the agency believes that the criteria for "high" and "source" should be the same percentages of the RDI or DRV proposed as for individual foods but on an amount per 100 g basis, not per serving. Therefore, consistent with these definitions, the agency is proposing in § 101.54(c)(2) that "source" be defined for a meal-type product as 10 to 19 percent of the RDI or DRV per 100 g of product, and in § 101.54(b)(2) that "high" be defined as 20 percent or more of the RDI or DRV per 100 g of product. Consequently, to be considered a "source" of a nutrient, a 10 oz meal-type product would contain 7 to 13.5 g of fiber. (25 g of fiber is the DRV for fiber. 10 to 19 percent of the DRV is 2.5 to 4.75 g. 10 oz × 28.35 g/oz = 284 g. 284/100 g = 2.8 g. 2.5 (10 percent of the DRV) × 2.8 = 7 g; 4.75 × 2.8 = 13.5 g.)

Consistent with section 403(r)(2)(A)(v) of the act, which states that a claim may not state that a food is high in dietary fiber unless the food is low in total fat (as defined in § 101.62(b)), the agency is proposing in § 101.54(d) that claims that a meal-type product contains "more" fiber be required to disclose the level of total fat on a per serving basis.

5. Disclosure Statements

The disclosure levels proposed in § 101.13(h) and discussed above in section II.D. of this document were derived for levels of nutrients found in individual foods. Because the definition of meal-type products encompasses a broad range of products, from entrees that may be a small portion of the total meal to complete meals, the issue of modifying these levels for use with such products become complex. Because of this complexity, the agency was not able to devise specific disclosure levels for use with meal-type products. FDA solicits comments on whether the disclosure levels should be different for meal-type products, and if so, what the levels should be and why.

E. Redesignation of Certain Requirements in Section 105.66 to Section 101.60

Because these proposed regulations on nutrient content claims include provisions similar or identical to some provisions in § 105.66, the agency has found that it is necessary to examine § 105.66 to determine what changes are necessary in that regulation in order to conform it to the 1990 amendments.

As discussed above, FDA is proposing to recodify current § 101.13, Sodium labeling, with minimal revisions, in new Subpart D—Specific Requirements for Nutrient Content Claims, so that it could be codified in close proximity to the requirements for other nutrient content claims. Section 105.66 is not amenable to that approach.

Section 105.66 was originally promulgated to provide regulations for label statements useful on products for reducing or maintaining caloric intake or body weight. Consequently, terms such as "low calorie," "reduced calorie," and "sugar free," which were thought to be useful attributes of a food in the maintenance or reduction of body weight, were included in this section. Over time, more and more people have become concerned with healthier eating and have begun to follow the guidelines established in Dietary Guidelines of Americans (Ref. 1), including the maintenance of a healthy weight. Consequently, terms such as "low" or "reduced calories" and "sugarless" have come to be used on foods intended for consumption by the general population. As such, they have lost their special significance in the labeling of foods intended solely for special dietary uses.

As is discussed elsewhere in this document, these terms are now more appropriately defined under the 1990 amendments as nutrient content claims. Consequently, the agency is proposing to place requirements for terms such as "low" and "reduced calorie," comparative claims, and sugar claims, originally provided for in § 105.66, in § 101.60. Requirements for label statements about nonnutritive sweeteners, "diet" foods, and other related terms are being retained in § 105.66.

Because definitions of terms in proposed § 101.60 would be redundant of certain provisions in § 105.66, the agency is proposing to delete, paragraphs (c), (d), and (f) of § 105.66 and to replace them with statements referring to the appropriate section in 101.60 for criteria for use of the respective term.

In addition, the agency is proposing to delete from § 105.66 any inappropriate reference to specific nutrient content claims or similar terms and any statement that is inconsistent with the 1990 amendments.

There is, however, a significant portion of § 105.66 that remains appropriate for regulating foods that are for special dietary uses. Such foods are those specifically represented or purported to be useful as part of weight control plan, as opposed to those that are simply represented as being low or reduced in calories (although such products can be useful in reducing or maintaining body weight). The agency is retaining those provisions in § 105.66. FDA plans to reexamine the provisions remaining in § 105.66 and to initiate additional rulemaking as appropriate.

In the interim, the agency is proposing to make the following specific changes to the remaining paragraphs in § 105.66: It is proposing to delete the words "caloric intake or" from the title, paragraph (a), paragraph (b)(2) and paragraph (e)(2) of the section because, as stated above, it considers information relative to the caloric content of a food to be of value to the general public in selecting diets that meet dietary guidelines. Consequently, the agency believes that this concept is more consistent with § 101.60 than § 105.66. It is also proposing to delete from paragraph (a) the words "including, but not limited to, any food that bears representations that it is low or reduced in calories" because "low" and "reduced" calories are defined in § 101.60.

FDA is also proposing to delete in § 105.66(a)(2) the phrase "The labeling provided for in paragraph (c) or (d) of this section or," because the terms "low" and "reduced," which were provided for in those paragraphs, are now defined in § 101.60. The agency is not proposing to delete the remainder of the sentence "a conspicuous statement of the basis upon which the food claims to be of special dietary usefulness." The agency cautions, however, that it will not consider reliance on this provision as justification for an undefined nutrient content claim.

In addition, the agency is proposing to delete from § 105.66(e)(1) the phrases "or other such terms representing or suggesting that the food is low calorie or reduced calorie or that the food may make a comparative claim or special dietary usefulness" and "in compliance with paragraph (c) or (d) of this section" because the terms are no longer codified in this section. The agency recognizes, however, that provisions for the terms "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener," may, consequently, not be clear. However, as stated above, the agency intends to reexamine § 105.66, particularly this paragraph, so that it can establish a more cohesive policy regarding foods for special dietary uses. The agency envisions that use of the term "diet," except on soft drinks exempt under section 403(r)(2)(D) of the act, and on products addressed in § 105.66(e)(2), will require that such foods meet the general requirements of § 105.66.

Finally, the agency is proposing to delete § 105.66(e)(3) and include reference to "formulated meal

replacement or other food that is represented to be of special dietary use as a whole meal," in paragraph (e)(1). The agency recognizes that this is a departure from the previous regulation that exempted such foods from paragraph (e)(1) pending issuance of a regulation governing them. However, in order that such claims not be prohibited as implied nutrient content claims under the 1990 amendments, they are being included in paragraph (e)(1) until such time as more appropriate regulations can be issued. FDA views claims that are permitted under § 105.66 to meet the requirements of section 403(r) of the act.

IV. An Alternative Approach to Comparative Nutrient Content Claims

The proposed approach to comparative nutrient content claims discussed in the preceding sections involves the adoption of specific and distinct definitions for such comparative terms as "reduced," "fewer," and "less," including minimum percentage reductions or differences that must be achieved to justify the claim (e.g., a "less" claim requires at least 25 percent less of the nutrient in question). FDA is concerned about whether the terms defined in the various nutrient content claim rules strike the proper balance between allowing an adequate number of terms such that consumers can distinguish the nutrient content across foods and minimizing the proliferation of terms that may tend to confuse consumers. It is possible that the comparative terms FDA proposes to define might still cause confusion, due to the natural vagaries of language, the fact that it will take a significant amount of time before consumers are familiar with the definition of the terms, and the fact that the terms are really only distinguished by the regulatory definition rather than some innately understood differences: In common parlance, "reduced," "fewer," and "less" do not have established, distinct meanings for most consumers as they apply to describing relative levels of nutrients in food.

In addition to avoiding consumer confusion and thus fostering the consumer's ability to select healthier foods, FDA also wants to provide manufacturers maximum flexibility in their use of nutrient content claims, consistent with the goals and requirements of the act. This is consistent with FDA's goal of assuring that the approach to defining nutrient content claims it ultimately adopts provides a clear incentive to manufacturers to produce innovative products that are improved in the nutritional attributes addressed by the comparative nutrient content claims e.g., products that are truly "reduced" in fat or contain "less" cholesterol than the products for which they substitute.

Consequently, FDA solicits comment on a very distinct regulatory approach that in essence defines all comparative nutrient content claims as synonyms and requires a numeric disclosure of the comparative difference. Unlike words, numbers are not as easily manipulated and therefore avoid the confusion of distinctly defined terms. Therefore, a number of terms given identical definitions could be used with conspicuous full disclosure of the percent by which the nutrient has been decreased and a comparison of the quantity of the nutrient in the labeled food and the reference food. For example, the following nutrient claims could be used interchangeably: "____ percent reduced calories," and "____ percent fewer calories," with a disclosure in absolute terms of the comparative amounts (in this example, the number of calories per serving in the labeled food and the number in the food to which it is being compared).

Under this approach, or even as a separate alternative, there would not be any single across-the-board minimum percent of reduction or difference required to support the claim, such as 25 percent, but any claimed reduction or difference in the level of a nutrient would have to be large enough to be considered nutritionally significant in accordance with criteria adopted by FDA.

FDA intends to seriously evaluate these alternatives as part of its continuing effort to devise an optimal approach to nutrient content claims. To facilitate a full airing of the issues, FDA is considering holding a public meeting on nutrient content claims and, within 60 days of the publication of this proposal, the agency will publish a supplemental notice of proposed rulemaking. FDA will then fully evaluate the alternative approach outlined above and the one proposed in this document and by November 8, 1992, FDA will select and adopt as a final rule the approach to comparative nutrient content claims that best achieves the agency's goals of avoiding consumer confusion, empowering consumers to choose healthier diets, and providing incentives for food manufacturers to produce nutritionally improved food products.

V. Petitions for Nutrient Content Claims

Section 403(r)(4) of the act provides that any person may petition the Secretary to make nutrient content claims that are not specifically provided for in FDA's regulations. It describes procedures for petitions that seek to define additional descriptors, to establish synonyms, and to use an implied nutrient content claim in a brand-name.

On March 14, 1991, the agency stated in a notice in the **Federal Register** (56 FR 10906) that it was developing procedural regulations that would prescribe the type of information needed to support each of these three types of petitions, in addition to the other types of petitions permitted by 1990 amendments. The agency stated that the most efficient use of its resources would be to establish these procedures in final form before considering, or acting on, any such petitions. The agency, therefore, advised that it is likely to deny any petition submitted under the 1990 amendments until final procedural regulations are issued. The agency requested information and comments on appropriate requirements for these petitions.

Ten comments pertaining to petitions for nutrient content claims were received from the food industry, industry trade associations, and consumer organizations. The agency has considered the comments, and many of the recommendations made in the comments are incorporated, or were otherwise used, in the development of this section of the proposed rule.

The agency is proposing to codify the procedural requirements for petitions for nutrient content claims in new § 101.69. Because the statute prescribes distinctly different procedures for petitions that relate to nutrient content claims, synonyms for those claims, and implied nutrient content claims in brand names, FDA will treat each separately in the following discussion. In the proposed procedural regulations the Commissioner of Food and Drugs is designated as the official authorized to act on these petitions consistent with the delegation of authority from the Secretary to the Commissioner under 21 CFR 5.10.

The agency is also proposing to amend § 5.61 (21 CFR 5.61) to add paragraph (g) to redelegate to the Director and Deputy Director of the Center for Food Safety and Applied Nutrition, all the functions of the Commissioner concerning petitions for label claims under section 403(r) of the act (i.e., petitions concerning nutrient content claims and health claims) that do not involve controversial issues. Such functions consist of issuing notices that seek comment on a petition; issuing notices of proposed rulemaking and final rules concerning authorized terms

for nutrient content claims; and issuing letters concerning the filing, denial, and granting of a petition. This redelegation is proposed to facilitate timely agency action on these petitions given the short timeframes for agency action imposed by the act.

A. Statutory Provisions

1. Nutrient Content Claim (Descriptor) Petitions

Section 403(r)(4)(A)(i) of the act grants to any person the right to petition the Secretary (and by delegation, FDA) to issue a regulation to define a nutrient content claim that has not been defined in the regulations issued under section 403(r)(2)(a)(i) of the act. The statute requires that such a petition include an explanation of the reasons why the claim that is the subject of the petition meets the requirements of section 403(r) of the act and a summary of the scientific data that support those reasons (section 403(r)(4)(B)) of the act.

These provisions of the act also apply to petitions to the agency to issue a regulation relating to a health claim to be made of a food label. However, because health claims and nutrient content claims are distinct types of claims that convey different types of information to consumers, the specific data requirements to substantiate these two types of petitions will differ significantly. Therefore, the procedural requirements for petitions relating to health claims are proposed separately in a proposal published elsewhere in this issue of the **Federal Register** that addresses the general requirements for health claims for food.

Section 403(r)(4)(A)(i) of the act provides that within 100 days of receipt of a petition for a regulation concerning descriptors, FDA must either issue a final decision denying the petition or file the petition for further action. If FDA denies the petition, it is not made available to the public. If it files the petition, FDA must either deny it or publish a proposed regulation responsive to the petition within 90 days of filing.

2. Synonym Petitions

Section 403(r)(4)(A)(ii) of the act grants to any person the right to petition the Secretary (and by delegation, FDA) for permission to use terms in a nutrient content claim that are consistent (i.e., synonymous) with terms defined in regulations issued under section 403(r)(2)(A)(i) of the act. The statute provides that within 90 days of the submission of a petition, FDA must issue a final decision denying the petition or granting such permission.

3. Brand-Name Petitions

Section 403(r)(4)(A)(iii) of the act also allows petitions requesting use of an implied claim concerning the level of a nutrient in a food in the food's brand name. The claim must not be misleading and must be consistent with the terms defined by FDA by regulations under section 403(r)(2)(A)(i) of the act. The agency is directed in the act to publish notice of an opportunity to comment on the petition in the **Federal Register**, to make the petition available to the public, and to issue a final decision no later than 100 days after the date of submission to grant or to deny the petition. The petition is to be considered granted if the Secretary does not act on it within 100 days.

B. Comments

1. Nutrient Content Claims Petitions

a. *Procedural issues.* Two comments stated that FDA appears to take the position that "free," "low," "light" or "lite," "reduced," "less," and "high" are the only nutrient content claims for which the agency is required to issue regulations within two years after the enactment of the 1990 amendments. The comments disagreed with this interpretation and contended that the congressional intent, and the wording of the 1990 amendments, contemplate a two-track system operating concurrently. The first track consists of establishment (by the agency) of definitions for the above nutrient claims identified in the 1990 amendments. The second track consists of agency consideration of those nutrient descriptors for which petitions are submitted by interested persons.

The comments stated that at no time did Congress indicate that FDA had authority to limit itself to the former and ignore the latter. The comments pointed out that any nutrient content claim that is not the subject of an FDA regulation issued by the effective date of the statute may not be used. The comments stated that as a result of this fact and of FDA's planned course of action, all nutrient content claims not explicitly required by statute to be the subject of a regulation would not be defined and thus could not be used after the effective date of the statute. Therefore, the comments requested that FDA withdraw the statement that it may defer or deny nutrient content claims petitions until it has adopted final procedural regulations and state that all petitions will be handled in the manner required by the new law.

The agency rejects these comments for three reasons. First, as explained in the March 1991 **Federal Register** notice, the 1990 amendments place an extraordinary burden on FDA's resources. FDA has great discretion in determining how its resources can best be used. Not only does the agency lack the resources to handle a large influx of petitions on nutrient content claims, but because the petitions would be submitted before FDA identified the kinds of information that a petition would have to include to substantiate the need for a new descriptor, it is questionable whether the petitions would contain the substantive information needed by the agency to make a decision. Such a situation would likely result in a waste of the agency's resources, as a great deal of effort would need to be spent in looking at inadequate petitions.

Secondly, and most importantly, the nutrient content claims petitions would request regulations that are in addition to or perhaps amendments of the regulations established by the agency in this rulemaking. As the agency stated in the March 14, 1991 notice, it is premature to request amendment of a regulation (by addition or revision) before the regulation is final. The procedural regulations will be made final at the same time as the substantive regulations, and therefore, the agency's procedure for handling petitions before final regulations is appropriate.

Consistent with the most effective use of its resources in pursuing this end, the agency believes that the nutrient content claims that it considers first should be those that are of greatest concern and usefulness to consumers because of their potential to be misleading. The agency is addressing those terms in this proposed rule. The agency notes that in doing so, it has not limited itself to the terms enumerated in section 3(b)(2)(A)(iii) of the 1990 amendments but has proposed to define a number of other terms (e.g., "source" and "more") that are of most significance to consumers.

b. *Evaluation criteria.* Several comments recommended that a nutrient content claim petition include a quantitative definition of the proposed descriptor, and that the definition be supported by data proving that the new term is quantitatively significantly different than those terms defined pursuant to section 403(r)(2)(A)(i) of the act. One comment further recommended that the petitioner be required to explain, using scientific data, why the agency-defined nutrient content claims are inadequate to describe the product's characteristics.

The agency agrees that petitions for nutrient content claims should address

the level of the nutrient that must be present to justify the use of the claim and is proposing to require in § 101.69(m)(1) in format item A that a petitioner specify the level at which a nutrient must be present for the use of the claim to be appropriate. The agency also believes that before it approves any additional claims, it should consider whether such approval would result in the availability of additional useful information to consumers that will enhance their ability to select foods of nutritional value. Therefore, the agency is proposing to require in § 101.69(m)(1) in format item B that the petitioner address what nutritional benefit to the public will derive from the use of the proposed claim, and why such benefit is not available through the use of the existing terms defined by regulation.

Other comments added that scientific or statistical data supporting the accuracy of the term, in and of themselves, are not sufficient, if such studies are not accompanied by broad-based, statistically valid studies demonstrating consumers' understanding of the term.

FDA believes that a petition should demonstrate that consumers will understand the proposed term. However, it does not believe that an extensive database would be required in all cases to substantiate that a proposed term would be understood. Therefore, the agency is proposing in § 101.69(m)(1) in format item C that a petition include data and information that demonstrate that the proposed term will be understood by consumers, but it is not specifying the type or degree of such data.

Another comment suggested that petitions include recommendations from health organizations. Information, including recommendations, from health organizations may be useful in evaluating potential nutrient content claims, and petitioners are free to include such recommendations. However, the agency does not believe that such recommendations should be required for a petition to meet the burden of proof contemplated by the act and is not proposing to require them. In addition, health organizations will be able to participate in the rulemaking process for these petitions by commenting on any proposed regulation issued in response to a petition.

Other comments suggested that in considering nutrient content claim petitions, the agency is required to use the statutory criteria established in section 403 (a) and (r) of the act, and that because these criteria are quite specific, no other elucidation of the statutory provision is necessary or desirable.

While the agency agrees that the statutory provisions cited in the comments, along with section 201(n) of the act, will provide the ultimate standards against which any petitions for additional terms must be judged, it believes that an additional elucidation by regulation is appropriate. The agency believes that by setting forth the kind of showing that will be necessary to justify a claim, it will facilitate the process. As a result the petitions that will be filed will be more focused, and potential petitioners will be able to judge in advance whether submitting a petition would likely be a useless gesture.

2. Synonym Petitions

a. *Procedural issues.* In general, the comments that addressed the procedures to be followed for synonym petitions dealt with four major areas: Publication of a notice of receipt of a synonym petition, opportunity for public comment, publication of the agency's decision, and necessity for codification of the final decision.

One comment stated that under section 403(r)(4)(A)(ii) of the act, there is no statutory requirement for a comment period, and therefore, none should be afforded. Other comments suggested that all petitions received by the agency should be published in the **Federal Register** with a 30-day comment period.

The agency received a similar range of comments on the need to publish a notice of denial of a synonym petition. While some comments argued that there is no need to publish such a notice, others argued that if a petition is denied, publication of this fact would discourage others from petitioning for use of the same term, thereby promoting more efficient use of the agency's resources.

One comment stated that a petition under section 403(r)(4)(A)(ii) requires only a decision by the agency in the nature of an advisory opinion and not the establishment of a regulation. The comment said that only if the petition is granted should notice of availability of the advisory opinion be published in the **Federal Register**. Others felt that it is appropriate that if the petition is granted, the synonymous term should be codified. These comments argued that this approach is consistent with the requirement in the 1990 amendments that all new nutrient content claims be codified. These comments also said that codification will lead to consistency of terms used for the labeling of food and, thereby, better consumer understanding of label statements.

The proposed procedures for agency action on synonyn petitions are discussed below along with the factors that the agency considered in arriving at its tentative positions. Given the very short timeframe established by the act, the agency is proposing neither to solicit public comment on the petition nor to establish regulations for authorized synonyms. However, it intends to publish expeditiously a notice of its decision on the petition.

b. *Evaluation criteria.* Some comments recommended that the agency require petitioners to prove that the ordinary meaning of the term is not misleading and is synonymous with the agencydefined term. Inclusion of consumer surveys or other market research data was recommended to demonstrate that consumers understand the new term to be synonymous with the agency-defined term, and that consumers are not confused by the new term. The comments also stated that the etitioner should be required to show why the existing terms are inadequate.

The agency generally agrees with the views expressed in these comments. It has included provisions in proposed § 101.69(n), the regulation on synonym petitions, that require that the petitioner address these items. This approach would differ under the alternative discussed in section IV above.

3. Brand-Name Petitions

One comment requested that the agency provide adequate time for comment on the notice that it is required to publish in the **Federal Register**. Other comments suggested that the agency consider codifying its decision to grant a brand-name petition, or, if this is not practicable, any final decision by the agency should be made public 30 days before its effective date, so that interested parties can petition for reconsideration.

The proposed procedures for agency action on brand-name petitions are discussed below along with the factors the agency considered in arriving at its tentative positions. FDA is proposing to provide 30 days for comment on the petition and to issue its decision by letter to the petitioner. In addition, the agency intends to announce the approval of a brand name in the **Federal Register**.

C. Proposal

1. Provisions Applicable to All Petitions for Nutrient Content Claims

The agency is proposing to establish § 101.69 as the general procedural regulation for all types of petitions for nutrient content claims. Proposed § 101.69(a) through (l) are general

provisions applicable to all such petitions. Section § 101.69(a) through (f) address general issues, such as how specific types of information can be incorporated into the petition and set forth standard agency requirements pertaining to clinical and nonclinical studies submitted to the agency for review. The agency is proposing in § 101.69(g) that the availability for public disclosure of petitions for nutrient content claims will be governed by the provisions of § 10.20(j), the general provision that governs the availability of material submitted to the Dockets Management Branch, such as petitions, comments, and objections.

Proposed § 101.69(h) requires all petitions to include either a claim for a categorical exclusion under § 25.24 or an environmental assessment under § 25.31. Section 101.69(i) sets forth how the submitted data in the petition are to be organized and identified and permits the petitioner to incorporate by reference any data from an earlier petition. Section 101.69(j) requires that the petition be signed by the petitioner, or his attorney or agent, or (if a corporation) by an authorized official. Section 101.69(k) requires that the petition include a statement signed by the person responsible for the petition that the petition is a representative and balanced submission containing all information, favorable and unfavorable, to the evaluation of the proposed claim. Section 101.69(l) states that all applicable provisions of part 10 may be used by the agency, the petitioner, or any outside party with respect to any agency action on a petition submitted under this section. The agency advises, however, that actions requested under part 10, e.g., a request for reconsideration of a decision on a § 101.69 petition, are not subject to the timeframes prescribed in the 1990 amendments for the petitions themselves.

2. Provisions for Descriptor Petitions

Proposed § 101.69(m)(1) sets forth the proposed data requirements specific to descriptor petitions. These requirements are, in FDA's opinion, those necessary for the petition to demonstrate that use of the proposed descriptor is not misleading and is consistent with the purpose of the 1990 amendments, i.e., to make the food label more meaningful and understandable to consumers.

Proposed format item A requires a statement identifying the descriptive term and the nutrient whose level the term is intended to characterize. The statement should address why the use of the term as proposed will not be misleading and provide examples of the claim as it will be used on labels or labeling, as well as examples of the types of foods on which the claim will be used. The statement must specify the level at which the nutrient must be present, or what other conditions concerning the food must be met for the appropriate use of the term, as well as any factors that would make the use of the term inappropriate.

Proposed format item B requires a detailed explanation, supported by any necessary data, of why the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that the claim would describe. The explanation must also state what nutritional benefit to the public will derive from the use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation. The explanation of any claim proposed for a specific group within the population should address the specific nutritional needs of that group. This format item also requires the petitioner to provide data and information, to the extent necessary, to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Proposed format item C requires data showing the amount of the subject nutrient that is present in the types of foods for which the claim is intended and specifies requirements for the assay methods used for these determinations. This information is necessary to assure the agency that the claim is realistic, and that there are foods that will actually be able to bear the claim.

Proposed format item D requires a detailed analysis of the potential effect of the use of the proposed claim on food consumption and of any corresponding changes in nutrient intake, with the latter item specifically addressing the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the analysis must address the dietary practices of that group, with data sufficient to demonstrate that the dietary analysis is representative of that group.

The procedures for agency handling of the petition are set forth in proposed § 101.69(m)(2) through (m)(4). These items reflect the timeframes in the act for agency action on descriptor petitions. Further, the agency is proposing for descriptor petitions (and also synonym and brand-name petitions) to notify the petitioner of receipt of a petition within 15 days of submission and to deny the petition at such time if it is incomplete. If a petition is not denied at this time, a docket number will be assigned to the petition, and any subsequent actions under the provisions of Part 10—Administrative Practices and Procedures regarding the petition will reference that docket number.

3. Provisions for Synonym Petitions

Proposed § 101.69(n)(1) sets forth the proposed data requirements specific to synonym petitions. These requirements are, in FDA's opinion, those necessary for the petition to demonstrate that use of the proposed synonym is not nsleading and is consistent with the purpose of the 1990 amendments. Because the agency foresees using many of the same criteria in evaluating a synonym petition as it is proposing to use for descriptor petitions, many of the proposed data requirements for synonym petitions are similar or identical to those proposed for descriptor petitions.

Proposed format item A requires a statement identifying the synonymous term and the nutrient content claim (defined by a regulation) with which the synonym is claimed to be consistent. The statement should address why the use of the synonymous term, as proposed, will not be misleading. The statement should also provide examples of the claim as it will be used on labels or labeling, as well as examples of the types of foods on which the claim will be used. The statement must specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

Proposed format item B requires a detailed explanation, supported by any necessary data, of why the proposed term is requested, including an explanation of whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. The explanation must also state what nutritional benefit to the public will derive from the use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation. Any claim proposed for a specific group within the population should address the specific nutritional needs of that group. This format item also requires data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Proposed format item C requires a detailed analysis of the potential effect

of the use of the proposed claim on food consumption and of any corresponding changes in nutrient intake, with the latter item specifically addressing the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the analysis must address the dietary practices of that group, with data sufficient to demonstrate that dietary analysis is representative of that group.

The proposed procedures for agency handling of a synonym petition are set forth in proposed § 101.69(n)(2) through (n)(4). These items reflect the timeframes in the act for agency action on synonym petitions. The agency is not proposing to provide for the publication of a notice soliciting public comment on the petition because, in contrast to petitions for new descriptors, the statute does not require such notice for synonym petitions, and under the statutory requirement of action on the petition in 90 days, there simply is not time to do so. Consistent with the act, the agency is proposing to issue its decision concerning a synonym petition by letter to the petitioner.

Although the act does not require that permission to use a synonym be provided by regulation, the agency is proposing that it will publish expeditiously a notice of its decision on the petition. Such notice will serve to inform the public of agency decisions and provide an opportunity for interested persons to petition the agency for reconsideration of the action under part 10. In addition, to avoid confusion about which synonymous terms have been approved by the agency, and because the procedure defined in the statue will result in a final agency decision that has the force and effect of law, FDA is proposing that when a synonym petition is granted, it will include the synonymous term in the applicable descriptor regulation.

4. Provisions for Brand-Name Petitions

Proposed § 101.69(o)(1) sets forth the proposed data requirements specific to brand-name petitions. These requirements are, in FDA's opinion, those necessary for the petition to demonstrate that use of the proposed implied claim is not misleading and is consistent with the purpose of the 1990 amendments. Because the agency foresees using many of the same criteria in evaluating a brand-name petition as it is proposing to use for descriptor and synonym petitions, many of the proposed data requirements for brand-name petitions are similar or identical to those proposed for descriptor and synonym petitions.

Proposed format item A requires a statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of the nutrient as defined by regulation, and the brand-name of which the implied claim is intended to be a part. The statement should address why the use of the brand-name as proposed will not be misleading. The statement should provide examples of the types of foods on which the brand-name will appear and must include data showing that the actual level of the nutrient in these foods qualifies them to bear the term defined by regulation.

Proposed format item B requires a detailed explanation, supported by any necessary data, of why use of the proposed brand-name is requested. This format item must also state what nutritional benefit to the public will derive from the use of the proposed brand-name. If the branded product is intended for a specific group within the population, the claim should address the specific nutritional needs of that group.

Proposed format item C requires a detailed analysis of the potential effect of the use of the proposed brand-name on food consumption and of any corresponding changes in nutrient intake, with the latter item specifically addressing the intake of nutrients that have beneficial and negative consequences in the total diet. If the branded product is intended for a specific group within the population, the analysis must address the dietary practices of that group, with data sufficient to demonstrate that dietary analysis is representative of that group.

The proposed procedures for agency handling of a brand-name petition are set forth in proposed § 101.69(o)(2) through (o)(5). These items reflect the timeframes in the act for agency action on brand-name petitions.

FDA recognizes that a short timeframe for brand name decisions is necessary in order to prevent inappropriate inhibition of production and marketing planning. Given the need for such planning and the need to ensure that the consumer is protected, the agency recognizes the need for it to make decisions on implied nutrient content claims in brand names within the 100 day timeframe.

The agency advises that it intends to deny a petition if it determines that the requested claim is not an implied nutrient content claim. FDA will make this determination using criteria consistent with any that have been developed for implied claims under section 403(r) of the act. The agency also intends to deny petitions for implied claims that do not include as a part of the label statement enough appropriate information so that it is clear that consumers will not be misled by the claim. In addition, FDA intends to deny a petition if it is not complete as prescribed in this regulation, or if the information in the petition is not clearly persuasive that the requested claim should be approved. Of course, as discussed above, any petitioner may request reconsideration of a denial under the provisions of 21 CFR part 10.

The agency is proposing to publish the **Federal Register** notice seeking comment on the petition as soon as possible after receipt of the petition (probably within 20 days) and to provide 30 days for public comment on the petition. The agency believes that 30 days is the longest comment period possible consistent with the agency's responsibility to act on the petition within 100 days. Consistent with the act, the agency is proposing to issue its decision concerning a brand-name petition by letter to the petitioner. However, to avoid confusion about which brand-names containing implied nutrient content claims have been approved by the agency, FDA is proposing that when a brand-name petition is granted, it will publish expeditiously a notice in the **Federal Register** informing the public of the granting of the petition.

As with synonym petition proceedings, the rulemaking prescribed by for implied nutrient content claims in brand names will result in binding final agency decisions. However, FDA does not plan to list approved brand name claims in the regulations. Unlike approved synonyms, which are available for use by any manufacturer of a qualifying food, approved brand name claims are proprietary and can be used by only one firm. Consequently, there is less need for a list of approved brand name claims in the Code of Federal Regulations than there is for a list of approved synonyms. However, there is a need for a publicly available, up-to-date list, and FDA intends to maintain such a list.

VI. Terms That Describe Other Aspects of Food

In the course of the Secretary's labeling initiative, another matter that has increasingly gained the attention of consumers, the food industry, and the agency is the use of terms such as "fresh," "natural," and "organic" on labels or in labeling. These terms are not used to characterize the level of a nutrient in a food but rather to describe other aspects of a food that are

considered desirable. Many comments to the 1989 ANPRM objected to the use of such terms as marketing tools that provide no consistent guidance to the consumer about the nature of the food. Some comments suggested that these terms should be defined by FDA or not permitted.

Because such terms are not used to make nutrient content claims, the 1990 amendments do not require that the Secretary define such terms. However, the agency believes that the misuse of "fresh" and related terms that has occurred in the marketplace necessitates that a definition be established in the labeling regulations to provide a basis for consumers to distinguish foods that have certain desirable attributes from those that do not and to remove any inconsistencies in the use of the term that may remain in the marketplace. The agency announced its intention to take such action with respect to "fresh" in a notice published in the **Federal Register** on February 12, 1991 (56 FR 5894). It also discussed the interim enforcement policy it planned to use until such rulemaking is completed.

FDA is proposing to amend its food labeling regulations to define, and to provide for the appropriate use of, the terms "fresh," "freshly ____," and "fresh frozen" ("frozen fresh") in the labeling of foods. FDA is also addressing the terms "natural" and "organic." However, as explained below, it is not proposing to establish definitions for the latter terms at this time.

A. "Fresh" and Related Terms

1. Use of the Term "Fresh" on Food Labels

a. *Previous FDA findings on use of the terms "fresh" and "fresh frozen" ("frozen fresh").* The agency's longstanding position on the appropriate use of the terms "fresh" and "fresh frozen" is set forth in Compliance Policy Guide (CPG) 7120.06 (Ref. 50). CPG 7120.06 makes two basic points: (1) "fresh" should not be used to describe foods that have been subjected to any form of heat or chemical processing; and (2) "frozen fresh" or "fresh frozen" are examples of terms appropriate for referring to foods that were quickly frozen while still fresh. FDA's position has been and continues to be that use of term "fresh" on foods that have been frozen or subjected to heat or chemical processing (e.g., canning, cooking, baking, pasteurization, smoking, or use of a preservative) is false and misleading.

The agency's position on the use of "fresh" dates back to the 1940s. In TC-71 (February 19, 1940) the agency stated that it would not take exception to such terms as "frozen fresh" on packaged frozen foods, provided that the foods are actually fresh when frozen. In TC-99 (February 21, 1940), FDA stated that the word "fresh" is generally understood by consumers to mean an article of recent origin, and that for butter the word would be appropriate only if the butter had been recently churned. The agency said that "fresh" would not be applicable to butter that had been kept for a length of time, such as in the usual commercial practice of storing butter in cold storage warehouses until it is marketed. In TC-281 (May 7, 1940), FDA stated that the term "fresh tomato juice" should not be applied to the ordinary canned products.

The agency has reiterated its policy over the years. FDA took a consistent position in the findings of fact that it published in the **Federal Register** of October 11, 1963 (28 FR 10900), with the final order establishing definitions and standards of identity for orange juice and various orange juice products, including pasteurized orange juice and orange juice from concentrate. One of the primary reasons for promulgating these standards was the misrepresentation of reconstituted and pasteurized orange juice as "fresh" orange juice. Finding of fact No. 2 stated:

> Fresh orange juice is not a suitable name for the commercially packaged expressed juice of oranges. The housewife who for many years has squeezed oranges knows this juice to be orange juice. The term "fresh" is ambiguous in that it is difficult to determine and to draw the line when a product is fresh and when it is no longer fresh. The use of the term "fresh" on commercially packed orange juice or orange juice products would tend to confuse and mislead consumers.

The findings of fact contain other similar and related comments concerning "fresh." Finding of fact No. 17 stated in part:

> The problem most encountered * * * is the adulteration of orange juice products with water and sugar. The next most frequent problem is misrepresentation of reconstituted orange juice and of pasteurized orange juice as fresh orange juice. The investigation further showed that even managers of retail food stores over the country are confused concerning the identity of various single-strength orange juice products. There is general confusion in the area.

The issuance of standards of identity for various orange juice products was intended, in part, to prescribe specific appropriate names for heat treated and reconstituted orange juice so as to eliminate confusing these products with fresh orange juice.

FDA has also stated in an informal opinion letter (Ref. 50) that irradiated food is a processed food and thus could not appropriately be labeled as "fresh."

b. *Current practices of concern to FDA.* Beginning in the late 1980s FDA received a number of complaints about the deceptive use of the term "fresh" on products (e.g., pasta sauce) that were preserved by heat treatment or products (e.g., fruit juices) that had been concentrated and reconstituted. FDA grew concerned about the proliferation of such misleading label claims and the resultant consumer confusion in the marketplace. In the agency's view, it is important that label statements using the terms "fresh" and "fresh frozen" ("frozen fresh") not convey a misleading impression about the food.

The IOM report (Ref. 5) took a consistent view. It noted that consumers want and expect a product's principal display panel to include short and understandable terms such as "fresh" and "fresh frozen" ("frozen fresh") that describe certain desirable characteristics of the food, because such terms allow them to select quickly foods that they believe are consistent with their dietary concerns. However, the report stated, the lack of uniform and consistent FDA and USDA definitions for these types of terms has led some to conclude that such terms should not be permitted because of the potential for confusion, exaggeration, and deception. Therefore, the IOM report recommended that terms like "fresh" be controlled by narrowing the conditions for their use.

FDA agrees with the recommendations of the IOM report and the general view expressed in many of the comments on the 1989 ANPRM that stronger control of the use of the terms "fresh" and "fresh frozen" ("frozen fresh") is needed so that consumers will not be misled in attempting to make intelligent use of factual information on the food label.

Since 1989, FDA has increased its surveillance of the use of the term "fresh" in the marketplace. In the spring of 1991, the agency instituted a major regulatory initiative against misleading uses of "fresh" on food labels. The agency took formal and informal actions against the use of the term on such products as juice products made from concentrate, juice drinks containing preservatives, and heat processed products such as pasta sauces and caviar. FDA issued letters to several firms citing their misleading use of "fresh" on food labels, warned firms that such misbranded products may be seized by the agency, and has seized some products.

The agency will continue to monitor the use of this term in the marketplace and remains prepared to take action where it encounters the misleading use of the term. However, FDA also believes that the lack of regulations defining "fresh" and "freshly frozen" ("frozen fresh") creates the possibility that these terms will again be abused. Therefore, FDA has tentatively concluded that it is both necessary and desirable to establish definitions by regulation that will standardize the use of these terms on food labels.

2. Proposed Regulation

a. *Legal basis and general provisions.* FDA is proposing to define the terms "fresh" and "fresh frozen" ("frozen fresh") in the labeling of food and to provide for the proper use of these terms. FDA has authority to take these actions under sections 201(n), 403(a)(1), and 701(a) of the act. Section 201(n) of the act allows for the consideration of the extent to which the labeling of a food fails to reveal a material fact in determining whether its labeling is misleading. Section 403(a)(1) of the act states that "A food shall be deemed to be misbranded if its labeling is false or misleading in any particular," and section 701(a) of the act vests the Secretary (and by delegation, FDA) with authority to issue regulations for the efficient enforcement of the act. If this proposal becomes a final rule, foods using these terms will be considered to be misbranded if they are not labeled in accordance with the proposed definitions.

FDA is proposing to redesignate subpart F of part 101 as subpart G and to establish a new subpart F that will contain requirements for claims that are neither nutrient content claims nor health claims. FDA is proposing to define and provide for the use of the terms "fresh," "freshly ____" (the blank to be filled with an appropriate verb such as "prepared," "baked," or "roasted"), and "fresh frozen" in § 101.95. The introductory paragraph of proposed § 101.95 sets out the general requirements for the use of the terms defined in the section, namely that they may be used on the label or in labeling of a food only in conformity with the provisions of the section.

b. *"Fresh," and "Freshly ____."* FDA is proposing to define the terms "fresh" and "freshly ____," to be used in separate contexts: (1) The term "fresh," as defined in proposed § 101.95(a), applies to a raw food that has not been frozen or subjected to any form of thermal processing or any other form of preservation; (2) The term "freshly ____" (e.g., prepared, baked, roasted) in proposed § 101.95(b) applies to a recently produced or prepared food that has not been frozen, or subjected to any form of thermal processing or any other form of preservation, during or subsequent to its manufacture or preparation, excluding a process inherent to the production of the basic product. As discussed below, proposed § 101.95(d) contains provisions for the use of these descriptors in cases that would otherwise be precluded under the definitions in § 101.95 (a) and (b).

FDA believes that consumers generally regard a food in its raw state as being fresh. Proposed § 101.95(a) therefore distinguishes a food in its raw state from the same food that has been processed or preserved for the purpose of defining which is fresh. For example, fish that is caught, cleaned, and displayed for sale under refrigeration may be labeled "fresh." However, if the fish was frozen aboard the fishing vessel, then thawed and prepared for sale in a central facility, it could not be labeled as "fresh" because it has been processed by freezing. A food such as unprocessed juice obtained directly from oranges by squeezing may be labeled as "fresh." However, if the juice is pasteurized, it is not fresh because it has been processed by pasteurization (a thermal process). Similarly, a product made with processed or concentrated ingredients is not "fresh."

Under proposed § 101.95(d)(1), the following conditions would not preclude use of the term "fresh": (1) If an approved wax or coating has been applied to raw produce, (2) if a mild chlorine or mild acid wash has been applied to raw produce, or (3) if raw produce has been treated with approved pesticides after harvest. Although these practices could possibly be viewed as methods of preserving food, they are routine practices in the distribution and handling of raw produce that essentially affect only the food surface and do not appreciably affect the body of the food or alter its raw state. Further, the agency believes that consumers regard such foods as fresh and are not misled when the term is used on these foods.

The agency solicits comments on the use of "fresh" to describe certain raw foods that have been treated with ionizing radiation in accordance with § 179.26 (21 CFR 179.26), specifically those foods for which irradiation at a maximum dose of 1 kiloGray (100 kilorads) is permitted. Currently, § 179.26(b) permits such treatment "for control of *Trichina spiralis* in pork carcasses," "for growth and maturation inhibition of fresh foods," and "for disinfestation of arthropod pests." The agency will determine, based on the comments, whether it should include a provision in § 101.95(d)(1) permitting the term "fresh" to be used on irradiated foods where the irradiation has had little effect on the attributes of the food associated with its raw state. Alternatively, if comments persuade the agency that consumers would be misled by such use of the term "fresh," the agency will consider including a provision in the final rule specifically prohibiting such practices.

Proposed § 101.95(d)(2) provides that refrigeration of a raw food that otherwise meets the definition of "fresh" does not preclude the use of that term. Although refrigeration is a means of preserving food for a finite time, the proposal includes this provision because the agency believes that consumers generally regard refrigerated raw foods as fresh and are not misled when the term is used on such foods.

Proposed § 101.95(b) states conditions for the use of "freshly ____" on labels and in labeling of prepared foods, e.g., soup and bread, as opposed to raw food items. Proposed § 101.95(d)(2) also provides that refrigeration of a food that otherwise meets the definition of "freshly ____" does not preclude the use of the term "freshly ____." In the case of prepared foods, FDA recognizes that recently prepared or produced foods that have not been processed or otherwise preserved are valued by consumers and are generally considered by consumers to be more desirable than comparable foods that have been processed or preserved. Examples of such valued foods would include salads (e.g., bean salad and tuna salad) or soups (e.g., clam chowder) that are prepared in a retail outlet or a central facility, packaged in a consumer package or bulk form without preservatives, and offered quickly for sale without further processing. The agency believes that it is appropriate to label such foods as "freshly prepared" or "freshly made" to emphasize that the food is of recent origin, is not preserved, and has not been processed after preparation. "Prepared" in this context means that the salad or soup was actually formulated from a recipe, versus simply transferring a canned salad to a tray and displaying it for sale in a refrigerated case, or simply heating a canned soup and offering it from a self-service soup bar.

Other examples of foods that meet the proposed definition in § 101.95(b) include: (1) Peanuts that are roasted and sold onsite; (2) shrimp that is steamed at a retail site or at a central facility and quickly offered at retail; and (3)

crabmeat that is steamed or broiled before picking and is sold without preservation. In these cases, the use of other verbs in conjunction with the adverb "freshly" would be appropriate, such as "freshly roasted peanuts," "freshly steamed shrimp," and "freshly picked crabmeat." It should be noted that in all the examples for proposed § 101.95(b), the term "freshly" is an adverb that modifies a verb such as "prepared" or "roasted," and does not describe the food itself as fresh. The agency believes that the proposed terminology is the most appropriate manner for conveying the desirable attributes of recently prepared or produced foods, and thus, it is not proposing to allow for the use of "fresh" to describe the food itself.

Under the proposed definition, recently baked bread, formulated without a chemical preservative, could be labeled as "freshly baked." The fact that the bread was processed by baking does not disqualify it because baking is inherent to the manufacturing of bread. However, if such a product included a chemical preservative, such as a mold growth inhibitor, among its ingredients, it could not be labeled as "freshly baked" because it would be a preserved product. The agency does not believe that the preserved product should bear the same qualitative term, i.e., "freshly baked," as unpreserved bread, because its quality results, in part, from the incorporation of a chemical preservative.

The term "recently" as used in this proposal is a qualitative term whose meaning depends in large degree on the food in question. For example, many consumers would consider a pasta salad to be recently made, and thus "freshly prepared," on the day it was actually prepared on-site or in a central facility. On the other hand, for "freshly roasted" peanuts, consumers would probably consider "recent" to mean that the peanuts are still warm. However, in general, FDA believes that it would not be appropriate for the terms permitted by proposed § 101.95(b) to be used on the label or labeling of a food that is available for sale more than 24 hours after its preparation. FDA has therefore included in proposed § 101.95(d)(3) a provision that states that a food shall not be considered to be recently prepared or made if it is available for sale more than 24 hours after its preparation or production.

The agency's intention in specifying a time period for "recently prepared" is to limit the use of the term "freshly ____" to foods that are qualitatively comparable to foods prepared by consumers for same day consumption. However, the agency realizes that given the variety of foods that are available for sale within a relatively short time after preparation, some foods available for sale more than 24 hours after preparation may merit use of the term "freshly ____." The agency requests comments on this matter. Comments should identify such foods and state why they merit use of the term "freshly ____." If the comments identify such foods, FDA will consider adding provisions to § 101.95(d) that will permit the use of "freshly ____" in the labeling of such foods. Alternatively, the agency would consider specifying a time period other than 24 hours in § 101.95(b) if the comments demonstrate that there are a large number of foods that merit such an exception, and that a more appropriate time period can be included in § 101.95(b).

The proposed definition of "freshly ____" in proposed § 101.95(b) will preclude the use of this term on foods that have been subjected to certain processes and any form of preservation "during or subsequent to" the preparation or production of the food. Thus, the focus of this definition is on the preparation of the product and subsequent treatment of the food item and not on to the ingredients contained in the product. FDA believes that it is common in the marketplace to find prepared foods that are valued for their recent preparation even though they contain processed ingredients, e.g., a pasta salad made with canned tuna. Thus, the agency believes that consumers will not be mislead by permitting such foods to bear terms such as "freshly prepared." However, the agency requests comments concerning whether situations exist in which it would be misleading to label a prepared food containing processed ingredients as "freshly ____." If such cases are identified in the comments, the agency will consider restricting the use of the term to situations where it would not be misleading.

FDA's proposed approach concerning ingredients in a freshly prepared food is generally consistent with the policy of the USDA's Food Safety and Inspection Service (FSIS). FSIS, which regulates meat and poultry based products, permits the use of the term "fresh" when it describes a recently prepared food consisting of ingredients that could not meet its policy criteria (e.g., a ham salad containing cured ham).

c. *"Fresh frozen" and "frozen fresh".* As noted above, it has been the agency's longstanding policy that the term "fresh" should not be used without qualification to describe foods that are frozen or have been frozen. Consistent with this policy, the agency is proposing in § 101.95(c) to define the terms "fresh frozen" and "frozen fresh," when used on the label of a food, to mean a food that is quickly frozen while fresh (i.e., a food that is recently harvested when frozen), by a freezing system such as blast-freezing (sub-zero Fahrenheit temperature with fast moving air directed at the food) that ensures the food is frozen quickly, even to the center of the food, and that virtually no deterioration has taken place.

d. *Use of terms in a brand name or as a sensory modifier.* FDA is aware of a number of foods that include as part of the brand or firm name the term "fresh." Brand names, firm names, logos, and mottos are label statements that sometimes make a false or misleading claim and have the potential to mislead. Some manufacturers have claimed that when the term is used as a brand name or with the word "brand" or "style," it is not subject to FDA regulation. Others have sought to insulate their use of the term "fresh" by using it to refer to sensory qualities such as texture, color, flavor, or taste.

The use of this descriptor in conjunction with one of these terms or similar terms is misleading to consumers on the label of a product that is not itself fresh. For example, some traditional canned vegetables have used such labeling in the past, where the product contains ingredients that enable it to undergo a less intense thermal process and to retain a higher level of sensory quality. The agency desires to make it clear that it regards any use of the terms defined in this section to be subject to the requirements of the regulation if the term expressly or implicitly refers to the food. FDA is, therefore, proposing to include in the introductory paragraph in § 101.95 a statement that the requirements of the section pertain to any use of the subject terms that expressly or implicitly refer to the food, on labels or labeling, including use in a brand name and use as a sensory modifier.

e. *Use of fresh ingredients in processed foods.* FDA is also considering whether a processed food made from fresh, as opposed to processed, fruits or vegetables should be permitted (by regulation) to include on the label a factual statement such as "spaghetti sauce—made with fresh mushrooms" FDA requests comments on whether use of the term "fresh" is appropriate in such circumstances.

FDA also requests comments on whether consumers understand such

statements and consider them to be useful in describing a processed product, whether it is important to the consumer to be able to distinguish between processed products made from fresh as opposed to processed (e.g., concentrated and then rehydrated or reconstituted) ingredients, and whether there are other appropriate means for making such distinctions on food labels. In addition, if designation of the ingredient as "fresh" is useful, FDA requests comments on whether the inclusion of blanching as a part of a continuous process at a facility should preclude labeling the ingredient as "fresh." For example, if fresh raw material mushrooms are blanched and then added to the product in a continuous process, should the label be permitted to bear the phrase "made with fresh mushrooms"? FDA will consider the comments it receives and determine whether to include a provision in the final rule addressing use of the term "fresh" to describe ingredients in processed foods.

An issue that has come to the agency's attention in its review of "fresh" claims is the use of remanufactured ingredients. The agency solicits comments on whether the use of remanufactured ingredients affects the attributes of a finished product, such as a tomato product, to such a degree that the consumer is misled about the product if its labeling does not specifically declare the remanufactured nature of the ingredient. For example, would it be useful to consumers for processed products made from remanufactured ingredients to bear a term on its principal display panel such as "made from ____ concentrate," "remanufactured," or "reconstituted?"

If the comments persuade the agency that such a declaration on the product's principal display panel is necessary to not mislead consumers about the nature of a product, the agency will consider including a provision in the final rule requiring such a declaration.

f. *Extended shelf life foods.* Extended shelf life (ESL) is a term that describes a category of foods made possible by relatively recent developments in food processing and packaging technology. Generally, ESL describes a food that is unprocessed or minimally processed (in some cases, the product is cooked just as it would be by a consumer), and thus is not shelf stable, but that is packaged in such a manner so as to maintain its quality for an extended period of time when compared to traditional packaging methods. Such products are often refrigerated (many require refrigeration for safe distribution) and often rely on the use of "barrier" packaging and "modified or controlled atmospheres" in the package to retard aging of the food. For example, one such pasta product packaged in a barrier container with a modified atmosphere, reportedly has a refrigerated shelf life of 34 days (Ref. 52).

FDA notes that ESL do not meet the requirements of § 101.95(b) for the use of the term "freshly ____." However, FDA recognizes that such products may be of a degree of quality similar to that of traditional prepared foods that could appropriately be labeled as "freshly ____." FDA is requesting information on ESL foods that would enable it to determine whether any foods of this type merit use of the term "freshly ____," and if so, what factors about such foods justify the use of the term in a nonmisleading manner. If the comments identify nonmisleading uses of the term "freshly ____" to describe ESL foods, the agency will consider explicitly limiting the proposed definition in § 101.95(b) to foods prepared and packaged by traditional means, and it will consider including provisions in the final rule permitting the use of the term "freshly ____" or other terms to describe foods prepared and packaged using ESL techniques.

B. Natural

The word "natural" is often used to convey that a food is composed only of substances that are not manmade and is, therefore, somehow more wholesome. In the past, FDA has not attempted to restrict use of the term "natural" except for added color, synthetic substances, and flavors under § 101.22. In its informal policy (Ref. 53), the agency has considered "natural" to mean that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there. For example, the addition of beet juice to lemonade to make it pink would preclude the product being called "natural."

The meaning and use of the term "natural" on the label are of considerable interest to consumers and industry. Data suggest that uses of "natural" claims are confusing and misleading to consumers and frequently breach the public's legitimate expectations about their meaning. For example, two FTC reports (Refs. 54 and 55) cite numerous studies indicating a general lack of consumer understanding and scientific agreement about the meaning of the term.

The term "natural" is used, however, on a variety of products to mean a variety of things. Because of its widespread use, and the evidence that consumers regard many uses of this term as non-informative, the agency is considering establishing a definition for this term. FDA believes that if the term "natural" is adequately defined, the ambiguity surrounding use of the term that results in misleading claims could be abated.

In considering this issue, FDA has reviewed definitions of the term "natural" used by other government agencies, other countries, state governments, and industry. For example, USDA permits the use of the term "natural" on the labeling of meat and poultry products if: (1) They contain no artificial flavor or flavoring, coloring ingredient, chemical preservative, or any other artificial or synthetic ingredient, and (2) they and their ingredients are not more than "minimally processed." "Minimally processed" may include traditional processes such as smoking, roasting, freezing, drying, and fermenting. It may also include those processes that do not fundamentally alter the raw product and that only separate a whole, intact food into component parts such as grinding meat or pressing fruits to produce juices. Solvent extraction, acid hydrolysis, chemical bleaching, and other such relatively complex processes do not meet the criteria for minimal processing, and, thus, if they have occurred, the product would not be allowed by USDA to be labeled as "natural" (Ref. 56).

USDA's policy also provides that all labels of meat and poultry products bearing the term "natural" must be accompanied by a brief statement informing consumers that the product is natural because it contains no artificial ingredients and is only minimally processed. This statement may appear either directly beneath or beside all natural claims or may be placed elsewhere on the principal display panel provided an asterisk is used to tie the explanation to the claim. USDA has approved labels for "All Natural Wingettes" and "All Natural Chili."

Some of the definitions established by other government agencies, other countries, state governments, and industry are more restrictive than the USDA definition, while others are less so. There are numerous inconsistencies among the definitions as well as unanswered questions. Consequently, FDA has concluded that more consumer and industry input is needed before it can develop a definition for "natural." However, the agency notes that after considerable input from various groups, including scientists, consumers, industry, and regulatory professions, the

Federal Trade Commission (FTC) was unable to establish a definition for "natural." (See Refs. 54 and 55 and 48 FR 23270, May 24, 1983—Termination of rulemaking proceeding).

One possible meaning of the term "natural" as it applies to food is the absence of artificial or synthetic ingredients of any kind. This meaning, however, has been degraded by inappropriate use of the term in the marketplace. Should FDA establish a meaningful definition for "natural" so that this term has a common consumer understanding? Because of the multiple and diverse meanings currently in use, establishing a definition for the term "natural" that will be readily accepted and understood will be difficult. The agency is seeking comments on whether it should define this term or should prohibit such claims entirely on the grounds that they are false or misleading.

In reaching a decision on any future FDA course of action, the agency seeks comments on how, or if, it should proceed in developing a definition for the term "natural." FDA is particularly interested in the views of consumers and industry on how "natural food" should be defined. Given past consumer confusion on what "natural" means, FDA seeks comments that provide examples of what a natural food is. In addition, FDA seeks comments on whether a food represented to be natural should be considered to be misbranded under section 403(a) of the act: (1) If it has undergone more than "minimal processing" (the agency also requests comments on what "minimal processing" means), or (2) if it contains any artificial or synthetic ingredients such as food and color additives.

How FDA proceeds will depend largely on response to the agency's concerns regarding a definition of the term "natural" and the identification of a suitable direction that the agency might explore in establishing a definition for such a term.

In addition to information on these broad uses of the term "natural," FDA is also seeking comment on how it distinguishes between artificial and natural flavors in § 101.22. The agency is concerned that its existing definition of "natural flavor" may not be consistent with the current interpretation of "natural" as implying minimal processing. For example, while removing the essential oil from a food is probably well understood to be minimal processing, and the oil is therefore a natural flavor of the food, it is less clear whether hydrolysis or enzymolysis of a food is minimal processing and therefore results in a natural flavor. The agency requests comments with substantiating information to provide a basis for a clearer, more appropriate distinction between natural and artificial flavors.

C. Organic

A review of the comments from consumers to the 1989 ANPRM on the use of the term "organic" demonstrated that consumer perceptions of the term encompass more than is generally intended by the term. Many of the comments suggested that they wanted either:

(1) Organic to mean "pesticide free" (organically grown) food;

(2) Label declaration of any pesticide, growth enhancer, fungicide, chemical, or radiation used; or

(3) At least label declaration of any potentially harmful pesticides and fertilizers used.

On November 28, 1990, Title XXI—Organic Certification, known as the "Organic Foods Production Act of 1990 (OFPA), was enacted as part of the 1990 Farm Bill. The purpose of the statute was:

(1) To establish national standards governing the marketing of certain agricultural products as organically produced products, (2) to assure consumers that organically produced products meet a consistent standard, and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

The OFPA stated that to be sold or labeled as an "organically produced" agricultural product, an agricultural product must, with certain exceptions, (1) have been produced and handled without the use of synthetic chemicals, (2) not be produced on land to which any prohibited substances, including synthetic chemicals, have been applied during the three years immediately preceding the harvest of the agricultural products, and (3) be produced and handled in compliance with an organic plan agreed to by the producer and handler of such product and the certifying agent.

This statute charges USDA with establishing a certification program for producers and handlers of agricultural products that have been produced using organic methods. In addition, the USDA was instructed to permit each state to implement a State organic certification program for producers and handlers of agricultural products that have been produced using organic methods. The OFPA also established certain requirements under which a processed food could be labeled directly or indirectly as "organically grown."

The OFPA provides that exemptions to certain labeling requirements for processed foods may be made to the extent that the Secretary of Agriculture, in consultation with the National Organic Standards Board and the Secretary of DHHS, determines that they are appropriate.

Because responsibility for regulating use of the term "organic" has been assigned by Congress to USDA, FDA will defer issuing of any regulations governing the term "organic" until USDA has adopted appropriate regulations. At this time, FDA will determine whether any additional regulations governing the term "organic" are necessary.

VII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.24 that this proposed rule is of a type that does not individually or cumulatively have a significant effect on the human environment. The proposed actions pertaining to food labeling meet the criteria in 21 CFR 25.24(a)(11) for exclusion from preparation of any environmental assessment and an environmental impact statement. The proposed regulations pertaining to petitions for nutrient content claims meet the criteria for exclusion described in 21 CFR 25.24(a)(8). Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

FDA notes, however, that in section 10(a)(3)(B) of the 1990 amendments, Congress provides that if the Secretary of Health and Human Services (the Secretary), and by delegation FDA, finds that requiring compliance with section 403(q) of the act, on mandatory nutrition labeling, or with section 403(r)(2) of the act, on nutrient content claims, 6 months after publication of the final rules in the

Federal Register would cause undue economic hardship, the Secretary may delay the application of these sections for no more than 1 year. In light of the agency's tentative findings in its regulatory impact analysis that compliance with the 1990 amendments by May 8, 1993, will cost $1.5 billion, and that 6 month and 1 year extensions of that compliance date will result in savings that arguably outweigh the lost benefits, FDA believes that the question of whether it can and should provide for an extension of the effective date of sections 403(q) and (r)(2) of the act is squarely raised.

FDA has carefully studied the language of section 10(a)(3)(B) of the 1990 amendments and sees a number of questions that need to be addressed. The first question is the meaning of "undue economic hardship" FDA recognizes that the costs of compliance with the new law are high, but those costs derive in large measure from the great number of labels and firms involved. The agency questions whether the costs reflected in the aggregate number represent "undue economic hardship." Therefore, FDA requests comments on how it should assess "undue economic hardship." Should it assess this question on a firm-by-firm basis, as was provided in the bill that passed the House Committee on Energy and Commerce (H. Rept. 101-538, 101st Cong., 2d sess., 24 (1990)), an industry-by-industry basis, or should it assess this question on an aggregate basis? If the agency should take the latter approach, comments should provide evidence that would permit the agency to make a determination that there is "undue economic hardship" for most companies. FDA also points out that assessing hardship on a firm-by-firm basis would likely be extremely burdensome because of the likely number of requests.

FDA will consider the question of the meaning and appropriate application of section 10(a)(3)(B) of the 1990 amendments as soon as possible after the comment period closes. The agency intends to publish a notice in advance of any final rule announcing how it will implement this section to assist firms in planning how they will comply with the act. The early publication of this notice is to assist firms in avoiding any unnecessary expenses that could be incurred by trying to comply with a compliance date that may cause "undue economic hardship."

X. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with section 3(b)(1)(B) of the 1990 amendments, FDA must issue by November 8, 1992, final regulations for nutrient content claims. If the agency does not promulgate final regulations by November 8, 1992, section 3(b)(2) of the 1990 amendments provides that the regulations proposed in this document shall be considered as the final regulations. The agency has determined that 90 days is the maximum time that it can provide for the submission of comments and still meet this statutory timeframe for the issuance of final regulations. Thus, the agency is advising that it will not consider any requests under 21 CFR 10.40(b) for extension of the comment period beyond February 25, 1992. The agency must limit the comment period to no more than 90 days to assure sufficient time to develop a final rule based on this proposal and the comments it receives.

XI. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the provisions of § 101.69 *Petitions for nutrient content claims* relating to submission of petitions to FDA will be submitted for approval to the Office of Management and Budget (OMB). These provisions will not be effective until FDA obtains OMB approval. FDA will give notice of OMB approval of these requirements in the **Federal Register** as part of any final rule that is based on this proposal.

XII. References

The following references have been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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3. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, National Academy of Sciences, "Diet and Health, Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.

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6. Crane, N. T., memorandum to file, Modification of USDA's Nutrient Data Base for Standard Reference, Ref. 9, October 16, 1991.

7. Crane, N. T., memorandum to file, Data Analysis No. 1—Nutrient Content on a 100 Gram Basis, October 16, 1991.

8. Crane, N. T., memorandum to file, Data Analysis No. 2—Nutrient Content on a 100 Gram Dry Weight Basis, October 16, 1991.

9. Pennington, "Descriptive Terms for Food Labeling," p. 51, June, 1990, February, 1990.

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11. Market Facts, Inc., "Summary Report, FDA Nutrition Labeling Focus Groups," available from Clinical Nutrition Branch (HFF-265), Division of Nutrition, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, October 1990.

12. Gardner, S., and E. T. Guarino, letter to Fred R. Shank, May 10, 1991.

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16. Humphrey, H. H. III, letter to Virginia Wilkening, February 12, 1991.

17. Levy, A. S., and J. T. Heimbach, Division of Consumer Studies (HFF-240), Center for Food Safety and Applied Nutrition, Food and Drug Administration, "Recent Public Education Efforts About Health and Diet in the United States," 200 C St. SW., Washington, DC 20204, 1989.

18. National Food Processors Association, "Summary of Findings, Food Labeling and Nutrition * * * What Americans Want," Washington, DC.

19. Tri-Agency Task Group on Nutrition Labeling of Sugars, "Task Group Report on Nutrition Labeling of Sugars," available from the Office of Nutrition and Food Sciences, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, July, 1981.

20. Frattali, V., memorandum to Judith Kraus, August 9, 1988.
20a. Kraus, J. to M. Crown, memorandum of telephone conversation August 17, 1988.
21. Frattali, V., memorandum to Judith Kraus, August 15, 1988.
22. Frattali, V., memorandum to Judith. Kraus, August 13, 1989.
23. Lake, L. R., letter to J. Radzius, Burditt, Bowles and Radzius, Chartered, August 2, 1989.
24. Franz, M. J., "Relaxing the Rules," Diabetes Forecast, pp. 9–10, June, 1989.
25. Glinsmann, W. H., H. Irausquin, and Y. K. Park, Report from FDA's Sugars Task Force; Evaluation of Health Aspects of Sugars Contained in Carbohydrate Sweeteners, *Journal of Nutrition*, Vol. 9, pp. 161–186, 1989.
26. Miller, S. A., letter to Dr. C. Norris Bollenback, The Sugar Association, Inc., September 21, 1979.
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28. Riggins, J. W., letter to Mr. Peri Dura, North Dakota State Laboratories, July 2, 1985.
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30. Panzica, A., letter to President, R. W. Frookies, Inc., January 3, 1990.
31. Pennington, J. A. T., L. Wisniski, and G. W. Logan, "In-store Nutrition Information Programs," *Journal of Nutrition Education*, Vol. 20, No. 1, pp. 5–10.
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35. Crane, N. T., memorandum to file, Data Analysis No. 3—Distribution of Nutrient Across Food Categories, October 16, 1991.
36. Crane, N. T., memorandum to file, Data Analysis No. 4, Foods with Twenty Percent or More of Reference Value per Service, October 16, 1991.
37. Crane, N. T., memorandum to file, Data Analysis No. 5, 20 percent of reference value per serving, October 16, 1991.
38. Consumer and Corporate Affairs, Canada, Guide for Manufacturers and Advertisers. Hull, Quebec: Bureau of Consumer Affairs, 1988:67–69.
39. USDA, "Composition of Foods, Raw, Processed, Prepared," Agriculture Handbook No. 8–1 to 8–16, Human Nutrition Information Service, Washington, DC, 1976–1987.
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41. Crane, N. T., memorandum to file, Data Analysis of the 1988 Food Labeling and Package Survey, October 16, 1991.
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51. Holloway, J., letter to Roessler, C., May 31, 1991.
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53. Raymond E. Newberry, letter to Clinton K. Davies, PhD, September 29, 1988.
54. Staff Report and Recommendation, Proposed Trade Regulation Rule on Food Advertising, 16 CFR Part 437 Phase 1, United States of America Before Federal Trade Commission, September 25, 1978.
55. Muris, T. J., memorandum to Federal Trade Commission, Subject Food Rule, Phase I, May 17, 1982.
56. USDA, FSIS, Policy Memo 055, November 22, 1982.
57. National Heart, Lung, and Blood Institute, National Cholesterol Education Program, "Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents," DHHS, Public Health Service, National Institutes of Health, April 7, 1991.
58. Henry, C. B., memorandum to file, Fat and Calories—A Variety of Chocolate Chip Cookies, October 18, 1991.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

21 CFR Part 105

Dietary foods, Food grades and standards, Food labeling, Infants and children.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 5, 101, and 105 be amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309, secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354–360F, 361, 362, 1701–1706, 2101–2672 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1–300ff); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

2. Section 5.61 is amended by revising the section heading and by adding a new paragraph (g) to read as follows:

§ 5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, health claims, and nutrient content claims and health claims.

* * * * *

(g) The Director and Deputy Director, Center for Food Safety and Applied Nutrition are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuing of decisions to grant or deny, letters of filing, notices seeking comment, and notices of proposed rulemaking in response to petitions for nutrient content claims and health claims that do not involve controversial issues.

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

4. Section 101.13 is revised to read as follows:

§ 101.13 Nutrient content claims—general principles.

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale.

(b) A claim that expressly or implicitly characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling under § 101.9, may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium."

(2) An implied nutrient content claim is any claim that describes the food or

an ingredient therein in such a manner that leads a consumer to assume that a nutrient is absent or present in a certain amount (e.g., "high in oat bran") or that the food because of its nutrient content may be useful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy").

(3) No nutrient content claims may be made on food intended specifically for use by infants and toddlers less than 2 years of age.

(c) Information that is required or permitted by § 101.9 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A "substitute" food is one that may be used interchangeably with another food that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation."

(1) If there is a difference in performance characteristics, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(ii) of this section, informing the consumer of such difference (e.g., not for use in cooking).

(2) This disclaimer must be in easily legible print or type and in a size no less than one-half the size of the type of the descriptive term but in no case less than one-sixteenth of an inch in height.

(e)(1) Because the use of a "free" or "low" claim before the name of a food implies that the food has been altered compared to other foods of the same type to lower the amount of the nutrient in the food, only foods that have been specially processed, altered, formulated, or reformulated so as to remove the nutrient from the food may bear such a claim (e.g., low sodium potato chips).

(2) Any claim for the absence of a nutrient in a food, or that a food is low in a nutrient, when the food has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the food inherently meets the criteria and shall clearly refer to all foods of that type and not merely to the particular brand to which the labeling attaches (e.g., "corn oil, a sodium free food").

(f) A nutrient content claim shall be in type size and style no larger than that of the statement of identity.

(g) The label or labeling of a food for which a nutrient content claim is made shall contain prominently and in immediate proximity to such claim the following referral statement: "See _____ for nutrition information" with the blank filled in with the identity of the panel on which nutrition labeling is located.

(1) The referral statement "See [*appropriate panel*] for nutrition information" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than one-half the size of the type of the nutrient content claim but in no case less than one-sixteenth of an inch in height.

(2) The referral statement shall be immediately adjacent to the nutrient content claim and may have no intervening material other than, if applicable, other information in the statement of identity or any other information that is required to be presented with the claim under this section (see e.g., paragraph (j)(2) of this section or under a regulation in subpart D of this part (see, e.g., §§ 101.54 and 101.62)). If the nutrient content claim appears on more than one panel of the label, the referral statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information.

(3) If a single panel of a food label or labeling contains multiple nutrient content claims or a single claim repeated several times, a single referral statement may be made. The statement shall be adjacent to the claim that is printed in the largest type on that panel.

(h) In place of the referral statement described in paragraph (g) of this section, if a food contains more than 11.5 grams (g) of fat, 4.0 g of saturated fat, 45 milligrams (mg) of cholesterol, or 360 mg of sodium per reference amount customarily consumed, per labeled serving size, or per 100 grams, then that food must disclose, as part of the referral statement, that the nutrient exceeding the specified level is present in the food as follows: "See [*appropriate panel*] for information about [*nutrient requiring disclosure*] and other nutrients," e.g., "See side panel for information about fats and other nutrients."

(i) Except as provided in paragraph (o)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient that implies that the food is high or low in that nutrient only if the food actually meets the definition for either "high" or "low" as defined for the nutrient that the label addresses. Such a claim might be, "contains 100 mg of sodium per serving."

(j) Products may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference food. These statements shall be known as "relative claims" and include "reduced," "light" and comparative claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the food must be compared as specified below to a reference food. Such foods are:

(i) For all relative claims, an industry wide norm, i.e., a composite value weighted according to a national market share on a unit or tonnage basis of all the foods of the same type as the food for which the claim is made;

(ii) For reduced and comparative claims only, a manufacturer's regular product that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name; or

(iii) For comparative claims only, a food or class of food whose composition is reported in a current valid data base such as U.S. Department of Agriculture's Handbook 8, *Composition of Foods, Raw, Processed, Prepared.*

(2) For foods bearing relative claims:

(i) The label or labeling must bear, immediately adjacent to the claim that is in the most prominent location on the labeling or labeling and in type no less than one-half the size of the type of the claim but no less than one-sixteenth of an inch, the following accompanying information:

(A) The identity of the reference food;

(B) The percentage (or fraction) of the amount of the nutrient in the reference food by which the nutrient has been modified, (e.g., "50% less fat," "⅓ fewer calories"), and

(C) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that of the reference food.

(ii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iii) Relative claims for decreased levels of nutrients may be made on the label or in labeling of a food only if the nutrient content for that nutrient differs

from that of the reference food by more than the amount specified in the definition of "low" for that nutrient.

(k) The term "modified" may be used in the statement of identity of a food that bears a comparative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., "Modified fat cheesecake"). This statement of identity must be immediately followed by the comparative statement such as "Contains 35% less fat than _____" and all other information required in paragraph (j)(2) of this section for comparative claims.

(l) For purposes of making a claim, a "meal-type product" shall be defined as a food that:

(1) Makes a significant contribution to the diet by:

(i) Providing at least 200 calories per serving (container); or

(ii) Weighing at least 6 ounces per serving (container); and

(2) Contains ingredients from 2 or more of the following 4 food groups:

(i) Bread, cereal, rice and pasta group;

(ii) Fruits and vegetables group;

(iii) Milk, yogurt, and cheese group;

(iv) Meat, poultry, fish, dry beans, eggs, and nuts group; and

(3) Is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Such representations may be made either by statements, photographs, or vignettes.

(m) Nutrition labeling shall be provided for any food for which a nutrient content claim is made in accordance with §§ 101.9 and 101.36.

(n) Compliance with requirements for nutrient content claim in this section and in regulations in subpart D of this part, will be determined using analytical methodology prescribed for determining compliance with nutrition labeling in § 101.9 of this chapter.

(o) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to October 25, 1989, may continue to be used as part of that brand name, provided they are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act).

(2) A soft drink that used the term "diet" as part of its brand name before October 25, 1989, and whose use of that term was in compliance with § 105.66 of this chapter as that regulation appeared in the Code of Federal Regulations on that date, may continue to use that term as part of its brand name, provided that its use of the term is not false or misleading under section 403(a) of the act.

(3) A statement that describes the percentage of a vitamin or mineral in the food in relation to a reference daily intake (RDI) as defined in § 101.9 may be made on the label or in labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral unless such claim is expressly prohibited by regulation under 403(r)(2)(A)(vi) of the act.

(4) The requirements of this section do not apply to:

(i) Infant formulas subject to section 412(h) of the act; and

(ii) Medical foods defined by section 5(b) of the Orphan Drug Act.

(5) A nutrient content claim used on food that is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments shall comply with the requirements of this section and the appropriate definition in subpart D of this part, except that such claim is exempt from the requirements for disclosure statements in paragraphs (g) and (h) of this section and §§ 101.54(d), 101.62(c), (d)(1)(ii)(C), (d)(2)(ii)(C), (d)(3), (d)(4)(ii)(C), and (d)(5)(ii)(C).

(6) Nutrient content claims that were part of the common or usual names of foods that were subject to a standard of identity on November 8, 1990, are not subject to the requirements of paragraphs (b), (g), and (h) of this section or to definitions in subpart D of this part.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by the Food and Drug Administration. Petitions requesting approval of such a claim may be submitted under § 101.50(h).

(8) The terms "sugar free," "sugarless," and "no sugar" may be used on the label and in labeling of chewing gums containing no sucrose provided that when the product is not "low calorie" or "reduced calorie" under § 101.60(b), the label also bear immediately adjacent to the claim each time it is used, the statement "Not a reduced-calorie food," "Not a low calorie food," "Not for weight control," or "Useful Only in Not Promoting Tooth Decay."

5. Subpart D is added to read as follows:

Subpart D—Specific Requirements for Nutrient Content Claims

Sec.
101.54 Nutrient content claims for "source," "high," and "more."
101.56 Nutrient content claims for "light" or "lite."
101.60 Nutrient content claims for the calorie content of foods.
101.61 Nutrient content claims for the sodium content of foods.
101.69 Petitions for nutrient content claims.

Subpart D—Specific Requirements for Nutrient Content Claims

§ 101.54 Nutrient content claims for "source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a food in relation to the Reference Daily Intake (RDI) established for that nutrient in § 101.9(c)(11)(iv) or Daily Reference Value (DRV) established for that nutrient in § 101.9(c)(12)(i), (excluding total carbohydrates and unsaturated fatty aids) may only be made on the label and in labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or, where applicable, § 101.36.

(b) *"High" claims.* (1) The terms "high," "rich in," or "major source of" may be used on the label and in the labeling of a food except meal-type products as defined in § 101.13(l), provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed and per labeled serving size.

(2) These terms may be used on the label and in the labeling of a meal-type product as defined in § 101.13(l), provided that it contains per 100 grams (g) of product, an amount of the nutrient that is equal to 20 percent or more of the RDI or DRV.

(c) *"Source" claims.* (1) The terms "source," "good source of," or "important source of" may be used on the label or in the labeling of a food when the food except meal-type products as described in § 101.13(l) contains 10 to 19 percent of the (RDI) or the (DRV) per reference amount customarily consumed and per labeled serving size.

(2) These terms may be used on the label and in the labeling of a meal-type product as defined in § 101.13(l), provided that it contains per 100 g of product, an amount of the nutrient that is equal to 10 to 19 percent of the RDI or DRV.

(d) *"Fiber" claim.* If a nutrient content claim is made with respect to the level

of dietary fiber, that is, that the product is high in fiber, a source of fiber, or that the food contains "more" fiber, and the food is not low in total fat as defined in § 101.62(b)(2), then the label shall disclose the level of total fat per labeled serving. The disclosure shall appear in immediate proximity to such claim and precede the referral statement required in § 101.13(g) (e.g., "Contains [*x amount*] of total fat per serving. See [*appropriate panel*] for nutrition information.")

(e)(1) *"More."* A comparative claim using the term "more" may be used on the label and in the labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a food, including meal-type products as defined in § 101.13(l), provided that:

(i) The food contains at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or potassium (expressed as a percent of the Daily Value) than the reference food that it resembles and for which it substitutes as specified in § 101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii);

(ii) Where the claim is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in § 104.20 of this chapter; and

(iii) As required in § 101.13(j)(2) for relative claims, the identity of the reference food; the percentage (or fraction) that the nutrient was increased relative to the RDI or DRV; and quantitative information comparing the level of the nutrient in the product per labeled serving size, with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., "Contains 10% more of the daily value for fiber than white bread. Fiber content of white bread is 1 g per serving; (this product) 3.5 g per serving.")

(2) A comparative claim using the term "more" may be used to describe the level of complex carbohydrates in a food, including meal-type products as defined in § 101.13(l), provided that the food contains at least 4 percent more of the DRV for carbohydrates than the reference food, and the difference between the two foods is only complex carbohydrates as defined in § 101.9(c)(6)(i). The identity of the reference food and quantitative information comparing the level of complex carbohydrates with that of the reference food that it replaces shall be declared in immediate proximity to the most prominent such claim.

(3) A comparative claim using the term "more" may be used to describe the level of unsaturated fat in a food including meal-type products as defined in § 101.13(l) provided that the food contains at least 4 percent more of the DRV for unsaturated fat than the reference food, the level of total fat is not increased, and the level of *trans* fatty acids does not exceed 1 percent of the total fat. The identity of the reference food and quantitative information comparing the level of unsaturated fat with that of the reference food that it replaces shall be declared in immediate proximity to the most prominent such claim.

§ 101.56 Nutrient content claims for "light" or "lite."

(a) *General requirements.* A claim using the term "light" or "lite" to describe a food may only be made on the label and in labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food is labeled in accordance with § 101.9 or, where applicable, § 101.36.

(b) The terms "light" or "lite" may be used on the label and in the labeling without further qualification to describe a food, except meal-type products as defined in § 101.13(l). provided that:

(1) The food has at least a ⅓ (33⅓ percent) reduction in the number of calories compared to a reference food as specified in § 101.13(j)(1)(i) with a minimum reduction of more than 40 calories per reference amount customarily consumed and per labeled serving size;

(2) If the food derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more compared to the reference food that it resembles or for which it substitutes as specified in § 101.13(j)(1)(i) with a minimum reduction of more than 3 grams (g) per reference amount customarily consumed and per labeled serving size; and

(3) As required in § 101.13(j)(2) for relative claims, the identity of the reference food; the percent (or fraction) that the calories, and, if appropriate, the fat, were reduced; and quantitative information comparing the level of calories and, if appropriate, fat content, in the product per labeled serving size, with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim, (e.g., "⅓ fewer calories and 50% less fat than our regular cheese cake: lite cheese cake—200 calories, 4 grams fat; regular cheese cake—300 calories, 8 grams fat per serving").

(c) A product, other than a salt substitute, that is low, reduced or otherwise altered in sodium content cannot use the term "light" solely because of this alteration but rather shall use, as appropriate, the term "reduced sodium" or "low sodium."

(d) The term "light" or "lite" may be used to describe a salt substitute if the sodium content of the product has been reduced by at least 50 percent compared to ordinary table salt.

(e) The term "light" or "lite" may not be used to refer to a food that is not reduced in calories by ⅓ and, if applicable, in fat by 50 percent, unless:

(1) It describes some physical or organoleptic attribute of the food such as texture or color and the qualifying information (e.g., "light in color" or "light in texture") so stated clearly conveys the nature of the product; and

(2) The qualifying information is in the same type size, style, color, and prominence as the word "light" and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word "light" has been associated, through common use, with a particular food (e.g., light brown sugar, light corn syrup, or light molasses) to the point where it has become part of the statement of identity, such use of the term "light" shall not be considered a nutrient content claim subject to the requirements in this part.

§ 101.60 Nutrient content claims for the calorie content of foods.

(a) *General requirements.* A claim about the calorie content of a food may only be made on the label and in the labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or, where applicable, § 101.36.

(b) *"Calorie content claims."* (1) The terms "calorie free," "free of calories," "no calories," "zero calories," "trivial source of calories," "negligible source of calories," or "dietarily insignificant source of calories" may be used on the label and in the labeling of a food provided that:

(i) The food contains less than 5 calories per reference amount customarily consumed and per labeled serving size; and

(ii) As required in § 101.13(e)(2), if the food meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to disclose that calories are not usually

present in the food (e.g., "soda water, a calorie free food").

(2) The terms "low calorie," "few calories," "contains a small amount of calories," or "low source of calories" "low in calories" may be used on the label and in labeling of foods except meal-type products as defined in § 101.13(1) provided that:

(i) The food does not provide more than 40 calories per reference amount customarily consumed, per labeled serving size, and, except for sugar substitute, per 100 grams (g); and

(ii) If a food meets these conditions without the benefit of special processing, alteration, formulation or reformulation to vary the caloric content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "celery, a low calorie food").

(3) The terms listed in paragraph (b)(2) of this section may be used on the label or in labeling of meal-type products as defined in § 101.13(1) provided that:

(i) The product contains 105 calories or less per 100 g; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the calorie content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which it attaches.

(4) The terms "reduced calorie," "reduced in calories" or "calorie reduced" may be used to describe a food, except mealtype products as defined in § 101.13(1), provided that:

(i) The food has been specifically processed, altered, formulated, or reformulated, to reduce its calorie content by 33⅓ percent or more with a minimum reduction of more than 40 calories per reference amount customarily consumed and per labeled serving size from the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i) and (j)(1)(ii); and

(ii) As required in § 101.13(j)(2) for relative claims, the identity of the reference food, the percent (or fraction) that the calories have been reduced, and quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., Reduced calorie cupcakes "33⅓% fewer calories than regular cupcakes. Calorie content has been reduced from 150 to 100 calories per serving").

(5) A comparative claim using the term "fewer" may be used on the label or in labeling of a food, including meal type products as defined in § 101.13(1), provided that:

(i) The food contains at least 25 percent fewer calories, with a minimum reduction of more than 40 calories per reference amount customarily consumed and per labeled serving size, than the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii); and

(ii) As required in § 101.13(j)(2) for relative claims, the identity of the reference food, the percent (or fraction) that the calories have been reduced, and quantitative information comparing the level of the calories in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., "This cheese cake contains 25 percent fewer calories than our regular cheese cake. Calorie content has been lowered from 200 to 150 calories per serving").

(c) *Sugars content claims*—(1) *Use of terms such as "sugars free," "no sugars," or "zero sugars."* Consumers may reasonably be expected to regard terms that represent that the food contains no sugars or sweeteners e.g., "sugar free," or "no sugars," as indicating that a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a food may not be labeled with such terms unless:

(i) The food contains less than 0.5 g of sugars, as defined in § 101.9(c)(6)(ii)(A), per reference amount customarily consumed and per labeled serving size;

(ii) The food contains no added ingredients that are sugars; and

(iii)(A) it is labeled "low calorie" or "reduced calorie" or bears a comparative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), or (b)(4) of this section; or

(B) Such term is immediately accompanied, each time it is used, by either the statement "not a reduced calorie food," "not a low calorie food," or "not for weight control."

(2) The terms "no added sugars," "without added sugars," or "no sugars added" may be used only if:

(i) No amount of sugars as defined in § 101.9(c)(6)(ii)(A) is added during processing or packaging;

(ii) The product does not contain ingredients containing added sugars such as jam, jelly, and concentrated fruit juice;

(iii) The sugars content has not been increased above the amount naturally present in the ingredients by some means such as the use of enzymes;

(iv) The food that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement indicating that the food is not low calorie or calorie reduced (unless the food meets the requirements for a low or reduced calorie food) and directing consumers' attention to the nutrition panel for further information on sugars and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a food is unsweetened or contains no added sweeteners in the case of a food that contains apparent substantial inherent sugar content, e.g., juices.

(4) A comparative claim using the term "less" may be used on the label or in labeling of a food, including meal type products as defined in § 101.13(l), provided that:

(i) The food contains at least 25 percent less sugars per reference amount customarily consumed and per labeled serving size than the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii); and

(ii) As required in § 101.13(j)(2) for relative claims, the identity of the reference food, the percent (or fraction) that the sugars have been reduced, and quantitative information comparing the level of the sugars in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim (e.g., "These corn flakes contains 25 percent less sugars than our sugar coated corn flakes. Sugars content has been lowered from 8 g to 6 g per serving").

§ 101.61 Nutrient content claims for the sodium content of foods.

(a) *General requirements.* A claim about the level of sodium in a food may only be made on the label and in the labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or, where applicable, § 101.36.

(b) *"Sodium content claims."* (1) The terms "sodium free," "free of sodium," "no sodium," "zero sodium," "trivial source of sodium," "negligible source of sodium," or "dietary insignificant source of sodium" may be used on the label and in labeling of a food provided that:

(i) The food contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving size; and

(ii) The food does not contain any added sodium (sodium chloride) or other ingredient that contains sodium; and

(iii) As required in § 101.13(e)(2) if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to disclose that sodium is not usually present in the food (e.g., "leaf lettuce, a sodium free food").

(2) The terms "very low sodium," or "very low in sodium," may be used on the label and in labeling of foods, except mealtype products as defined in § 101.13(l) provided that:

(i) The food contains 35 mg or less sodium per reference amount customarily consumed per labeled serving size, and per 100 grams (g) of food; and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "potatoes, a very low sodium food.").

(3) The term "very low sodium," or "very low in sodium," may be used on the label and in labeling of meal-type products as defined in § 101.13(l) provided that:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms "low sodium," or "low in sodium," "little sodium," "contains a small amount of sodium," or "low source of sodium" may be used on the label and in the labeling of foods, except meal-type products as defined in § 101.13(l), provided that:

(i) The food contains 140 mg or less sodium per reference amount customarily consumed, per labeled serving size, and per 100 g; and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "fresh spinach, a low sodium food").

(5) The terms listed in paragraph (b)(4) of this section may be used on the label and in labeling of meal-type products as defined in § 101.13(l) provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(6) The term "reduced sodium," "reduced in sodium," or "sodium reduced" may be used on the label and in labeling, except meal-type products as defined in § 101.13(l) provided that:

(i) The food has been specifically processed, altered, formulated, or reformulated to reduce its sodium content by 50 percent or more with a minimum reduction of more than 140 mg per reference amount customarily consumed and per labeled serving size from the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i) and (j)(1)(ii); and

(ii) As required for § 101.13(j)(2) for relative claims, the identity of the reference food; the percent (or fraction) that the sodium has been reduced; and quantitative information comparing the level of the sodium in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim. (e.g., "reduced sodium—50 percent less sodium than regular peanuts. Sodium content has been reduced from 300 to 150 mg of sodium per serving").

(7) A comparative claim using the term "less" may be used on the label and in labeling of a food, including meal-type products as defined in § 101.13(l), provided that:

(i) The food contains at least 25 percent less sodium with a minimum reduction of more than 140 mg per reference amount customarily consumed and per labeled serving size than the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii).

(ii) As required in § 101.13(j)(2) for relative claims, the identity of the reference food; the percent (or fraction) that the sodium has been decreased; and clear and concise quantitative information comparing the level of the sodium in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim. (e.g., "This tomato soup contains 25% less sodium than our regular tomato soup. Sodium content has been lowered from 500 to 375 mg per serving.")

(c) The term "salt" is not synonymous with "sodium." Salt refers to sodium chloride. However, references to salt content such as "unsalted," "no salt, "no salt added" are potentially misleading.

(1) The term "salt free" may be used on the label or in labeling of foods only if the food is "sodium free" as defined in paragraph (b)(1) of this section.

(2) The terms "unsalted," "without added salt," and "no salt added" may be used on the label or in labeling of foods only if:

(i) No salt is added during processing;

(ii) The food that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the food is not sodium free, such claims are immediately accompanied each time they are used by the statement, "Not a sodium free food" or "Not for control of sodium in the diet."

§ 101.69 Petitions for nutrient content claims.

(a) This section pertains to petitions for claims, expressed or implied, that:

(1) Characterize the level of any nutrient which is of the type required to be in the label or labeling of food by section 403(q)(1) or (q)(2) of the Federal Food, Drug, and Cosmetic Act (the act); and

(2) That are not excepted under section 403(r)(5)(A) through (C) of the act from the requirements for such claims in section 403(r)(2).

(b) Petitions included in this section are:

(1) Petitions for a new (heretofore unauthorized) nutrient content claim;

(2) Petitions for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient; and

(3) Petitions for the use of an implied claim in a brand name.

(c) Petitions to be filed under the provisions of section 403(r)(4) of the act shall be submitted in quadruplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which published notices as required by section 403 of the act may be sent.

(d) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other

than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies are included in a petition submitted under section 403(r)(4) of the act, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations are included in a petition submitted under section 403(r)(4) of the act, the petition shall include a statement regarding each such clinical investigation relied upon in the petition that the study either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.104 or § 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(g) The availability for public disclosure of petitions submitted to the agency under this section will be governed by the rules specified in § 10.20(j) of this chapter.

(h) All petitions submitted under this section shall include either a claim for a categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31.

(i) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application from the petitioner, the present petition may incorporate it by specific reference to the earlier petition.

(j) The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(k) The petition shall include a statement signed by the person responsible for the petition, that to the best of his knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him pertinent to the evaluation of the petition.

(l) All applicable provisions of Part 10—Administrative Practices and Procedures, may be used by the Commissioner of Food and Drugs, the petitioner or any outside party with respect to any agency action on the petition.

(m)(1) Petitions for a new nutrient content claim shall include the following data and be submitted in the following form.

(Date)
Name of petitioner _____
Post office address _____
Subject of the petition _____
Regulations and Industry Activities Branch (HFF-312),
Food and Drug Administration,
Department of Health and Human Services,
Washington, DC 20204.
Dear Sirs:

The undersigned, _____ submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the descriptive term and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement should address why the use of the term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of foods on which the claim will be used. The statement shall specify the level at which the nutrient must be present or what other conditions concerning the food must be met for the use of the term in labels or labeling to be appropriate, as well as any factors that would make the use of the term inappropriate.

B. A detailed explanation, supported by any necessary data, of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation under section 403(r)(2)(A)(i) of the act. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose. The petition shall include data and information, e.g., surveys to the extent necessary, to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

C. Analytical data that shows the amount of the nutrient that is the subject of the claim and that is present in the types of foods for which the claim is intended. The assays should be performed on representative samples using the Association of Official Analytical Chemists (AOAC) methods where available. If no AOAC method is available, the petitioner shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data should include a statistical analysis of the analytical and product variability.

D. A detailed analysis of the potential effect of the use of the proposed claim on food consumption and of any corresponding changes in nutrient intake. The latter item shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such group and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner _____
By _____
(Indicate authority)

(2) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received by the agency. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition), and the petitioner will subsequently be notified of the agency's decision to file or deny the petition; or

(ii) That the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 100 days of the date of receipt of the petition, the Commissioner of Food and Drugs will notify the petitioner by letter that the petition has either been filed or denied. If denied, the notification shall state the reasons therefor. If filed, the date of the notification letter becomes the date of filing for the purposes of section 403(r)(4)(A)(i) of the act. A petition that has been denied shall not be made available to the public. A filed petition shall be available to the public as provided under paragraph (e) of this section.

(4) Within 90 days of the date of filing the Commissioner of Food and Drugs will by letter of notification to the petitioner:

(i) Deny the petition; or

(ii) Inform the petitioner that a proposed regulation to provide for the requested use of the new term will be

published in the **Federal Register**. The Commissioner of Food and Drugs will publish the proposal to amend the regulations to provide for the requested use of the nutrient content claim in the **Federal Register** within 90 days of the date of filing. The proposal will also announce the availability of the petition for public disclosure.

(n)(1) Petitions for a synonymous term shall include the following data and be submitted in the following form.

(Date)
Name of petitioner ———
Post office address ———
Subject of the petition ———
Regulations and Industry Activities Branch (HFF-312),
Food and Drug Administration,
Department of Health and Human Services,
Washington, DC 20204.
Dear Sirs:

The undersigned, ——— submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under section 403(r)(2) of the act).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the synonymous descriptive term, the existing term defined by a regulation under section 403(r)(2)(A)(i) of the act with which the synonymous term is claimed to be consistent. The statement should address why the use of the synonymous term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of foods on which the claim will be used. The statement shall specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

B. A detailed explanation, supported by any necessary data, of why use of the proposed term is requested, including an explanation of whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This item shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing term defined by regulation. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose. This item shall include data and information, e.g., surveys, to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

C. A detailed analysis of the potential effect of the use of the proposed claim on food consumption and of any corresponding changes in nutrient intake. The latter item shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such group and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner ———
By ———
(Indicate authority)

(2) Within 15 days of receipt of the petition the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner:

(i) that the petition is undergoing agency review (in which case a docket number will be assigned to the petition) and the petitioner will subsequently be notified of the agency's decision to grant the petitioner permission to use the proposed term or to deny the petition; or

(ii) that the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 90 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and consequently denied, the Commissioner of Food and Drugs will notify the petitioner by letter of the agency's decision to grant the petitioner permission to use the proposed term, with any conditions or limitations on such use specified, or to deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition.

(4) As soon as practicable following the granting of a petition, the Commissioner of Food and Drugs will publish a notice in the **Federal Register** informing the public of his decision. If the petition is granted the Food and Drug Administration will list, the approved synonymous term in the regulations listing terms permitted for use in nutrient content claims.

(o)(1) Petitions for the use of an implied nutrient content claim in a brand name shall include the following data and be submitted in the following form:

(Date)
Name of petitioner ———
Post office address ———
Subject of the petition ———
Regulations and Industry Activities Branch (HFF-312),
Food and Drug Administration,
Department of Health and Human Services,
Washington, DC 20204.
Dear Sirs:

The undersigned, ——— submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation under section 403(r)(2)(A)(i) of the act, and the brand name of which the implied claim is intended to be a part. The statement should address why the use of the brand-name as proposed will not be misleading. It should address in particular what information is required to accompany the claim or other ways in which the claim meets the requirements of sections 403(a) and 201(n) of the act. The statement should provide examples of the types of foods on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food qualifies the food to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient should meet the requirements stated under petition format item C in paragraph (k)(1) of this section.

B. A detailed explanation, supported by any necessary data, of why use of the proposed brand name is requested. This item shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group and should include scientific data sufficient for such purpose.

C. A detailed analysis of the potential effect of the use of the proposed brand name on food consumption and of any corresponding changes in nutrient intake. The latter item shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet. If the branded product is intended for a specific group within the population, the analysis should specifically address the dietary practices of such group, and should include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner ———
By ———

(2) Within 15 days of receipt of the petition the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition); or

(ii) That the petition is incomplete, e.g., one that lacks any of the data required by this part, one that states such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) The Commissioner of Food and Drugs will publish a notice of the petition in the Federal Register announcing its availability to the public and seeking comment on the petition. The petition shall be available to the public to the extent provided under paragraph (e) of this section. The notice shall allow 30 days for comments.

(4) Within 100 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and subsequently returned to the petitioner), the Commissioner of Food and Drugs will:

(i) Notify the petitioner by letter of the agency's decision to grant the petitioner permission to use the proposed brand name if such use is not misleading, with any conditions or limitations on such use specified; or

(ii) Deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition. Should the Commissioner of Food and Drugs not notify the petitioner of his decision on the petition within 100 days, the petition shall be considered to be granted.

(5) As soon as practicable following the granting of a petition, the Commissioner of Food and Drugs will publish a notice in the Federal Register informing the public of such fact.

6. Subpart F is redesignated as Subpart G and new Subpart F is added to read as follows:

SUBPART F—SPECIFIC REQUIREMENTS FOR CLAIMS THAT ARE NEITHER NUTRIENT CONTENT CLAIMS OR HEALTH CLAIMS

§ 101.95 "Fresh", "freshly," "fresh frozen", "frozen fresh."

The terms defined in this section may be used on the label or in labeling of a food only in conformity with the provisions of this section. The requirements of the section pertain to any use of the subject terms that expressly or implicitly refers to the food on labels or labeling, including use in a brand name and use as a sensory modifier.

(a) The term "fresh," which may be used only on the label of a raw food, means that the food has not been frozen or subjected to any form of thermal processing or any other form of preservation, except as provided in paragraph (d) of this section.

(b) The term "freshly_____" (the blank being filled with an appropriate verb, e.g., "prepared," "baked," "roasted"), which may be used on the label of a prepared or produced food, means that the food is recently made or prepared and has not been frozen, or subjected to any form of thermal processing, or any other form of preservation (except as provided in paragraph (d) of this section) during or subsequent to its manufacture or preparation, except a process inherent to the production of the basic food.

(c) The terms "fresh frozen" and "frozen fresh," when used on the label or in labeling of a food, mean that the food was quickly frozen while still fresh (i.e., the food had been recently harvested when frozen). "Quickly frozen" means frozen by a freezing system such as blast-freezing (sub-zero Fahrenheit temperature with fast moving air directed at the food) that ensures the food is frozen, even to the center of the food, quickly and that virtually no deterioration has taken place.

(b) Provisions and restrictions. (1) The addition of approved waxes or coatings, the post-harvest use of approved pesticides, or the application of a mild chlorine wash or mild acid wash on raw produce, does not preclude the food from use of the term "fresh."

(2) A food meeting the definition in paragraph (a) or (b) of this section that is refrigerated, is not precluded from use of "fresh" and "freshly prepared," as provided by this section.

(3) A food shall not be considered to be recently prepared or made if it is available for sale more than 24 hours after its preparation or production.

PART 105—FOODS FOR SPECIAL DIETARY USE

7. The authority citation for 21 CFR part 105 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 411, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 350, 371, 376).

8. Section 105.66 is revised to read as follows:

§ 105.66 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any food that purports to be or is represented for special dietary use because of usefulness in reducing or maintaining body weight shall bear:

(1) Nutrition labeling in conformity with § 101.9, or, where applicable, § 101.36 of this chapter, unless exempt under that section; and

(2) A conspicuous statement of the basis upon which the food claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any food subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary food may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the food under the applicable law and regulations of this chapter. Any food that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener, e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A food purporting to be "low calorie" must comply with the criteria set forth for such foods in § 101.60(b)(2) and (b)(3) of this chapter.

(d) *"Reduced calorie" foods and other comparative claims.* A food purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 101.60(b)(4) and (b)(5) of this chapter.

(e) *Label terms suggesting usefulness as low calorie or reduced calorie foods.* (1) Except as provided in paragraph (e)(2) of this section, and in § 101.13(o)(2) of this chapter for soft drinks, a food, including a formulated meal replacement, or other food that is represented to be of special dietary use as a whole meal, may be labeled with the terms "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false or misleading, and the food is labeled "low calorie" or "reduced calorie" or bears a comparative claim of special dietary usefulness in compliance with part 101 of this chapter and this section.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms

that is specifically authorized by regulation governing a particular food, or unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the food is offered solely for dietary use other than regulating body weight, e.g., "for low-sodium diets."

(f) *"Sugars free", and "no added sugars"*. Criteria for the use of the terms "sugars free" and "no added sugars" are provided for in § 101.60(c) of this chapter.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27150 Filed 11-26-91; 8:45 am]

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21 CFR Part 101

[Docket No. 84N-0153]

RIN 0905-AB68

Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the food labeling regulations to define, and to provide for the proper use of, the terms "fat free," "low fat," "reduced fat," "low in saturated fat," "reduced saturated fat," "cholesterol free," "low cholesterol," and "reduced cholesterol" in the labeling of foods and to provide for the use of other truthful and nonmisleading statements about a food's fat, fatty acid, and cholesterol content in food labeling. This proposed rule is intended to permit meaningful declarations about fat, fatty acid, and cholesterol content, while preventing misleading claims about these food components. In this document, FDA is responding to comments received in response to the tentative final rule on cholesterol claims (55 FR 29456, July 19, 1990) and to the provisions of the Nutrition Labeling and Education Act of 1990 regarding fat, fatty acid, and cholesterol content claims. In addition, this document sets forth related agency policies.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may be issued based upon this proposal become effective 6 months following its publication in accordance with the provisions of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Virginia L. Wilkening, Center for Food Safety and Applied Nutrition (HFF-204), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1561.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Regulatory History of Fat, Fatty Acid, and Cholesterol Labeling

The agency has had a long interest in the proper labeling of foods with information on fat, fatty acid, and cholesterol content. FDA's policies have reflected contemporary knowledge on the relationship between these dietary components and chronic disease conditions.

1. The 1959 Policy Statement

In the **Federal Register** of December 10, 1959 (24 FR 9990), the agency published a statement of policy concerning the status of food offered to the general public for the control or reduction of blood cholesterol levels and for the prevention and treatment of heart and artery disease. The policy statement acknowledged the public interest in the effect of various fatty foods on blood cholesterol and the relationship between blood cholesterol levels and diseases of the heart and arteries. However, the statement noted that the role of dietary cholesterol in heart and artery diseases had not been established. Therefore, FDA took the position that any labeling claim for fats and oils that indicated or implied that a food would prevent, mitigate, or cure diseases of the heart or arteries would be considered false or misleading and would misbrand the food under the Federal Food, Drug, and Cosmetic Act of 1938 (the act). FDA pointed out that the policy statement was not intended to interfere with clinical research on the possible role of dietary unsaturated fats in lowering blood cholesterol. The policy statement was, the agency stated, intended to prevent the promotion of foods for use by the public without medical supervision.

2. Quantitative Labeling of Fatty Acid and Cholesterol Content

In the **Federal Register** of May 25, 1965 (30 FR 6984), the agency proposed to establish requirements for label statements relating to oils, fats, and fatty foods used as a means of reducing the dietary intake of fatty acids. FDA received a number of comments on this proposal. After considering the comments and other available information, FDA terminated the rulemaking (31 FR 3301, March 2, 1966) because comments convinced the agency that the role of fats in the diet had not been sufficiently studied to make a definitive decision.

In the 5 years that followed, the terms "saturated," "monounsaturated," and "polyunsaturated," as applied to food fats or fatty acids, received considerable publicity, which led to consumer demand for more information about fat-containing foods. In 1970, the White House Conference on Food, Nutrition, and Health recommended that regulatory agencies permit and encourage the food industry, on a voluntary basis, to label the fat and fatty acid content of foods that constitute the major sources of fats in typical diets (Ref. 1).

Accordingly, in response to the consumer requests and to a report of the American Medical Association's Council on Foods and Nutrition, which contained a number of recommendations regarding the labeling of fat and fatty acids, FDA proposed in the **Federal Register** of June 15, 1971 (36 FR 11521) to adopt a regulation (21 CFR 125.12) on the requirements for label statements intended to provide guidance for regulating intake of fatty acids. This proposal would have established labeling requirements for foods represented for special dietary use containing 10 percent or more fat on a dry weight basis and no less than 3 grams (g) of fat in an average serving.

In the same issue of the **Federal Register** (36 FR 11521), FDA also proposed to amend the agency's policy statement on labeling foods for the prevention and treatment of heart and artery disease to make it clear that claims such as "lower cholesterol" were deemed to be false or misleading. However, the agency also proposed to provide that labeling statements would be acceptable if they set out only the fat content of the food, the source of the fat, and the content of saturated, monounsaturated, and polyunsaturated fatty acids in accordance with proposed § 125.12.

After considering the comments on these proposals and other available information, FDA concluded that information associated with the cholesterol and fatty acid content of foods should be combined into a single regulation. Accordingly, in the **Federal Register** of January 19, 1973 (38 FR 2132)

(amended March 14, 1973, 38 FR 6961) FDA removed the 1959 policy statement and established a new § 1.18 *Labeling of foods in relation to the fat and fatty acid and cholesterol content* (21 CFR 1.18; recodified as 21 CFR 101.25 in the **Federal Register** of March 15, 1977 (42 FR 14302)), which established requirements for labeling the cholesterol and fatty acid composition of food products. (Requirements for labeling the fat content of food were included in the rulemaking for general nutrition labeling (38 FR 2132) (amended March 14, 1973, 38 FR 6951).)

Section 101.25 provides for the voluntary listing of the cholesterol and fatty acid content of the food as part of the food's nutrition labeling (21 CFR 101.9). This regulation provides that cholesterol be declared (to the nearest 5-milligram (mg) increment) in mg per serving and in mg per 100 g of food, and that fatty acid content be declared (to the nearest g) in g per serving in two categories: "Polyunsaturated fatty acids" and "saturated fatty acids." It limits fatty acid declarations to foods containing not less than 2 g of fat per serving and 10 percent or more fat on a dry weight basis. FDA said that any food that contains less than these levels was deemed "not suitable for use by man as a means of regulating the intake of fatty acids" (§ 101.25(c)(1)). In other words, FDA believed that foods that contained less than these levels were so low in fat as to not be a significant source of fatty acids, and, thus, that lowering the levels at which these foods were eaten would not affect blood cholesterol levels. Therefore, FDA decided that such foods should not be permitted to bear claims about the relative amounts of polyunsaturated fatty acids in such small amounts of fat. Since FDA promulgated this provision (currently codified as § 101.25(c)(1)), the agency has advised those who have requested guidance on the use of the term "low fat" that "a definition for the term 'low fat' can be inferred from § 101.25(c)(1)" (Ref. 2). The definition that FDA is proposing in this document for "low fat" differs from these criteria.

3. Food Standards

In addition to issuing 21 CFR 101.25, the agency, in response to recommendations in the 1970 report of the White House Conference on Food, Nutrition, and Health (Ref. 1), issued a limited number of food standard regulations that describe nonfat and lowfat food products. Food standards specifically prescribe the composition and name of particular products to protect the public from economic fraud. Presently, the agency has food standards of identity for various types of nonfat and lowfat milk products (21 CFR part 131), lowfat cottage cheese (21 CFR part 133), nonfat and lowfat yogurt (21 CFR part 131), macaroni products containing nonfat milk (21 CFR part 139), and low-fat cocoa (21 CFR 163.114).

4. The 1978 Food Labeling Initiative

In the **Federal Register** of June 9, 1978 (43 FR 25296), FDA, the U.S. Department of Agriculture (USDA), and the staff of the Federal Trade Commission's Bureau of Consumer Protection published a notice requesting the public's views on numerous food labeling issues and announcing public hearings across the nation to elicit comments on improving food labeling.

The results of the joint hearings were published in a notice in the **Federal Register** of December 21, 1979 (44 FR 75990). In that notice, FDA announced its plans to undertake a major food labeling initiative, including its plans to propose regulations to define cholesterol claims in food labeling and to consider proposing regulations to define fatty acid claims in food labeling.

5. The 1986 Proposed Cholesterol Nutrient Content Claims

In the **Federal Register** of November 25 1986 (51 FR 42584), FDA published a proposal to define terms that describe the cholesterol content of foods and to provide for their proper use in food labeling. FDA proposed to amend § 101.25 to define the terms "cholesterol free," "low cholesterol," and "reduced cholesterol" and to provide for truthful comparative statements that describe significant reductions in cholesterol content. Specifically, FDA proposed that "cholesterol free" be defined as less than 2 mg of cholesterol per serving, "low cholesterol" as less than 20 mg of cholesterol per serving, and "reduced cholesterol" as a 75 percent reduction. FDA proposed to require that whenever these terms or statements about cholesterol content appear on labels, the amount of cholesterol be declared in the nutrition label. FDA also proposed to amend § 101.9, the nutrition labeling regulation, to require that when cholesterol content is declared on the nutrition label, fatty acid content also be declared, and that when fatty acid content is declared, cholesterol content also be declared. FDA received over 1,000 comments in response to this proposal.

B. Current Food Labeling Initiative

1. The 1989 ANPRM

In the **Federal Register** of August 8, 1989 (54 FR 32610), FDA published an advance notice of proposed rulemaking (ANPRM) that announced a major initiative of the Department of Health and Human Services (DHHS) to take a new look at food labeling as a tool for promoting sound nutrition for the nation's consumers. FDA asked for public comment on five areas of food labeling, including the use of nutrient content claims such as "cholesterol free" to characterize foods.

In response to the ANPRM, FDA received over 2,000 written comments, plus over 5,000 copies of a questionnaire that had been distributed by a consumer organization. Over 500 of the written comments addressed issues related to specific nutrient content claims. These comments made clear that both consumers and food manufacturers are strongly in favor of improving food labels and, in particular, that FDA should define additional food nutrient content claims. In addition, approximately 3,500 of the over 5,000 questionnaires supported the need for additional descriptor definitions. Many comments stated that the proliferation of undefined terms has resulted in confusion for consumers and unfair competition for manufacturers. One comment stated that terms are "meaningless the way they are used now and are primarily used as marketing tools rather than guides for the health conscious consumer." Many comments suggested that commonly used nutrient content claims should either be defined by FDA or not permitted.

As part of this DHHS initiative, FDA announced in the **Federal Register** of September 20, 1989 (54 FR 38806) a series of four public hearings to discuss nutrition labeling and other issues related to food labeling, including the use of nutrient content claims. Representing a cross-section of interested parties, some 200 people including consumers, health professionals, trade associations, other industry representatives, and State and local health officials, testified at these hearings. In addition, 1,500 more persons participated in 50 local "consumer exchange" meetings conducted by FDA. Comments received as a result of the ANPRM and testimony from people at the hearings approved of FDA's past efforts to define terms relating to the content of calories, sodium, and cholesterol. The comments supported FDA's basic approach of defining terms such as "no ____," "low ____," and "reduced ____." They urged FDA to proceed immediately to define the other terms that are commonly used, giving priority to terms with the greatest

impact on public health. There was general agreement that top priority should be given to the terms that describe the fat content of foods.

On March 7, 1990, Secretary of Health and Human Services, Louis W. Sullivan, announced that FDA would undertake a comprehensive, phased response to the comments on the ANPRM. Subsequently, FDA prepared and published, in the **Federal Register** of July 19, 1990, three proposed rules that would: (1) Make nutrition labeling mandatory on foods that are a meaningful source of nutrients and revise the content of the nutrition label (55 FR 29487); (2) establish standard serving sizes (55 FR 29517); and (3) establish reference values for declaring nutrient and other food component content in nutrition labeling (55 FR 29476). In the same issue of the **Federal Register**, FDA published a tentative final rule defining terms that may be used in food labeling to describe the cholesterol content of foods.

2. Tentative Final Rule on Cholesterol Nutrient Content Claims

In the tentative final rule that published in the **Federal Register** on July 19, 1990 (55 FR 29456), FDA addressed the comments received in response to the proposed rule on cholesterol nutrient content claims (51 FR 42584, November 25, 1986) as well as the comments received in response to the 1989 ANPRM and the public hearings. Many of the comments requested that FDA limit the amount of fat and of saturated fatty acids in foods claiming to be "cholesterol free" or "low in cholesterol." FDA agreed with these comments and in the tentative final rule (55 FR 29456) proposed to limit the content of fat and saturated fatty acids in foods bearing these claims. FDA proposed to limit the use of the terms "cholesterol free" and "low cholesterol" to foods that contain not more than 5 g of fat and not more than 2 g of saturated fatty acids per serving, as well as the requisite cholesterol levels. On a dry weight basis, these foods could contain not more than 20 percent fat and not more than 6 percent saturated fatty acids.

The requisite cholesterol levels remained the same as proposed in the 1986 proposal, except that FDA proposed: (1) To define "low cholesterol" as "20 mg or less of cholesterol per serving" rather than as "less than 20 mg per serving," and (2) to add a second criterion based on density to the definition of "low cholesterol," namely that the food contain 0.2 mg or less cholesterol per g of food. The first change was made to be consistent with FDA's other definitions for "low," for calories (§ 105.66(c)(1)(i)) and for sodium (§ 101.13(a)(3)), that include the integer in the definition.

FDA made the second change to prevent "low cholesterol" label claims from conveying a misleading impression about the cholesterol content of certain foods. Comments pointed out that a single criterion based on serving size could result in widely recognized "high cholesterol" foods with small serving sizes (e.g., butter, lard, and some processed cheese foods) being labeled as "low cholesterol". These comments stressed that despite their small serving sizes, such foods actually may be consumed frequently and in large amounts, resulting in a substantial total daily intake of cholesterol. In addition, the comments were concerned that a "low cholesterol" claim on such foods could encourage increased consumption of the food, significantly adding to an individual's total cholesterol intake.

Additionally, in the tentative final rule FDA proposed to limit comparative statements about cholesterol content to products with at least a 25 percent reduction in cholesterol content. This requirement was added to prevent deceptive comparative claims and to help ensure that consumers are not misled into believing that an inconsequential reduction in cholesterol content will provide significant health benefits.

FDA advised that it considered the tentative final rule to contain the agency's final determination on all substantive issues other than on the threshold levels of fat and saturated fatty acids, and that a comment would have to be very significant to make any changes in the rule other than to the threshold levels.

3. Nutrition Labeling

On July 19, 1990, FDA also published a proposed rule (55 FR 29487) (the mandatory nutrition labeling proposal) to require nutrition labeling on most foods that are meaningful sources of nutrients and to revise the list of nutrients required to be declared. The agency proposed to require that nutrition labeling include fat, saturated fat (which could also be declared as "saturated"), and cholesterol content of the food, as well as the amount of calories from fat. In addition, the following items could be included voluntarily: unsaturated fat (which the proposal said could also be stated as "unsaturated" or, alternatively, as "monounsaturated" and "polyunsaturated"), calories from unsaturated fat, and calories from saturated fat.

The agency proposed that the listing of unsaturated fatty acid content would be mandatory when a claim is made about fatty acids or cholesterol, or when calories from unsaturated fatty acids are voluntarily declared. Moreover, under the proposal, the specific listing of the monounsaturated and polyunsaturated fatty acid content would become mandatory when a claim is made about a particular type of unsaturated fatty acid. Finally, the agency proposed to prohibit any claim that a food is nutritionally superior to another food in fat or saturated fatty acid content unless the level of these substances is at least 25 percent less than in the food to which the comparison is being made.

4. Reference Daily Intake (RDI) and Daily Reference Values (DRV)

In a proposed rule related to nutrition labeling (55 FR 29476, July 19, 1990) (the RDI/DRV proposal), FDA updated the U.S. Recommended Daily Allowances (U.S. RDA's) used in food labeling and proposed to replace the term "U.S. RDA" with "Reference Daily Intake". In the same proposal, the agency also introduced the term "Daily Reference Value" and proposed DRV's for seven food components, including total fat (75 g), saturated fatty acids (25 g), unsaturated fatty acids (50 g), and cholesterol (300 mg). These DRV's are based upon a diet of 2,350 calories, which is the population-adjusted mean of the recommended energy allowances for persons 4 or more years of age, as indicated in the 10th edition of the "Recommended Dietary Allowances" (Ref. 3). The DRV for cholesterol is, however, independent of calories.

5. Serving Size

FDA proposed standardized serving sizes for the major categories of foods in a third proposed rule (55 FR 29517, July 19, 1990) to assure reasonable serving sizes and to provide for comparison among similar products. FDA said that these serving sizes, if adopted, would ensure that claims, such as "low cholesterol," were the result of the characteristics of the food and not manipulation of the serving size. The agency stated that these standardized serving sizes would help to ensure that food label claims are not misleading to consumers.

6. Institute of Medicine Report

On September 26, 1990, the National Academy of Sciences (NAS's) Institute of Medicine (IOM) issued a report entitled "Nutrition Labeling: Issues and Directions for the 1990's" (the IOM report) (Ref. 4). The IOM report was

written under contract to the Public Health Service, DHHS, and the Food Safety and Inspection Service, USDA. This report makes recommendations for changes in food labeling that will assist consumers in implementing the recommendations of "The Surgeon General's Report on Nutrition and Health" (Ref. 5) (the Surgeon General's Report) and NAS's recent report, "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 6) (the NAS report). The IOM report recommends, among other things, that FDA define nutrient content claims for fat, fatty acid, and cholesterol content.

7. Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535). The 1990 amendments make the most significant changes in food labeling law since passage of the act. They strengthen DHHS's food labeling initiative by clarifying FDA's legal authority to require nutrition labeling on foods and by defining the circumstances under which claims may be made about the nutrients in foods. Section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)), which was added by the 1990 amendments, states that a food is misbranded if a claim is made in its label or labeling that characterizes the levels of any nutrient of the type required in nutrition labeling under section 403(q) of the act, including fat, fatty acids, and cholesterol, unless the claim is made in a manner that conforms to the requirements of the act. These requirements, and the agency's proposed regulations implementing these requirements, are generally discussed in a companion proposed rule entitled "Food Labeling; Nutrient Content Claims, General Principles, Petitions, Definition of Terms" published elsewhere in this issue of the **Federal Register** (hereinafter referred to as the "companion document on nutrient content claims"). However, the requirements that specifically apply to nutrient content claims (synonymously referred to as "nutrient content claims") with respect to fat, fatty acids, and cholesterol are the subject of this document.

The 1990 amendments directly affect FDA's tentative final rule on cholesterol claims of July 19, 1990. Because a number of changes in the tentative final rule are necessary to bring it into conformity with the requirements of the 1990 amendments, the agency is issuing this new proposed rule on cholesterol nutrient content claims. In doing so, the agency is including proposed definitions for fat and fatty acid nutrient content claims in this document because of the interrelationship among these components and cholesterol in the etiology of cardiovascular disease. The agency is also providing for the use of other truthful and nonmisleading comparative statements about the levels of fat, fatty acids, and cholesterol in foods.

8. Supplementary Nutrition Labeling Proposal

Elsewhere in this issue of the **Federal Register**, FDA is publishing a reproposal entitled "Food Labeling: Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter identified as the "supplementary nutrition labeling proposal") to bring its earlier mandatory nutrition labeling and RDI/DRV proposals into conformity with the 1990 amendments. In addition to the changes required by the legislation, FDA is proposing some changes to assist the implementation of the final regulations and to help clarify the earlier proposals. With respect to fat and fatty acids, the agency is proposing that they be declared in increments of ½ g rather than 1 g.

II. Scientific Background to Proposed Action

A. Overview

The Surgeon General's Report (Ref. 5) and the NAS report "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 6) considered the evidence on the effect of diet on an individual's health. One of the main conclusions from these reports is that consumption of diets high in fat, saturated fat, and cholesterol is associated with increased risks of developing certain chronic diseases. These reports recommend that Americans reduce their consumption of these substances in their diets.

Given the significance of dietary intake of fat, saturated fatty acids, and cholesterol, FDA is seeking ways to assist consumers in modifying their diets to reduce their intake of these food components. One way to do so is to ensure that the food label provides information on the fat, fatty acid, and cholesterol content of the food. To this end, FDA is issuing proposed nutrition labeling regulations that will require that most foods bear nutrition labeling that discloses the quantitative amounts per serving of total fat, saturated fat, and cholesterol as well as the number of calories derived from fat.

In this document, FDA is proposing to provide for the use of descriptor (nutrient content) claims on food labels or labeling to describe the fat, fatty acid, and cholesterol content of the food. This document does not, however, address whether it is possible to use the food label to communicate explicit health-related information, nor does it address what type of health information, if any, on dietary fat, fatty acids, and cholesterol would be appropriate for food labeling. FDA is addressing these issues in the ongoing rulemaking proceeding on "Health Messages and Label Statements" (see proposed rule, 55 FR 5176, February 13, 1990).

The following discussion describes dietary fats and the scientific background for this proposal to define fat and fatty acid nutrient content claims. Similar information on cholesterol can be found in the 1986 proposed rule (51 FR 42584).

B. Description of Dietary Fats

Fats provide the most concentrated source of energy in the diet. Each gram of fat furnishes approximately nine calories, while carbohydrates and protein furnish approximately four calories per gram. (FDA is using the term "calories" throughout this document rather than the more precise "kilocalories" or "energy" because the term "calories' is more readily understood by consumers.) The major sources of fat in the American diet are meat, poultry, and fish; dairy products; and the category of foods referred to as ("fats and oils" Ref. 5, p. 10).

Most fats occur in food as triglycerides, which, upon hydrolysis (which occurs during the digestion of fats), yield fatty acids and glycerol. A fatty acid is composed of a carboxylic acid group attached to a chain of carbon atoms. Most carbon atoms in the chain have two hydrogen atoms attached to them. However, sometimes two adjacent carbon atoms each have only one hydrogen atom attached to them instead of two and are joined together by what is called "a double bond."

The number of carbon atoms joined by double bonds determines the degree of unsaturation of a fatty acid. Fatty acids with no double bonds are saturated, those with one double bond are monounsaturated, and those with two or more double bonds are polyunsaturated. The fatty acids commonly found in foods are usually composed of an even number of carbon atoms, usually 12 to 22, and contain from 0 to 6 double bonds.

The fatty acid composition of fats and oils may be modified through a process

known as "hydrogenation," in which double bonds gain hydrogen atoms and become single bonds. Fats and oils are hydrogenated to reduce their susceptibility to rancidity and to change the fat from a liquid to a solid form. The degree of hydrogenation can vary considerably. The composition of the original fat or oil and the degree of hydrogenation affect the fatty acid composition of the final product.

Complete hydrogenation of a fat or oil results in a solid fat containing only saturated fatty acids. More commonly, a fat or oil is partially hydrogenated. Hydrogenation reduces the content of polyunsaturated fatty acids and increases the content of monounsaturated and saturated fatty acids. Partial hydrogenation of fats or oils may produce additional changes in the chemical structure of the fatty acids, such as changes in the location of double bonds along the carbon chain and in the formation of "trans" double bonds, which have a geometric configuration different from that which occurs predominately in nature.

All dietary fats consist of a mixture of saturated, monounsaturated, and polyunsaturated fatty acids. In general, animal-derived fats contain a higher proportion of saturated fatty acids than fats or oils derived from plants. The latter generally contain more monounsaturated and polyunsaturated fatty acids. There are some exceptions to this generalization. Coconut oil and palm kernel oil, for example, contain a high proportion of saturated fatty acids even though they are derived from plants, and some fish oils are good sources of polyunsaturated fatty acids (Ref. 5, p. 57). Furthermore, some hydrogenated vegetable oils that are used in processed foods as alternatives to animal fat or coconut or palm kernel oil may contain high levels of saturated fatty acids.

In regard to the effect of dietary fats on serum cholesterol levels, the amount of saturated fatty acids present in the final food product is more important health information than the source of the fat or oil (Ref. 7).

C. Diet and Chronic Diseases

Although much remains to be learned about the impact of diet on chronic disease risk, the overall evidence supports a relationship between certain dietary patterns and chronic diseases. As stated in the Surgeon General's Report:

High intake of total dietary fat is associated with increased risk for obesity, some types of cancer, and possibly gall bladder disease. Epidemiologic, clinical, and animal studies provide strong and consistent evidence for the relationship between saturated fat intake, high blood cholesterol, and increased risk for coronary heart disease * * *. Excessive saturated fat consumption is the major dietary contributor to total blood cholesterol levels. Dietary cholesterol raises blood cholesterol levels, but the effect is less pronounced than that of saturated fat * * *.

Dietary fat contributes more than twice as many calories as equal quantities (by weight) of either protein or carbohydrate, and some studies indicate that diets high in total fat are associated with higher obesity rates. In addition, there is substantial, although not yet conclusive, epidemiologic and animal evidence in support of an association between dietary fat intake and increased risk for cancer, especially breast and colon cancer. Similarly, epidemiologic studies suggest an association between gallbladder disease, excess caloric intake, high dietary fat and obesity.
(Ref. 5, p. 10).

The NAS report similarly stated the general conclusion that "total amounts and types of fats and other lipids in the diet influence the risk of atherosclerotic cardiovascular diseases and, to a less well-established extent, certain forms of cancer and possibly obesity." The report went on to state that, "Intake of total fat per se, independent of the relative content of the different types of fatty acids, is not associated with high blood cholesterol levels and coronary heart disease," but rather that, "saturated fatty acid intake is the major dietary determinant of the serum total cholesterol and LDL cholesterol levels in populations and thereby of coronary heart disease risk in populations." (Ref. 6). On the basis of the current scientific evidence, both reports recommend that individuals reduce their consumption of fat (especially saturated fat) and cholesterol.

Coronary heart disease (CHD) remains the leading cause of death in the United States today. The causes of CHD are multifactorial. Evidence from animal and human studies and from epidemiologic surveys continues to accumulate, implicating among other factors high blood cholesterol, high blood pressure, and cigarette smoking as causative agents in the development of atherosclerosis. Atherosclerosis, in turn, leads to narrowing of the arteries and development of CHD. The scientific evidence supporting these conclusions has been extensively reviewed in the Surgeon General's Report (Ref. 5) and the NAS report (Ref. 6). In regard to blood cholesterol levels, the Surgeon General's Report states:

An extensive body of clinical evidence supported by animal, epidemiologic, and metabolic studies has established the relationship between high blood cholesterol and increased CHD risk. The relationship is strong, continuous, and graded.
(Ref. 5, p. 86.)

The Surgeon General's Report also states:

Numerous expert bodies have examined the evidence relating diet to CHD and its implications for public health. Although there are many determinants of blood cholesterol levels, no modifiable factor has been shown to influence cholesterol and low-density lipoproteins more than diet.

Accordingly, many expert health organizations have made recommendations for modifying dietary intake of fat, fatty acids, and cholesterol for the purpose of improving the public health. These recommendations are summarized as follows:

1. *The Surgeon General's Report:* Reduce consumption of fat (especially saturated fat) and cholesterol. Choose foods relatively low in these substances, such as vegetables, fruits, whole grain foods, fish, poultry, lean meats, and low-fat dairy products. Use food preparation methods that add little or no fat (Ref. 5).

2. *The NAS Report:* Reduce total fat intake to 30 percent or less of calories, reduce saturated fatty acid intake to less than 10 percent of calories, and the intake of cholesterol to less than 300 mg daily (Ref. 6).

3. *U.S. Department of Health and Human Services and U.S. Department of Agriculture in "Nutrition and Your Health, Dietary Guidelines for Americans":* Choose a diet low in fat, saturated fat, and cholesterol (Ref. 8).

4. *The National Cholesterol Education Program (NCEP) Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction (Population Panel):* Healthy Americans should consume less than 10 percent of total calories from saturated fatty acids, an average of 30 percent of total calories or less from all fat, less than 300 mg of cholesterol per day, and energy (calorie) levels needed to reach or maintain a desirable body weight (Ref. 9).

5. *Report of the NCEP Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults:* For adults with borderline to high blood cholesterol, the NCEP recommended two diets to assist in lowering high blood cholesterol levels. In the step-one diet, less than 30 percent of total calories are to come from dietary fat, with less than 10 percent coming from saturated fatty acids; up to 10 percent

from polyunsaturated fatty acids, and 10 to 15 percent from monounsaturated fatty acids. In addition, cholesterol intake is to be less than 300 mg per day. The step-two diet (for persons requiring greater dietary modifications to lower serum cholesterol) differs in that saturated fatty acid intake is to be less than 7 percent of total calories and cholesterol less than 200 mg per day (Ref. 10).

6. *American Heart Association:* Calories derived from fat should be less than 30 percent of total caloric intake, calories derived from saturated fat should be less than 10 percent of calories, and the daily cholesterol intake should be less than 300 mg (Ref. 11).

7. *American Medical Association (AMA):* Persons with hypercholesterolemia (high serum cholesterol) and hypertriglyceridemia (high serum triglycerides) should consume a diet in which no more than 30 to 35 percent of calories are derived from fat, in which less than 10 percent of calories are from sources of saturated fat, and in which there is less than 300 mg of cholesterol per day (Ref. 12). While these recommendations were originally made in 1983, the AMA currently supports the NCEP recommendations.

8. *Inter-Society Commission on Heart Disease Resources:* Reduce dietary cholesterol to no more than 250 mg per day, reduce total fat intake to less than 30 percent of calories, and adjust fat intake to provide no more than 8 percent of calories from saturated fat (Ref. 13).

9. *World Health Organization Expert Committee on Prevention of Coronary Heart Disease:* In countries with a high incidence of CHD, such as the United States, blood cholesterol levels should be lowered through progressive changes in eating patterns, including consumption of under 300 mg of cholesterol per day and less than 10 percent of energy intake as saturated fat (Ref. 14).

III. Provisions of the Proposed Regulation—Use of Defined Terms and Comparative Statements

A. Introduction

1. Legal Basis

FDA is proposing to define terms that describe the fat, fatty acid, and cholesterol content of food, to provide for the proper use of these terms, and to provide for the use of comparative claims regarding the level of these substances in food labeling. FDA has authority to take these actions under sections 201(n), 403(a), 403(r), and 701(a) of the act (21 U.S.C. 321(n), 343(a), 343(r), and 371(a)). Those sections authorize the agency to adopt regulations that prohibit labeling that is false or misleading in that it fails to reveal material facts with respect to consequences that may result from use of the food and that uses terms to characterize the level of any nutrient in a food that have not been defined by regulation by FDA.

Because the consensus reports cited above suggest that consumers limit their dietary intake of fat, fatty acids, and cholesterol, and because comments to the 1989 ANPRM and testimony at FDA's public hearings on labeling show that consumers are concerned about, and wish to reduce their dietary intake of these substances, it is important that label statements not convey a misleading impression about the fat, fatty acid, or cholesterol content of a food. Without clear definitions of the terms that describe the levels of these nutrients in food, manufacturers could use a term like "low fat" on products that vary widely in fat content. Inconsistent use of the same term on various products could only lead to consumer confusion and nonuniformity in the marketplace. To ensure that consumers are not misled and are given reliable information, Congress found, and FDA agrees, that it is appropriate for the agency to establish specific definitions to standardize the terms used by manufacturers to describe the fat, saturated fatty acid, and cholesterol content of foods. FDA is proposing to do so in this document.

2. Organization of Regulations

As discussed in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**, FDA is proposing to reorganize part 101 of its regulations to add Subpart D—Specific Requirements for Nutrient Content Claims. In doing so, FDA is proposing to redesignate current § 101.25 *Labeling of foods in relation to fat and fatty acid and cholesterol content* as § 101.62 *Nutrient content claims for fat, fatty acid, and cholesterol content of foods.* This change will allow this section on fat, fatty acid, and cholesterol content claims to be grouped with the other descriptor definitions in new subpart D.

The companion document on nutrient content claims also proposes to add a new section, § 101.13 *Nutrient content claims—general principles*, which sets forth general rules for all nutrient content claims. FDA is proposing in § 101.62(a)(2) to require that fat, fatty acid, and cholesterol content claims comply with the provisions of § 101.13 as well as § 101.62.

Among the most significant of the proposed general provisions are §§ 101.13(g) and (h), which set forth the requirements for the statement that, under the act, must accompany any nutrient content claim. Pursuant to section 403(r)(2)(B) of the act, the labels or labeling of foods that bear nutrient content claims must contain the following statement that refers the consumer to the nutrition label: "See _____ for nutrition information." Under section 403(r)(2)(B)(i) of the act, the blank must identify the panel of the package on which the nutrition label is located. Proposed § 101.13(g) reflects this requirement.

Proposed § 101.13(h) provides, in accordance with section 403(r)(2)(B)(ii) of the act, that the statement must also identify any nutrient that is present in the food at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet-related. The section also proposes to define specific levels of fat, saturated fat, cholesterol, and sodium that present such a risk.

Thus, some foods that meet the definition for "low fat," for example, contain cholesterol at levels that require identification of this nutrient (proposed in § 101.13(h) as levels of more than 45 mg of cholesterol per serving or per 100 g of food). Many species of fish and shellfish are examples of such foods. To refer consumers to the cholesterol content of these foods, the agency is proposing in § 101.13(h) that the label of such foods bear, in immediate proximity to the "low fat" claim, the following statement: "See _____ for information on cholesterol and other nutrients," with the blank filled in with the identity of the panel of the label where the nutrition information is located.

For other general provisions, the reader is referred to the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**. Consistent with the discussion in that document, to ensure that foods that bear fat, saturated fat, and cholesterol claims bear nutrition labeling, FDA is proposing to require such labeling as a general requirement in proposed § 101.62(a)(3).

3. Serving Size to Evaluate Nutrient Content Claims

FDA proposed in § 101.12(f) of the 1990 serving size proposal (55 FR 29517) that for any container with more than one serving the proposed standard serving size would be used to determine the appropriateness of a nutrient content claim, such as "cholesterol free." For single-serving containers containing 100 percent or less of the standard serving, the agency proposed to evaluate the

label claim based on the standard serving size. However, for single-serving containers containing more than 100 percent, but 150 percent or less of the standard serving, the agency proposed to evaluate the claim on the basis of the entire content of the package.

A majority of comments on FDA's proposal supported the proposed basis for evaluation of nutrient content claims. However, many food industry and trade organization comments objected to the proposed evaluation criteria. Such comments generally stated that the standard serving size, not the package content, should be used to evaluate descriptor claims on all types and sizes of packages. Manufacturers pointed out that under the 1990 proposal on serving size, the same food product that could be labeled as "low sodium" on the basis of the standard serving size might not qualify for a "low sodium" claim when packaged in a single-serving container containing between 100 percent and 150 percent of the standard serving. For example, an 8 fluid ounce container of skim milk containing 126 mg of sodium would meet the criteria for a "low sodium " claim, but a 10 fluid ounce container of the same milk containing 158 mg of sodium would not.

Because of the complexity of the issues with respect to serving size and the need to obtain further public comment on the impact of the 1990 amendments and the IOM report (Ref. 4) on this subject, FDA announced a public meeting to discuss issues related to serving size determination (56 FR 8084, February 26, 1991). In the notice of the public meeting, FDA raised the question of whether the discrepancies in the use of nutrient content claims on food products would be confusing and asked for data to support any views presented. The public meeting was held on April 4, 1991, and provided opportunity for both oral and written comments.

In comments, a manufacturer suggested that FDA establish reference serving sizes, and that both the reference serving size and the serving size declared on the label be required to be used to evaluate the compliance with FDA criteria for the nutrient content claims. The agency believes that this suggestion is a reasonable approach to regulating the use of nutrient content claims not only on single-serving containers but also on all other products when the serving size declared on the label differs from the reference standard (e.g., products in discrete units such as muffins). Therefore, in proposed § 101.12(b) in the agency's reproposal on serving sizes published elsewhere in this issue of the **Federal Register**, FDA has set forth reference amounts customarily consumed per eating occasion (reference amounts) for 131 food product categories. In accordance with provisions of the 1990 amendments that require label serving sizes to be expressed in common household measures, proposed § 101.9(b)(2) in the same document provides procedures for manufacturers to use in converting the reference amounts, which generally are in metric measures, to label serving sizes most appropriate for their specific products.

In proposed § 101.12(g), FDA is proposing that, if the serving size declared on the product label differs from the reference amount listed in proposed § 101.12(b), both the reference amount and the serving size declared on the product label must be used to determine whether the product meets the FDA criteria for nutrient content claims as set forth in 21 CFR part 101, subpart D.

Consistent with proposed § 101.12(g), FDA is proposing for the subject fat, fatty acid, and cholesterol claims (as well as for all other nutrient content claims discussed in the companion document on nutrient content claims) that all per serving criteria (e.g., less than 2 mg of cholesterol per serving for "cholesterol free" claims) will apply to the serving size declared on the product label and, where the labeled serving size and the reference amount differ, to the reference amount as well. Therefore, taking the preceding example of skim milk, the proposed reference amount customarily consumed for all beverages is 240 milliliters which is equivalent to 8 fluid ounces. When considering the 8 fluid ounce container, the reference amount and the labeled serving size are the same. Therefore, because 8 fluid ounces of skim milk contain 126 mg of sodium and the definition for "low sodium" is an amount of 140 mg or less, the container could bear a "low sodium" claim.

However, when considering the 10 fluid ounce container, the labeled serving size is larger than the reference amount. Ten fluid ounces of skim milk contain 158 mg of sodium, an amount exceeding the definition for "low sodium." Therefore, while the amount of sodium in the reference amount of skim milk is within the definition, the amount of sodium in the labeled serving size is not. Hence, if this proposed rule is adopted, the 10 fluid ounce container could not bear a "low sodium" claim. While acknowledging the apparent contradiction this difference in treatment causes, FDA tentatively concludes that it would be misleading to allow claims based only on the reference amount because, particularly with single-serving containers, the consumer is expected to consume the entire labeled serving size. Likewise, it could also be misleading to allow claims based only on the labeled serving size, because this could cause manufacturers to attempt to manipulate serving sizes, even within the proposed constraints.

In the regulations in subpart D of 21 CFR part 101, the agency will describe the applicability of these dual criteria to the quantitative amounts in the proposed regulations as per reference amount customarily consumed and "per labeled serving size." Rather than complicating the discussions concerning proposed quantitative amounts in this preamble, however, FDA will abbreviate "per reference amount customarily consumed and per labeled serving size" as "per serving."

B. Total Fat Claims

1. "Fat free"

a. *Definition.* In response to the 1989 ANPRM, FDA received a few comments on the definition of the term "fat free." Most of these comments recommended that "fat free" be defined as 0.5 g or less per serving.

The agency finds merit in these comments and is proposing in § 101.62(b)(1)(i) to define the term "fat free" ("free of fat," "no fat," "zero fat," "nonfat," "trivial source of fat," "negligible source of fat," or "dietarily insignificant source of fat") to include foods that contain less than 0.5 g of fat per serving.

FDA has discussed in the companion document on nutrient content claims, published elsewhere in this issue of the **Federal Register**, its general approach to defining "free" levels of nutrients. This approach is that the level of a nutrient that is described as "free" should be at or near the reliable limit of detection for the nutrient in foods and should be dietetically trivial or physiologically inconsequential.

In the case of analytical methodologies for fat, 0.5 g of fat per serving defines a level of fat in food that is at or near the reliable limit of detection of fat in food. The actual limit of detection of fat in food varies with different food products. However, 0.5 g represents the limit of quantitation in essentially all foods (i.e., analytical precision and accuracy below this amount is difficult). In proposed § 101.9(c)(4) of the supplementary nutrition labeling proposal, the agency is proposing that less than 0.5 g of fat

could be declared as "0" in nutrition labeling.

In addition, the agency has selected 0.5 g per serving as the definition for "fat free" because it believes that a cutoff of 0.5 g is low enough compared to the DRV for fat, which is 75 g, to be considered dietetically trivial or physiologically inconsequential. For example, a person consuming 16 to 20 servings per day (Refs. 15 through 17) of food containing 0.5 g of fat per serving would consume only 8 to 10 g of total fat per day, or no more than 90 calories from fat per day and (for a diet of 2,350 calories) less than 4 percent of calories from fat. This level of fat is insignificant compared to the recommended level of 30 percent or less of calories from fat in the diet (Refs. 6, 9 through 11, and 13).

FDA established a policy of using "free" as a descriptor of physiologically insignificant levels of a food component when it adopted the regulation for sodium nutrient content claims (49 FR 15510, April 18, 1984). The agency has received comments that contend that the term "fat free" will mislead consumers into believing that food so labeled is completely without fat. However, the agency believes that no harm will result from any misunderstanding caused by the use of this term on foods that meet the definition because, as discussed above, foods containing less than 0.5 g of fat per serving contain a trivial amount of fat compared to the total dietary intake of fat for any particular individual. FDA is proposing to express this requirement on a per serving basis because it believes that consumers are most familiar with nutrient content claims being defined in this manner. The agency has used this basis in defining terms that describe the calorie, sodium, and cholesterol content of foods and is therefore proposing an approach that is consistent with that used by the agency in the past. Comments that the agency has received in response to the 1989 ANPRM and public hearings also supported continued use of serving sizes in the definition of nutrient content claims, as did the IOM report (Ref. 4).

The agency is not proposing a second criterion based on the amount of fat per 100 g for the definition of "free" because the first proposed criterion for this nutrient requires that the food contain such a trivial level of fat from a public health perspective that even frequent consumption in large amounts of foods that bear a "fat free" descriptor would not affect in any meaningful way the overall fat level in the diet.

b. *Use of "fat free" on products with added fat.* The agency is aware that the claim "fat free" appears on the labels of certain products to which small amounts of fat have been deliberately added as an ingredient. For example, some products that declare a fat content of "zero" and that bear the claim "fat free" list soybean oil as an ingredient. The agency has received letters expressing confusion about this type of labeling. The Minnesota State Attorney General, writing on behalf of eight other State attorneys general, has written to the agency to express their view that such labeling would be misleading to consumers (Ref. 18).

In response to these concerns, the agency is proposing in § 101.62(b)(1)(ii) to add a second criterion to the definition of "fat free" to disallow the use of the term on the labels of products to which fats or oils have been added as ingredients. Without this criterion, it would be possible for a food that meets the quantitative criterion for the "fat free" descriptor (i.e., contains less than 0.5 g of fat per serving) to have a small amount of fat or oil added as an ingredient.

The claim "fat free" is a representation that the food is free of fat. The agency believes that this representation can be made in good faith if the food inherently contains very small amounts of fat (i.e., less than 0.5 g per serving) because the food does not contain a dietarily significant amount of fat. Such a representation cannot be made in good faith, however, if the manufacturer intentionally adds a fat or oil to the food. In such circumstances, even though the fat might not be dietarily significant, it is obvious from reading the ingredient statement that it has been added, and, thus, FDA tentatively concludes that representing the food as free of fat would cause confusion and be false and misleading under sections 201(n) and 403(a) of the act. The agency solicits comments on this tentative conclusion.

As an alternative approach, it would be possible to allow "free" claims even though the nutrient is added, if the label includes a disclosure statement in association with the claim acknowledging the addition of the nutrient. In order for the claim to not be misleading, such a disclosure statement would need to be prominent and immediately adjacent to the claim each time it is made. Such a disclosure might state, "An insignificant amount of fat has been added to this product as an ingredient." This approach was suggested by the Minnesota Attorney General as an alternative if FDA determined that it was not feasible to prohibit nutrient free claims on products that contained a very small amount of a nutrient added as an ingredient (Ref. 18). The agency solicits comments on whether nutrient free claims should be allowed on products that contain a very small amount of a the nutrient as an ingredient if such products provide an appropriate disclosure statement and, if so, what such a disclosure statement should be. The agency points out, however, that although, under this proposal, a product would not be allowed to call itself "free" of a nutrient if a manufacturer intentionally added the nutrient to the food as an ingredient, the label could make other positive, true, and nonmisleading statements about the product such as how little of the nutrient is actually in the product. For example, if a manufacturer found that it was necessary to add a very small amount of fat to a product to assure that the product was palatable to consumers, the label could make a statement reflecting the amount of fat in the product provided that that amount of that nutrient could meet the definition for "low fat." Such a statement might be "contains less that ½ gram of fat per serving," or if accurate, "99 percent fat free." This labeling is consistent with § 101.13(i) which states that, in addition to statements about the percent of a vitamin or mineral in a food relative to the RDI, the label or labeling of a product may contain a statement about the percent or amount of a nutrient that implies that the food is high or low in a nutrient if the food actually meets the definition for either "high" or "low" as defined for the nutrient that the label addresses.

In addition, the label or labeling of a product may bear a variety of other positive statements about the product such as the product is "low," or in the case of sodium, "very low," in the nutrient or that the amount of the nutrient in the food is reduced, if that is the case, or that there is less of the nutrient in the product than some in another product.

c. *Foods inherently fat free.* Section 403(r)(2)(A)(ii) states that absence (i.e., "free") claims may not be made for foods unless the nutrient for which the claim is made is usually found in the food, or in a food that substitutes for the food (see proposed § 101.13(d)), or the Secretary allows such a claim based on a finding that the claim would assist consumers to maintain a healthy diet. Thus the act gives the agency the authority to limit "free" claims on foods inherently free of a nutrient.

However, FDA believes that highlighting "fat free" foods can help consumers maintain healthy dietary practices whether the food is inherently free of fat or is processed to be that way. Many respondents to FDA's

consumer surveys have reported difficulty in understanding the quantitative information presented in nutrition labeling (Ref. 19). Furthermore, FDA surveys have shown that consumers want nutrient content claims and find them useful in making food selections. Supermarket studies by FDA have shown that shoppers are using descriptive terms that highlight positive nutritional attributes (such as "fat free") to make food purchase selections (Refs. 20 and 21). In addition, they help to educate consumers on the intrinsic properties of foods. FDA believes that the definitions established in this proposed rule respond to consumers' needs. Therefore, FDA has tentatively concluded that it is not necessary to limit "fat free" claims to foods in which fat is usually present or that substitute for foods that usually contain fat.

However, the agency believes that the unqualified use of the term "free" on foods that are inherently free of a nutrient can be misleading because such terminology would imply that the food has been altered to reduce the nutrient as compared to other foods of the same type. Accordingly, FDA is proposing in this document (§ 101.62(b)(1)(iii)) and in the companion document on nutrient content claims (§ 101.13(e)) to require that if a food is free of a nutrient without the benefit of special processing, alteration, formulation, or reformulation to lower the content of the nutrient, it must refer to all foods of that type and not merely to the particular brand to which the labeling is attached. For example, many fruits and vegetables are foods that would meet the definition for the term "fat free." Therefore, if the agency adopts this policy, broccoli that bears a "fat free" descriptor would have to bear labeling such as "broccoli, a fat free food."

This requirement is consistent with the general policy on "free" and "low" claims discussed in the preamble to the final rule on sodium labeling in relation to sodium claims (49 FR 15510 at 15517) and proposed in § 101.25(a)(2)(i) and (a)(2)(ii) of the tentative final rule for both "free" and "low" cholesterol claims (55 FR 29456). The agency believes that this requirement is necessary to prevent the consumer from being misled by an implication that a particular food has been altered to lower its fat, when, in fact, all foods of that type are naturally free of, or low in, that nutrient.

FDA is aware that the effect of this proposed action will be to allow "free" claims on foods that do not usually contain the nutrient (e.g., "Brand A soft drink, a fat-free food"). However, because of the importance of highlighting "fat free" foods, the agency believes that this course is the appropriate one. FDA specifically requests comments on this aspect of its proposal.

Therefore, FDA is proposing in § 101.62(b)(1) to allow "fat free" claims on all foods that contain less than 0.5 g of fat per serving and contain no added fat or oil and, in § 101.62(b)(1)(iii), to require that "fat free" claims on foods that are inherently "fat free" disclose that fat is not usually present in the food.

2. "Low Fat"

a. *Definition.* Most of the comments on the 1989 ANPRM that dealt with fat nutrient content claims favored a single, uniform maximum cutoff ranging from 2 to 5 g of fat per serving for all food categories for defining the term "low fat."

The comments favoring 5 g of fat per serving for all food categories were primarily from representatives of the dairy industry, who suggested that the cutoff for "low fat" be consistent with the cutoff in the food standard for lowfat milk (21 CFR 131.135). This standard, which was promulgated in 1973, allows milk containing 0.5-, 1-, 1.5- or 2-percent milkfat to be named "lowfat milk." Two percent milkfat in an 8-fluid ounce serving equates to 5 g of fat.

The agency, however, has derived its proposed definition for "low fat" and the synonyms "low in fat," contains a small amount of fat, "low source of fat," or "little fat" from the proposed general principles for nutrient content claims that appear in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register.** Under these general principles, the agency is defining a "low" claim for a nutrient that is ubiquitous in the food supply as an amount equal to 2 percent of the DRV for the nutrient. FDA has selected 2 percent as the starting point based on its historical use of 2 percent of the U.S. RDA as a measurable amount of a nutrient in a food (§ 101.3(e)(4)(ii)).

To arrive at a defined value for "low" when a nutrient is not ubiquitous, the agency is proposing to increase the 2 percent amount to adjust for the nutrient's uneven distribution in the food supply. This adjustment recognizes the practice of dietary planning in which a person consumes in a day a reasonable number of servings of foods labeled as "low," balanced with a number of servings of foods that do not contain the nutrient in question and a small number of servings of foods that contain the nutrient at levels above the "low" level, and is still able to stay comfortably within the guidelines of the various dietary recommendations. This adjustment to reflect the nutrient's distribution in the food supply has the effect of permitting a wider variety of foods to be labeled as "low" than would be possible if the 2 percent of the DRV standard was used generally to define "low."

With respect to fat, current dietary guidelines (Refs. 6, 8, and 9) recommend that a person consume a maximum of 30 percent of calories from fat, which in a diet of 2,350 calories per day would allow for consumption of a maximum of 75 g of fat per day. This value has been proposed as the DRV for fat (55 FR 29476). Two percent of this proposed DRV is 1.5 g.

The agency is not proposing 1.5 g as the cutoff of a "low fat" claim, however, because fat is not ubiquitous in the food supply. For instance, very little fat is found in most fruits, vegetables, and grains. Because fat is not ubiquitous and yet is found in more than a few food categories, FDA tentatively concludes that an appropriate upper limit for a "low fat" claim should be set at two times 2 percent of the DRV, or 3 g per serving. The agency tentatively concludes that this amount is a reasonable definition for "low fat" because an average level of 3 g in 16 to 20 servings of food per day (balancing the number of foods that do not contain fat with those that contain higher levels of fat to yield an average of 3 g of fat per serving) would supply 48 to 60 g of fat daily, comfortably within the DRV of 75 g of total fat. Therefore, the agency is proposing in § 101.62(b)(2)(i) that a "low fat" food contain 3 g or less of fat per serving.

It should be noted that in deciding whether a food meets the criteria for "low fat" (and all other nutrient content claims except "free"), FDA considers the per serving criterion to pertain to the amount that is appropriately declared in nutrition labeling under § 101.9 rather than the amount that is actually present in the food product. Therefore, a food may meet the "low fat" criterion of "3 g or less fat per serving" even though it actually contains slightly more than 3 g of fat per serving. This anomaly occurs because of the rounding rules that FDA is proposing in the nutrition labeling regulations. Proposed § 101.9(c)(4) states that fat is to be expressed to the nearest 1/2 g. Accordingly, if FDA adopts that provision in the final nutrition labeling regulations, a food containing up to 3.24 g of fat would declare the level of fat as 3 g in nutrition labeling and would thus meet the criterion of "3 g or less fat per serving."

This anomaly will not occur with "free" claims because FDA is proposing to define them as "less than X amount" rather than "X amount or less." Because the integer is not included in the definition, FDA is proposing not to allow rounding above that amount.

b. *Need for criterion based on weight.* The agency is proposing in § 101.62(b)(2)(i) that a "low fat" food would have to contain 3 g or less fat per 100 g as well as per serving. FDA has stated in the companion document on nutrient content claims that an additional criterion based on weight is needed in some cases to prevent claims from being misleading. For example, some nutrient-dense foods have small serving sizes. Although these foods would meet the "low fat" definition on a per serving basis, because they may be consumed frequently throughout the day, they could produce a substantial total daily intake of a nutrient like fat. Thus, the agency has tentatively concluded that a second density criterion is appropriate for "low fat" foods. A density criterion has been used in conjunction with "low calorie" claims since 1977 (see current § 105.66(c)(1)(ii)) and was proposed as part of the definition for "low cholesterol" in § 101.25(a)(2)(ii) of the tentative final rule for cholesterol nutrient content claims (55 FR 29456).

Examples of foods that do not meet the definition of "low fat" because they do not meet the serving and density criteria include semi-solid frozen dessert toppings (2.3 g of fat per serving but 25 g of fat per 100 g of the food) and thick vanilla shakes (10.4 g of fat per serving although only 3 g of fat per 100 g of the food).

The agency notes that the proposed criteria for the definition of "low fat" differ from the criteria of 2 g or less of fat per serving and 10 percent or less of fat on a dry weight basis that the agency in the past has advised those interested to infer from § 101.25(c)(1) as a definition of "low fat" (Ref. 2). Although the first criterion (3 g per serving) of the proposed definition is more lenient than past agency advice (2 g per serving), the second criterion (3 g per 100 g of food) makes the total number of foods that meet the proposed definition essentially equivalent to the total number of foods that met the criteria of 2 g or less of fat per serving and 10 percent or less of fat on a dry weight basis. The assortment of foods varies somewhat however. For instance, some of the foods that meet the proposed criteria and not the previous criteria include 1 percent lowfat milk, and some soups. Foods that would meet either "low fat" definition include most fruit and vegetables, certain fish, shellfish, soups, and a few types of bread and cereal. Foods that do not meet the proposed criteria that had met the previous criteria include some breads, cookies, cereals (particularly presweetened cereals), and dehydrated soups. FDA tentatively finds it is appropriate to no longer permit these foods to make "low fat" claims because, if they are consumed frequently, they could result in a substantial total daily intake of fat.

c. *Foods inherently "low fat."* Consistent with the discussion above for foods inherently fat free, the agency believes that the use of the term "low fat" on foods that are inherently low in fat can be misleading. Accordingly, FDA is proposing in § 101.62(b)(2)(ii) to require that "low fat" claims on foods that inherently meet the definition for "low fat" refer to all foods of that type and not merely to the particular brand to which the labeling is applied.

For example, frozen perch would inherently meet the definition for the term "low fat." Therefore, if the agency adopts proposed § 101.62(b)(2)(ii), a package of frozen perch would be labeled "frozen perch, a low fat food." This requirement is consistent with the general policy on "free" and "low" nutrient content claims proposed in § 101.13(e)(2), which is published elsewhere in this issue of the **Federal Register.**

d. *"Low fat" meal-type products.* FDA has discussed in the companion document on nutrient content claims the requests that the agency has received for definitions for nutrient content claims that can be used on labels and in labeling of meal-type products. It is apparent that the per serving criteria in the agency's proposed definitions for claims for individual food products are too restrictive to apply to these products.

In 1986, in an effort to establish nutrient content claims that would help consumers identify positive nutritional characteristics of meal-type products, the agency proposed as a guideline that a meal containing less than 100 mg of cholesterol could be described as a "low cholesterol meal." However, in its tentative final rule on cholesterol nutrient content claims, the agency withdrew from this position because there was no clear definition of the term "meal" and asked for further comment.

To meet this need, and based on a letter submitted by the Grocery Manufacturers of America, Inc. (GMA) (Ref. 22), FDA is proposing in § 101.13(l) in its companion document on nutrient content claims to define a "meal-type product" as a food that: (1) Makes a significant contribution to the diet (a) by providing at least 200 calories or (b) weighing at least 6 ounces, and (2) contains ingredients from 2 or more of the following four food groups: bread, cereal, rice, and pasta group; fruit and vegetable group; milk, yogurt, and cheese group; and meat, poultry, fish, dry beans, eggs, and nuts group, and (3) is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, meal, main dish, entree, or pizza.

In its letter, GMA suggested that for meal-type products "low fat" be defined as 3.5 g or less fat per 100 g of food. FDA finds merit in setting nutrient content claims for meal-type products on the basis of the amount of the nutrient per 100 g rather than on the basis of the amount per serving and per 100 g as is done for individual foods. A review of meal-type products on the market (Ref. 23) shows that such a criterion would allow nutrient content claims on meal-type products that can be used in a diet that is consistent with dietary recommendations set forth in the Dietary Guidelines for Americans. However, FDA believes it would be beneficial and less confusing if it used the same quantitative amounts to qualify for nutrient content claims for meal-type products that it is proposing for individual foods. Such consistency would assist consumers and health professionals to be able to recall and to use these amounts. Accordingly, the agency is proposing in § 101.62(b)(3)(i) to provide that a "low fat" claim may be made for a meal-type product that contains 3 g or less total fat per 100 g of product. The agency is also proposing in § 101.62(b)(3)(ii) to provide for such claims on meal-type products that meet the criterion without special processing.

e. *Related issues.* The agency received a comment that urged the establishment of different cutoffs for "low fat" for different foods (i.e., varying the quantitative definition of "low fat" according to food category).

The agency rejects this comment. The use of different criteria for different food categories has several disadvantages that affect both consumers and the food industry. When different criteria are used for different categories of foods, consumers cannot use the nutrient content claims to compare products across categories and will likely find it difficult to use the descriptor in substituting one food for another in their diets.

Although an argument can be made that different criteria for different foods would permit consumers to identify the

products with the lowest fat levels in each category, the agency believes that such a system would have a high potential for misleading the consumer about the fat content of foods. To identify the product that has the lowest fat content in a category does not mean that the product is low in fat. Furthermore, by having different criteria for different food categories, it would be possible that some foods that did not qualify to use the descriptor would have a lower fat content than foods in other categories that did qualify. This situation would contribute to consumer confusion and misunderstanding.

FDA has received many comments asking for increased consistency among nutrient content claims to aid consumers in recalling and using the defined terms. In addition, the IOM report recommended such consistency stating that "low sodium, for example, should have the same meaning, whether it is applied to soup, frozen peas, or meat" (Ref. 4, p. 251). Accordingly, the agency concludes that establishing different cutoffs for each descriptor according to food category would greatly increase the complexity of the task given to consumers who would use nutrient content claims to plan diets that meet dietary recommendations.

The agency wishes to emphasize that it is not necessary for persons to limit their diets solely to "low fat" and "fat free" foods. However, the agency believes that nutrient content claims identifying "low fat" and "fat free" foods will help the American public to attain the nutrition objective in "Healthy People 2000" to "reduce dietary fat intake to an average of 30 percent or less of calories and saturated fat intake to less than 10 percent of calories among people aged 2 and older" (Ref. 24). The current U.S. diet is reported, on average, to provide about 37 percent of calories from fat (Ref. 5).

The agency recognizes that the definition of "low fat" that it is proposing differs from the use of the term in certain standardized foods (e.g., 1½ and 2 percent lowfat milk). In 1987, the Center for Science in the Public Interest petitioned FDA to prohibit the use of the term "lowfat" on 2 percent milk because it contains 5 g of fat per serving and is 18 percent fat on a dry weight basis. The agency is not, however, proposing any action to resolve the inconsistency between the proposed definition and this food standard use of the term at this time. FDA believes that it would be inappropriate to act before a definition for "low fat" is finalized.

In addition, section 403(r)(5)(C) of the act, which was added by the 1990 amendments, specifies that nutrient content claims required by a standard of identity do not have to be defined by regulation or to comply with the definitions that FDA does adopt and do not require the referral statement required in § 101.13(g). The use of nutrient content claims in conjunction with names of standardized foods is outside the scope of this document and is addressed in a separate document in this issue of the **Federal Register**.

3. "Reduced Fat"

a. *Percent reduction.* Most of the comments received in response to the 1989 ANPRM on the term "reduced fat" supported FDA's general policy of requiring reductions that are nutritionally significant. Fewer than 15 comments offered suggestions on how much of a reduction should be required for a "reduced fat" claim. Most of those comments favored a reduction of at least 25 or 33 percent. The comments favoring 33 percent were primarily from cheese manufacturers, who stated that a greater reduction is not feasible for cheese.

The agency has considered these comments. However, it is proposing in § 101.62(b)(4)(i) that the term "reduced fat" ("reduced in fat" or "fat reduced") be used to describe a food that has been specifically formulated or processed to reduce its fat content by 50 percent or more, with a minimum reduction of more than 3 g per serving, from the food that it resembles and for which it substitutes (hereinafter referred to as "reference food").

The agency has tentatively selected the level of 50 percent for the minimum fat reduction to qualify for the "reduced fat" descriptor in accordance with general criteria for "reduced" nutrient content claims discussed in the preamble to the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**. These general criteria take into consideration the level of reduction that would result in substantial reductions in the nutrient content of foods, the need for consistency of terms, and the technological feasibility of reducing levels of nutrients in foods. They also take into consideration the need for dietary changes relative to current intakes of nutrients.

FDA states in the companion document on nutrient content claims its belief that to make a reduced claim, there should be a substantial reduction in the amount of the nutrient present in the food. This belief is supported by comments that it received in response to the agency's 1989 ANPRM and public hearings. FDA believes that in defining the amount that constitutes a substantial reduction in a nutrient, it must take into consideration the distribution of the nutrient in the food supply. If a nutrient is ubiquitous, it will be consumed in a wide range of foods, and therefore, a dietary reduction in consumption of the nutrient can be spread out over all or most food categories. Thus, a smaller reduction on a food-by-food basis would be needed to achieve a substantial reduction in consumption of such a nutrient than would be needed if the nutrient were present in only some food categories. In the latter case, the nutrient would not be found in as many foods, and therefore, the reduction in the nutrient on a food-by-food basis would have to be greater to achieve a substantial dietary impact.

Fat is not ubiquitous throughout the food supply. Most fruit and vegetables and many grain products contain little or no fat. Reductions in the fat content of foods that are inherently low in fat are difficult and less cost effective than modifying foods that are high in fat. Therefore, to make substantial reductions in dietary fat intake, it is necessary to make significant reductions in foods containing high levels of fat.

Of the total number of foods on FDA's Regulatory Food Composition Data Base, approximately half are either fat-free or low-fat foods (Ref. 25). While this data base may not be representative of the entire food supply, it suggests that a large portion of the food supply is not amenable to a substantial reduction of fat content.

FDA notes that for calories, a nutrient that is ubiquitous in the food supply, the agency has determined that a percent reduction of 33 percent is necessary to justify a "reduced" claim. 21 CFR 105.66(d)(1)(i). Given this precedent, and the fact that at best only half the food supply is available to produce a substantial reduction in the fat content of the diet, FDA is proposing that a 50 percent reduction in the fat content of a food from the food that it is intended to resemble and to replace is necessary to justify a "reduced fat" claim. FDA notes that this level is consistent with the guidance that it has been giving the retail food industry for many years on "reduced fat" claims (Refs. 2 and 26).

The appropriateness of a 50 percent reduction is supported by calculations of the dietary changes needed to meet recommended intake levels. Dietary guidelines recommend reducing the intake of fat from foods from the current level in the average U.S. adult diet of approximately 37 percent of calories (Ref. 5) to 30 percent of calories (Refs. 6, 8, and 9). This change would require a

reduction in total fat intake of approximately 23 percent (Ref. 27). Since substantial reductions in fat can only be made in half of the foods in the food supply, it is reasonable to require that for foods making a "reduced fat" claim the fat content should be reduced by at least twice the reduction needed in the total diet in order to meet dietary recommendations (i.e., twice the 23 percent reduction, or 46 percent, which can be rounded to 50 percent).

As mentioned above, the agency's general criteria for "reduced" claims include consideration of the need for consistency of terms and the technological feasibility of achieving the specified levels of reduction. The continued use of the 50 percent criterion would allow not only for consistency with past guidelines but also with the values FDA is proposing for "reduced" claims for sodium, saturated fat, and cholesterol. In regard to technological feasibility, current technology has demonstrated that for many foods, including dairy products, a reduction in fat of 50 percent or more is readily achievable (Ref. 28).

The agency requests that interested persons submit comments on the proposed 50-percent reduction. Comments containing technical information supporting this or other suggested reduction levels will be particularly helpful.

b. *Absolute reduction.* Additionally, the agency is proposing, in § 101.62(b)(4)(i), a second criterion that would require a minimum absolute reduction of fat from the reference food that it replaces. As stated in the companion document on nutrient content claims, because the use of the term "reduced" is based on a percentage change rather than a specified amount per serving, the agency believes that an additional criterion specifying a minimum absolute amount of reduction for the nutrient is necessary to preclude manufacturers from making inconsequential changes in their products, which, given the initial low level of the nutrient, result in considerable reductions in terms of percent but not in terms of absolute amounts. For instance, without the inclusion of an additional criterion, a food containing only 4 g of fat per serving could be reformulated to contain 2 g of fat per serving and thereby qualify to use the term "reduced" when, in fact, the reduction of 2 g of fat cannot be considered either substantial or of nutritional significance.

In its companion document on nutrient content claims, FDA has tentatively concluded that, if a food is to make a consequential as well as a measurable reduction in a nutrient, the absolute reduction should not be less than that amount which is considered to be "low" on a per serving basis. A measurable amount of a nutrient is an amount greater than 2 percent of the label reference value (the amount defined in current § 101.3(e)(4)(ii) as a measurable amount of a nutrient). Two percent of the proposed DRV for total fat is 1.5 g (0.02 times 75 g). However, this amount is less than the amount of the per serving criterion for "low fat" (i.e., 3 or less g of fat per serving). Therefore, to bear a "reduced fat" claim, a food would have to have a minimum reduction that exceeds the per serving criterion for "low fat" (i.e., the reduction must be more than 3 g of fat per serving).

Guidelines or definitions for determining amounts of nutrients in foods that can be considered consequential or nutritionally meaningful are not available. However, as described in the companion document on nutrient content claims, FDA is proposing to use the definition for a "low" claim as the minimum amount of reduction in a nutrient in a food that would justify a "reduced" claim because a diet made up of exclusively "low" foods would contain a small but not insignificant amount of the nutrient. Total intake of the nutrient would not exceed the recommended DRV level, but would be as much as 50 percent or more of that level. Therefore, in considering consequential reductions for "reduced" foods, FDA has tentatively concluded that the amount per serving specified for "low" is a consequential amount of a nutrient, and that it is appropriate to define a consequential or nutritionally meaningful reduction in a nutrient as an amount that is not less than that amount considered to be "low" for the nutrient. Accordingly, FDA is proposing in § 101.62(b)(4)(i) that a "reduced fat" claim may be used on the label of a food in which the fat content has been reduced by more than 3 g of fat per serving, in addition to a reduction of fat of 50 percent or more from the reference food.

c. *Reference food.* As proposed in § 101.13(j)(1) of the companion document on nutrient content claims, the reference point against which a food can be said to contain a reduced level of a nutrient is either an industry-wide norm or the manufacturer's regular product. FDA is proposing to define an "industry-wide norm" in § 101.13(j)(1)(i) as a composite value weighted on a unit or tonnage basis according to a national market share of all foods of the same type as the food for which the claim is made. The agency is proposing to define a manufacturer's regular product in proposed § 101.13(j)(1)(ii) as a food that has been offered for sale to the public by the same business (or one entitled to use its name) and in the same locale on a regular basis for a substantial period of time.

These reference points were initially identified in comments to the agency's proposed regulation defining cholesterol content claims (51 FR 42584). The comments and FDA's response were discussed in the tentative final rule on the subject (55 FR 29456 at 29463). In the cholesterol rulemaking, FDA also proposed to allow a third reference point for a reduced claim, that of a similar product or class of products as found in a current, valid, composite data base. The agency has reconsidered permitting the use of this third reference point with "reduced fat" claims and now tentatively concludes that for a "reduced" claim a manufacturer should be required to compare the fat content of a food product either with its own product or with an actual market average as represented by the "industry-wide" norm for two reasons.

Foremost, the agency believes that the term "reduced" is a specific claim that requires that the comparison be made to products that are most like the product bearing the claim. A data base for a class of products will most likely include a spectrum of products that is too broad to support such a claim. For example, if a product is labeled as "reduced fat imitation bacon bits," it is claiming that it contains reduced fat when compared to other imitation bacon bits. If such a claim could be made on the basis of a data base of products similar to imitation bacon bits, the data base would likely include a range of products, including bacon. The imitation bacon bits could have reduced fat when compared to the data base but no less fat than other imitation bacon bit products. In such circumstances, the claim would clearly be misleading. Thus, FDA believes that comparison to a data base of similar products is not an appropriate basis for a "reduced fat" claim.

Moreover, particularly as a data base ages, the values in the base may no longer represent the nutrient composition of foods that are on the market. If, for example, all manufacturers have reduced the fat in their products, it would not be appropriate for an individual manufacturer to make a "reduced" claim against the higher value represented by the older average value. By requiring that the comparison be made against an

"industry-wide norm" or the manufacturer's regular product, the agency believes that this problem is minimized.

The agency is proposing in § 101.62(b)(4)(ii) that a food that bears a "reduced fat" claim be labeled in compliance with § 101.13(j)(2) as proposed in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**. Proposed § 101.62(b)(4)(ii) thus requires information in immediate proximity to the most prominent use of the claim of the extent (percent or fraction) that the fat is reduced, the identity of the reference food to which it is compared (e.g., "50 percent less fat than our regular brownie"), and quantitative information comparing the actual amount of fat in a serving of the food to the amount in the reference food (e.g., "Fat content has been reduced from 8 grams to 4 grams per serving").

The agency currently requires the comparative quantitative information and the identification of the reference food for reduced claims for sodium (§ 101.13(a)(4)) and calories (§ 105.66(d)(1)(ii)) to help prevent consumer misunderstanding. The agency believes that such information must be presented with a "reduced fat" claim for the same reason. The agency is proposing to add the requirement that the label or labeling declare the percent (or fraction) that fat and other nutrients have been reduced to give consumers additional information to evaluate the significance of the claim. This information will also allow consumers to more readily compare the levels of reduction in different foods making "reduced fat" claims. Thus, it is a material fact in light of the representations being made in the labeling.

In this and other situations where information is required to be in "immediate proximity" to a claim, the information must be immediately adjacent to the claim with no intervening material. This interpretation of "immediate proximity" is set forth in proposed § 101.13(g)(2) in the companion document on nutrient content claims and is required to prevent possible consumer misunderstanding.

Similarly, to identify the location in which the comparative information for relative claims is required, proposed § 101.13(j)(2)(ii) in the companion document defines "the most prominent location" as, in descending order: (1) A claim on the principal display panel (PDP) adjacent to the statement of identity, (2) a claim elsewhere on the PDP, (3) a claim on the information panel, or (4) a claim elsewhere on the label.

4. Comparative Claims

In proposed § 101.62(b)(5), the agency is providing for the use on food labels of comparative claims that use the term "less" to describe the fat content of the food expressed on a per serving basis. The agency recognizes that there are some foods that can achieve significant reductions in fat content but not reductions of 50 percent or greater. Because these foods do not attain a 50-percent reduction, they could not bear a "reduced fat" claim under this proposal. However, the agency believes that such foods should be able to be labeled with comparative statements using the term "less" that specify the extent of the fat reduction that has been made. For example, the label of a pound cake could bear the statement "40 percent less fat than our regular pound cake—fat lowered from 10 grams to 6 grams per serving."

To ensure that consumers are not misled by claims for reductions that are inconsequential, the agency is proposing in § 101.62(b)(5)(i) to permit a comparative statement on the label of a food only if the food has been formulated or processed to reduce its fat content by 25 percent or more, with a minimum reduction of more than 3 g of fat per serving. The requirement for a reduction of 25 percent or more is consistent with the agency's current policy for comparative claims for sodium (49 FR 15521, April 18, 1984) and proposed regulations for cholesterol (55 FR 29456). These positions were based on agency findings that products in which there has been a 25 percent or greater reduction will serve a useful role in the diet of those individuals who are attempting to limit their consumption of the nutrient. These criteria are also consistent with USDA guidelines that permit comparative fat claims for meat and poultry products when fat is reduced by 25 percent or more.

Improvements in food technology or other factors may make it practicable for manufacturers to measure reductions in nutrient content of less than 25 percent. The agency solicits comments, including data, on whether 25 percent is necessary as a minimum reduction requirement for all foods, or whether a lower level is possible.

However, FDA acknowledges that permitting comparative claims for foods with a percentage reduction of less than 25 percent may serve to facilitate consumers efforts to improve their diets if such claims are reliably made and the absolute reduction referred to by the comparative claim is nutritionally significant.

Consistent with "reduced fat" claims, the agency is also proposing to require an absolute reduction of more than 3 g of fat per serving from the reference food. While this criterion is new, FDA stated above its belief that an additional criterion specifying the absolute amount of reduction for the nutrient is necessary in order to preclude manufacturers from making inconsequential changes in a product, which, because of the initial low level of the nutrient, result in considerable reductions in terms of percent but not in terms of absolute amounts.

In determining the absolute reduction to be required, FDA considers that the amount must be both measurable in foods and nutritionally consequential. To meet these criteria, the amount would have to be, as discussed above with respect to "reduced fat" claims, not less than that amount that is considered to be "low." The amount defined as "low fat" is proposed to be 3 g or less per serving and per 100 g of food. Accordingly, FDA is proposing in § 101.62(b)(5)(i) that to bear a comparative claim for fat, an absolute reduction of more than 3 g of fat per serving is required.

In regard to reference foods, the agency is proposing in § 101.13(j)(1) in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register** that for comparative claims, comparisons may be made to an industry-wide norm, to the manufacturer's regular product, or to a current, valid composite data base such as USDA's Handbook No. 8, "Composition of Foods, Raw, Processed, Prepared." The first two reference points are identical to those listed above for a "reduced" claim. The agency is proposing to permit the third reference point, as initially proposed in FDA's tentative final rule on cholesterol content claims (55 FR 29456 at 29463), for comparative claims because it believes that consumers will benefit from label statements that make legitimate, appropriate comparisons with similar classes of products, and that comparative claims do not necessarily need to imply a comparison to the product itself or a narrow range of similar products. For example, a label statement such as "My amaranth chips have 25 percent less fat than other chip snack foods" would be appropriate (if the amaranth chips also contain more than 3 g less of fat than the named class of products). In making this comparison, the manufacturer could rely on values from a current, valid data base for the

similar class of products. FDA specifically solicits comment on this point.

The agency is proposing in § 101.62(b)(5)(ii) that, as required in proposed § 101.13(j)(2), labels or labeling of a food for which a comparative claim is made must include a statement in immediate proximity to the most prominent such claim of the extent (percent or fraction) that the fat is reduced, the identity of the reference food to which it is compared, and the quantitative information comparing the actual amount of fat in a serving of the food to the amount in the reference food that it resembles and for which it substitutes. This requirement is identical to that for "reduced fat" claims discussed above. An alternative approach to comparative nutrient content claims is discussed in the companion document on general principles for nutrient content claims published elsewhere in issue of the **Federal Register.**

5. " Percent Fat Free" Claims

The agency received many comments to the 1989 ANPRM stating that "____ percent fat free" claims on foods are confusing and misleading. These comments suggest that many consumers do not understand this type of claim. Additional comments suggested that the term be prohibited.

The agency is proposing to prohibit the use of this claim in those circumstances in which it would be misleading and thus would misbrand the product. Claims that a food is "____ percent fat free" emphasize how close the food is to being free of fat, that is, to containing no fat. They imply that the food has a very small amount of fat in it, and that the food is useful in structuring a diet that is low in fat. The impression that the claim makes is misleading, however, if the food, despite the percentage calculation, contains a significant amount of fat.

On June 6, 1991, in a speech given at the 20th Anniversary Conference sponsored by the Center for Science in the Public Interest, the Commissioner outlined the agency's concerns about "____ percent fat free" claims:

> The high number—often 90 percent, 93 percent, and even 97 percent—linked with a desirable characteristic—"fat free"—leads people to conclude that the food itself promotes good health. It can also lead people to conclude that they can eat as much of it as they want. * * * We believe that this kind of assertion confuses and misleads consumers. Foods that derive a high percentage of their calories from fat should not be making low-fat claims.
> (Ref. 29)

The Commissioner called on industry to remove these claims from their products.

To ensure that the consumer is not misled by the term "____ percent fat free," and that, as the claim implies, the food does in fact contain only a small amount of fat, FDA is proposing in § 101.62(b)(6)(i) to require that such claims can only be made in foods that meet the criteria: (1) For "low fat" foods as proposed in § 101.62(b)(2) of this document (i.e., such foods would contain 3 g or less of fat per serving and per 100 g of food) or (2) for "low fat" meal-type products as proposed in § 101.62(b)(3) (i.e., such meal-type products would contain 3 g or less of fat per 100 g of product). The agency believes the claim would be misleading on a food or meal-type product that contains more than this low level.

The agency advises that a "____ percent fat free" declaration would be misleading if the number of g of fat in a serving of the food were not presented in conjunction with the claim. Under section 201(n) of the act, a food label is misleading if it fails to reveal facts material in light of the representations that are made on the label. Clearly, the actual amount of fat in a food is a material fact when a " ____ percent fat free" claim is made. Therefore, in § 101.62(b)(6)(ii), FDA is proposing to require that the disclosure of the amount of total fat in a serving of food appear in immediate proximity to the most prominent such claim. In addition, given the potentially misleading nature of the claim, FDA believes that the quantitative disclosure of the amount of fat in a serving of the food should be in no less than one-half the size of the type of the "____ percent fat free" statement.

Finally, FDA is proposing in § 101.62(b)(6)(ii) that if the food contains less than 0.5 g of fat per serving (i.e., meets the criteria for "fat free"), the amount of fat may be declared as "0." This proposal is consistent with the rules set forward in the supplementary nutrition labeling proposal for declaration of fat in the nutrition label.

FDA is proposing in § 101.62(b)(6)(iii) that the type size of all components of the " ____ percent fat free" claim be uniform. FDA is concerned that claims that would give the numerical percentage in smaller type size than the words "fat free" would lead consumers to focus only on the "fat free" portion of the claim, misleading them into believing that the food was totally free of fat.

Finally, § 101.62(b)(6)(iv) proposes that a "100 percent fat free" claim must meet all of the criteria in § 101.62(b)(1) for "fat free" claims. This would require that, in addition to containing less than 0.5 g of fat per serving, the food will have to contain no added ingredient that is a fat or oil, and if the food is inherently free of fat, the label will have to so indicate by use of the term "a 100 percent fat free food."

The agency requests comments on these proposed provisions for the use of "____ percent fat free" claims. Specific comments on whether these provisions are sufficient to prevent such claims from being misleading, or whether such claims should be prohibited entirely, are requested.

C. Fatty Acid Claims

In response to the 1989 ANPRM, FDA received very few comments that addressed nutrient content claims regarding fatty acids. However, not only do the 1990 amendments require in section 403(r)(2)(A)(i) of the act that claims characterizing the level of nutrients required in nutrition labeling be made in accordance with definitions adopted by FDA, they add section 403(r)(2)(A)(iv) to the act. This section states that a claim "may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claims and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat."

In accordance with these provisions, the agency is proposing in § 101.62(c) to provide for the proper use of the terms "low in saturated fat" and "reduced in saturated fat" and of comparative statements about the content of saturates. As required in the 1990 amendments, proposed § 101.62(c) requires that labels of foods containing 2 mg or more of cholesterol per serving that bear any of the claims being proposed for saturated fat, disclose the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which must be no less than one-half of the size of the claim. FDA is proposing to exempt foods containing less than 2 mg of cholesterol per serving from this requirement because the agency is proposing in this rulemaking that such foods be considered "free" of cholesterol and the amount be declared as zero in nutrition labeling.

The agency is also proposing in § 101.62(c) to require that the amount of total fat be disclosed in immediate proximity to claims about saturated fat. The agency believes that disclosure of

total fat is needed because recent FDA research suggests that consumers often do not differentiate between total fat and saturated fat content (Ref. 30). This finding leads FDA to tentatively conclude that "low" or "reduced" saturated fat claims would often be interpreted as "low" or "reduced" total fat claims. Such an interpretation would be incorrect because not all foods that are low in saturates are low in total fat (e.g., some vegetable oils and nuts are low in saturates yet contain about 14 g of total fat per serving). Accordingly, the agency believes a saturated fat claim will be misleading under section 201(n) and 403(a) of the act if the total fat content is not disclosed in immediate proximity to such claim.

1. "Low in Saturated Fat"

a. *Definition.* The agency is defining the term "low in saturated fat" (or "low saturated fat," "contains a small amount of saturated fat," "low source of saturated fat," or "little saturated fat") in proposed § 101.62(c)(1)(i) to describe foods that contain 1 g or less of saturated fatty acids per serving and not more than 15 percent of calories from saturated fatty acids.

The agency derived the first criterion (i.e., 1 g or less of saturated fatty acids per serving) of its proposed definition for "low in saturated fat" following the general approach to defining "low" claims that is discussed in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register** and summarized under the above discussion for "low fat" claims. As discussed above, this general approach suggests that the starting point for the definition of "low" for a nutrient is 2 percent of its DRV. If a nutrient is not ubiquitous in the food supply, the percent of the DRV used as the cutoff is increased to adjust for its uneven distribution.

With respect to saturated fatty acids, current dietary guidelines (Refs. 6, 8, and 9) recommend that a person consume less than 10 percent of calories from saturated fats, which for a diet of 2,350 calories per day would allow for consumption of about 25 g of saturated fat per day. This value has been proposed as the DRV for saturates (55 FR 29476). Two percent of this proposed DRV is 0.5 g.

However, the agency is not proposing 0.5 g as the cutoff of a "low in saturated fat" claim because saturated fat is not ubiquitous in the food supply. Very little saturated fat is found, for example, in most fruit, vegetables, and grains. Because of the uneven distribution of saturated fat, the agency tentatively concludes that an appropriate upper limit for a "low saturated fat" claim should be set at two times 2 percent of the DRV, or 1 g per serving. Doubling the 2 percent level is consistent with the agency's treatment of fat, and the distribution of saturated fat in the diet roughly parallels the distribution of total fat. Moreover, this amount appears to be a reasonable definition for "low saturated fat" because if a person consumed an average level of 1 g in 16 to 20 servings of food per day, he or she would consume 16 to 20 g of saturated fat daily, comfortably within the DRV of 25 g of saturated fat.

Therefore, the agency is proposing in § 101.62(c)(1)(i) that the first criterion for the definition of "low in saturated fat" be 1 g or less of saturated fat per serving. According to FDA's Regulatory Food Composition Data Base (Ref. 25), this criterion would allow a "low saturated fat" claim on foods such as most fruit, vegetables, and grains; skim milk and other dairy foods made from skim milk; evaporated milk; a few nondairy cream substitutes and dessert toppings; egg substitutes; mayonnaise-style salad dressing; and many soups, breads, and low calorie salad dressings. Of the fats and oils food group, only a few oils, such as canola and safflower, and a few margarine spreads containing less than 40 percent fat meet the criterion of 1 g or less saturated fat. While FDA's Regulatory Food Composition Data Base is not representative of the entire food supply and does not contain foods that have recently been introduced in the marketplace, it gives an indication of the types of food categories that would meet the subject criterion.

b. *Need for second criterion.* A general discussion of the need for a second criterion in establishing definitions for nutrient content claims can be found in the companion document on nutrient content claims which is published elsewhere in this issue of the **Federal Register.** The agency has stated that it believes a second criterion is needed to control "low" claims on nutrient-dense foods with small serving sizes where such food items can be consumed frequently, resulting in a substantial intake of the nutrient. The agency then proposed using g of the nutrient per 100 g of food as the preferred second criterion.

In considering the appropriateness of using "per 100 g" as the second criterion for "low in saturated fat," two things become apparent. First, fats and oils that are commonly consumed generally contain only fat, and, second, 100 g of these foods would rarely, if ever, be consumed in a day. Furthermore, a review of FDA's Regulatory Food Composition Data Base (Ref. 25) revealed that of those fats and oils identified above as containing 1 g or less of saturated fat per serving, none would be able to make "low saturated fat" claims if a second criterion based on 100 g is included in that definition. Because all fats and oils contain more than 1 percent saturated fatty acids, they would exceed 1 g of saturated fat per 100 g.

The agency believes that it is important that consumers be able to easily identify fats and oils that contain especially low levels of saturated fats. While the information needed to make this assessment will be located on the nutrition label once the revised mandatory nutrition labeling regulations are finalized, comments have clearly shown that many consumers use nutrient content claims to make purchase decisions rather than relying on the more complete nutrient content information in the nutrition label. Accordingly, the agency tentatively concludes that a "low saturated fat" claim would be helpful to consumers in identifying such foods, and that the identification, and subsequent purchase, of such foods will help individuals to meet dietary recommendations. The agency also believes that it will assist in reaching population goals such as the "Healthy People 2000" national objective of reducing average saturated fat intake to less than 10 percent of calories (Ref. 24). Additionally, such claims will provide an incentive to the food industry to develop fats and oils with lower levels of saturated fatty acids.

Accordingly, FDA is not proposing to use a second criterion based on weight for "low saturated fat claims". However, the agency continues to be concerned about saturated fat content claims made on small servings of food that may be consumed frequently and thereby result in a substantial total daily intake of saturated fat. In addressing this issue, FDA looked at similar definitions used by other nations. Canada defines "low saturates" as foods containing no more than 2 g of saturated fatty acids per serving and not more than 15 percent calories from saturated fatty acids (Ref. 31). In the United Kingdom (UK), a food is considered to be low in saturated fat if it contains 3 g or less saturates per serving and per 100 g of food (Ref. 32). In setting their per serving criterion at 2 and 3 g, respectively, both countries are far less restrictive on that primary criterion than the subject proposal; however they both seem to share FDA's concern over the need for a second criterion. The British (UK) compensate

by setting a second criterion at 3 g per 100 g of food, a criterion what would eliminate many foods with small serving sizes.

FDA has studied and finds merit in Canada's approach of no more than 15 percent of calories coming from saturated fats. While dietary recommendations are for less than 10 percent of calories in the diet being provided by saturated fat, the fact that saturated fat is not ubiquitous in the food supply would allow higher amounts in those foods that contain saturated fats to balance off those that are lower, resulting in a total daily diet that meets dietary recommendations.

The use of a second criterion of no more than 15 percent of calories from saturated fat would continue to allow for "low saturated fat" claims on most fruit, vegetables, and grains; skim milk and other dairy foods made from skim milk; a nondairy liquid cream substitute; egg substitutes; mayonnaise-style salad dressing; many soups, breads, and low calorie salad dressings; and canola and safflower oils. Those foods that would meet the first criterion but not a criterion of no more than 15 percent of calories from saturated fats include evaporated milk, nondairy dessert toppings, and the margarine spreads. The agency tentatively concludes that it is appropriate to prohibit these foods from bearing a "low saturated fat" claim because they all could be consumed frequently, resulting in a substantial daily intake of saturated fat.

Accordingly, FDA is proposing in § 101.62(c)(1)(i) that "low saturated fat" claims may be used to describe the level of saturated fat provided the food contains 15 percent or less of calories from saturated fat as well as 1 g or less of saturated fat per serving. Comments are specifically requested on the suitability of, and need for, the proposed second criterion for "low saturated fat" claims.

c. *Foods inherently "low in saturated fat."* As previously discussed for "low fat" claims, the agency believes that the use of the claim "low in saturated fat" on the labels of foods that are inherently low in saturated fat can be misleading. Accordingly, FDA is proposing in § 101.62(c)(1)(ii) to require that "low in saturated fat" claims on foods that inherently meet the criteria specified in § 101.62(c)(1)(i) refer to all foods of that type and not merely to the particular brand to which the labeling is attached. This is consistent with the general policy on "free" and "low" nutrient content claims proposed in § 101.13(e)(2), which is published elsewhere in this issue of the **Federal Register**.

For example, raspberries would meet the definition for the term "low in saturated fat." Therefore, if the agency adopts proposed § 101.62(c)(1)(ii), a package of raspberries bearing a saturated fat claim would be labeled "raspberries, a low saturated fat food."

d. *"Low in saturated fat" meal-type products.* FDA is proposing in § 101.62(c)(2)(i) that a "low in saturated fat" claim may be made for a meal-type product that contains 1 g or less of saturated fat per 100 g of product. The proposed policy of basing nutrient content claims on the amount of the nutrient per 100 g rather than on the amount per serving and per 100 g as is done for individual foods is explained above for "low fat" meal-type products.

In its submission (Ref. 22), GMA suggested that for meal-type products "low saturated fat" be defined as 1.2 g or less of saturated fat per 100 g. FDA believes that it would be beneficial and less confusing if it used the same quantitative amount for "low saturated fat" claims for meal-type products that it is proposing on a per serving basis for "low saturated fat" claims on individual foods, 1 g. The proposed value of 1 g of saturated fat per 100 g would permit a "low saturated fat" claim on a 10-ounce meal when the declaration of saturated fat on the nutrition label is 3 g or less. GMA's suggestion would allow it on the same meal when the declaration is 3.5 g or less. FDA does not believe the difference is significant enough to warrant the confusion that would be caused by using different quantitative amounts.

As with other foods, if a meal-type product inherently meets the "low saturated fat" definition, its label will have to reveal that fact if a claim is made. This requirement is set out in proposed § 101.62(c)(2)(ii).

2. "Reduced Saturated Fat"

In proposed § 101.62(c)(3)(i), the agency is defining the term "reduced in saturated fat" ("reduced saturated fat," or "saturated fat reduced") to describe a food that has been specifically formulated or processed to reduce its content of saturated fat by 50 percent or more, with a minimum reduction of more than 1 g per serving from the reference food that it resembles and for which it substitutes.

The agency selected the level of 50 percent for the minimum reduction in saturated fat to qualify for the "reduced in saturated fat" descriptor in accordance with the general provisions for "reduced" nutrient content claims described above for "reduced fat" foods. These general provisions consider the level of reduction that would result in substantial reductions in the nutrient content of foods, the need for consistency of terms, and the technological feasibility of reducing levels of nutrients in foods. The provisions also consider the need for dietary changes relative to current intakes of nutrients.

Comments from both consumers and health professionals to the 1989 ANPRM and at the public hearings urged consistency in the definitions of terms to assist consumers in understanding the meaning of terms. They suggested that unless there were compelling reasons to the contrary, the agency should revise the current definitions for "reduced" calories, fat, and sodium that were 33 percent, 50 percent, and 75 percent, respectively, because it was not reasonable to expect consumers to remember the definition for each. Such variability, they argued, defeated the purpose of the terms.

In response to these comments and because of the many similarities between saturated fat and total fat, FDA believes that it is appropriate to use the same percent reduction to define "reduced" for both food components. Being absent from most fruit, vegetables, and grain products, neither food component is ubiquitous in the food supply. Therefore, similar levels of reduction could be expected to have a significant impact on dietary intakes of both.

In support of this position, FDA compared the need for dietary changes in saturated fat relative to current intakes with that for total fat discussed above under "reduced fat" claims. Current guidelines recommend reducing saturated fat from the current level in the average U.S. adult diet of 13 percent of calories (Ref. 1) to less than 10 percent of calories (Refs. 6, 8, and 9). This will require a reduction in saturated fat intake of 29 percent (Ref. 27). The need for dietary changes in total fat relative to current intakes is 23 percent, a comparable value. This information, and the agency's desire to provide for consistent definitions for similar terms so that consumer education efforts can be more easily implemented, have led FDA to propose that the first criterion for "reduced saturated fat" claims be a reduction of saturated fat of 50 percent or more.

FDA is also proposing in § 101.62(c)(3)(i) a second criterion that the amount of saturated fat in a food bearing a "reduced saturated fat" claim be reduced as a minimum by more than 1 g per serving from the reference food to which it is being compared. This criterion is consistent with the agency's

position discussed above for "reduced fat" claims and is intended to preclude manufacturers from making inconsequential changes in their products that, because of the initial low level of the nutrient, result in considerable reductions in terms of percent but not in terms of absolute amounts.

As stated above, the agency has tentatively concluded that if a food is to make a consequential as well as measurable reduction in a nutrient, the absolute reduction should not be less than that amount that is defined as "low" on a per serving basis. For saturated fat, that amount would be "more than 1 g."

As proposed in § 101.13(j)(1) of the companion document on nutrient content claims, the reference foods against which "reduced" claims may be measured are either an industry-wide norm or the manufacturer's regular product. These reference points are defined and discussed above in the section on "reduced fat" claims.

The agency is proposing in § 101.62(c)(3)(ii) that a food that bears the claim "reduced in saturated fat" be labeled as required in proposed § 101.13(j)(2), which is included in the companion document on nutrient content claims. Thus, proposed § 101.62(c)(3)(ii) requires that in immediate proximity to the most prominent use of the claim, information be presented on the extent (percent or fraction) that the saturated fat has been reduced, the identity of the reference food to which it is compared, and the actual quantity of saturated fat in a serving of the food compared to the amount in the reference food. For example, a nondairy creamer that had been reformulated to reduce its saturated fat content from the industry-wide norm could make a "reduced saturated fat" claim when accompanied by the following information: "Contains 50 percent less saturated fat than the national average for nondairy creamers. Saturated fat reduced from 3 grams per serving to 1.5 grams per serving."

3. Comparative Claims

Consistent with the discussion of comparative claims describing the fat content of foods, FDA is proposing in § 101.62(c)(4) to allow the use of comparative claims using the term "less" for foods that have been formulated, reformulated, altered, or processed in a way that has resulted in at least a minimum reduction in their saturated fat content. Proposed § 101.62(c)(4)(i) requires a reduction of 25 percent or more in saturated fat and a minimum reduction of more than 1 g of saturated fat per serving from a reference food. The agency believes that a reduction of 25 percent or more is necessary to ensure that consumers are not misled by claims for reductions that are inconsequential, i.e., that the products will serve a useful role in the diet of those individuals who are attempting to limit their consumption of saturated fat.

Additionally, the requirement for an absolute reduction of more than 1 g is necessary to preclude manufacturers from making comparative claims for products that are relatively low in saturated fat and therefore in which even a high percentage reduction in saturated fat content would be inconsequential. For example, without the inclusion of an additional criterion, a food containing only 2 g of saturated fat per serving could be reformulated to contain 1.5 g of saturated fat per serving and thereby qualify to use a comparative claim. In fact, the reduction of 0.5 g of saturated fat cannot be considered either substantial or of nutritional significance.

As discussed under comparative claims for fat, FDA is proposing in § 101.13(j)(1) in the companion document on nutrient content claims that for comparative claims, the reference food may be an industry-wide norm, the manufacturer's regular product, or, when the comparison is to a class of similar foods, to a current, valid data base such as USDA's Handbook No. 8, "Composition of Foods, Raw, Processed, Prepared."

Additionally, the labeling requirements proposed in § 101.62(c)(4)(ii) are identical to those for "reduced saturated fat" claims in proposed § 101.62(c)(3)(ii). The information that must be presented in immediate proximity to the most prominent use of the comparative claim is the percent or fraction that the saturated fat is reduced, the identity of the reference food to which the comparison is made, and the quantitative information that compares the actual amount of saturated fat in a serving of the food to the amount in the reference food.

4. Need for Additional Definitions

The agency is requesting comments on whether there are any other definitions that are necessary to effectively inform consumers about fat and fatty acid content. The agency is not proposing definitions for terms that describe the content of monounsaturated or of polyunsaturated fatty acids. Although the supporting text in some consensus reports (Refs. 6 and 9) noted the likelihood of reducing the risk for CHD (Ref. 9) and atherosclerotic cardiovascular disease (Ref. 6) when specific unsaturated fatty acids are substituted for saturated fatty acids in the diet, the conclusions of these reports did not include quantitative recommendations with respect to intakes of these fatty acids. Therefore, the agency has tentatively concluded that, except for use of the comparative term "more," which is discussed in the companion document on nutrient content claims, the scientific evidence is not sufficiently clear to establish the need for nutrient content claims for unsaturated fatty acids. The agency invites comments on this view.

The agency also is not proposing to define the term "saturated fat free." The agency has proposed in § 101.62(c)(1)(i) to establish a per serving criterion for "low in saturated fat" claims at 1 g or less. This amount is approximately ⅓ the level of fat that it has proposed would qualify for the "low fat" descriptor (3 g or less per serving) and corresponds with dietary guidance that saturated fat should amount to no more than ⅓ of the total fat intake in the diet. The agency believes that the amount of saturated fat that would justify a "saturated fat free" claim should similarly be ⅓ of the maximum fat content permitted to make a "fat free" claim. This standard would result in a criterion of 0.17 g or less of saturated fat per serving. Analytical methodologies for assessing saturated fat content are not precise at such low levels, however. Also, from a food processing point of view, control at such a low level may be difficult. Therefore, the agency has concluded that a "saturated fat free" claim is not feasible.

5. Other Comments

Several comments to the tentative final rule argued that the declaration of fatty acid content ought to be mandatory within nutrition labeling and recommended breaking out additional subcomponents, such as omega-3, omega-6, and trans fatty acids.

At the time the tentative final rule was issued, the 1990 amendments had not been passed. As a result, including saturated fatty acids as a required element of nutrition labeling was only a proposal, and the agency could not assume that this proposal would be adopted. Hence, FDA included discussions on the type and form of fatty acid labeling in the tentative final rule. With the passage of the 1990 amendments, the inclusion of saturated fat within nutrition labeling has become more of a certainty.

The issue of exactly what should be included in nutrition labeling, including what type of breakdown of fatty acid content should be included, is being considered as a part of the agency's supplementary nutrition labeling proposal. Therefore, there is no need to consider that issue as part of this rulemaking.

D. Cholesterol Claims and Responses to Comments to the Tentative Final Rule

1. Thresholds and Other General Requirements for Cholesterol Claims

a. *Saturated fat thresholds.* Several comments to the tentative final rule on cholesterol nutrient content claims (55 FR 29456) objected to the saturated fat thresholds on cholesterol claims. Many of these comments asserted that FDA did not have the legal authority to prohibit truthful claims. They stressed the need for consumer education rather than prohibition of claims. One comment argued that scientific evidence does not show that following dietary guidelines to reduce fat and saturated fat intake will decrease the risk of CHD.

While the agency concluded that it had the authority under sections 403(a)(1), 201(n), and 701(a) of the act to propose threshold levels of fat and saturated fat in the tentative final rule (55 FR 29456), its authority was clarified by passage of the 1990 amendments, particularly section 403(r)(2)(A)(vi) of the act. This section states that a nutrient content claim "may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food."

One of the main purposes of this rulemaking is, by defining cholesterol content claims, to provide consumers with information that they can use to reduce their risk of CHD. There is convincing evidence that dietary intake of saturated fatty acids is also a significant factor in the etiology of this disease. The Surgeon General's Report, for example, states that "excessive saturated fat consumption is the major dietary contributor to total blood cholesterol levels" (Ref. 5, p. 11), and the NAS's "Diet and Health" report found a strong relationship between blood cholesterol levels and the prevalence and incidence of atherosclerotic CHD (Ref. 6). Accordingly, the agency believes it would be misleading for a food that contains significant amounts of saturated fatty acids to make claims regarding cholesterol content and, thereby, to encourage consumers to buy the product for the purpose of reducing their risk of heart disease.

The agency agrees that consumer education programs are necessary to explain the relationship of cholesterol and saturated fat to the risk of cardiovascular disease. However, FDA is not persuaded that such programs can effectively reach and be understood by all consumers. A recent FDA consumer survey found that 40 percent of respondents thought that a "cholesterol free" food would also be low in saturated fat, and another 20 percent were not sure what the claim implies about saturated fat content (Ref. 33). The survey found that consumers are interested in cholesterol content claims because they believe that eating foods with no or low cholesterol will have a significant effect on their blood cholesterol levels and on their chances of developing heart disease (Ref. 33). These findings lead FDA to conclude that a significant number of consumers are likely to believe that a food that bears a cholesterol content claim will help to lower blood cholesterol levels and to reduce the risk of heart disease. In point of fact, foods containing little or no cholesterol can contain saturated fats at levels that can contribute to high blood cholesterol which, in turn, can contribute to atherosclerotic CHD (Ref. 6). Accordingly, FDA continues to believe that to ensure that cholesterol content claims do not mislead consumers, it is necessary to permit their use only when the foods also contain levels of saturated fats that are below a specified threshold level.

The agency, therefore, is proposing in § 101.62(d) to prohibit the use of cholesterol content claims, including, in a change from the tentative final rule, "reduced cholesterol" and comparative claims, on foods that contain more than 2 g of saturated fatty acids per serving.

b. *Appropriate threshold level for saturated fat.* Many comments suggested changing the threshold levels for saturated fatty acids. The agency had proposed levels of 2 g or less per serving and 6 percent or less saturated fat on a dry weight basis. Most of the comments were opposed to the percent dry weight criterion. They argued that a dry weight limit would discourage the development of new food products with lower fat and cholesterol contents, particularly those in which water is substituted, in part, for fat. Comments stated that the development of new food technologies to produce more healthful foods would be hampered, and that the dry weight criterion was unnecessary and would unfairly penalize foods that have a high moisture content. One comment also objected to the 2 g criterion and suggested lowering the threshold level to 1 g, related to suggested changes in the definition of "saturated fatty acids."

The agency is persuaded that the dry weight criterion is not necessary and is possibly counterproductive to the "Healthy People 2000" objective of increasing the availability of processed food products that are reduced in fat and saturated fat content (Ref. 24). Accordingly, FDA is deleting the dry weight criterion.

In regard to the definition for "saturated fatty acids," the agency noted in the tentative final rule on cholesterol nutrient content claims (55 FR 29469) that this definition was the subject of another rulemaking, namely the proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision." The discussion of this definition has been carried forward in the agency's supplementary mandatory nutrition labeling proposal. FDA recognizes the relationship between the definition, that is, the particular fatty acids that are included in the definition, and the numerical value associated with this threshold level (as well as the values defining "low" and "reduced" saturated fat) and will make adjustments in the proposed threshold level as necessary if the definition is modified in the associated rulemaking on nutrition labeling. However, if the definition of "saturated fatty acids" is not modified, the agency does not find compelling reasons, given in the comments, to revise the per serving value of 2 g. Accordingly, FDA is proposing in § 101.62(d)(1)(i)(B) and (d)(1)(ii)(B), (d)(2)(i)(B) and (d)(2)(ii)(B), and (d)(4)(i)(B) and (d)(4)(ii)(B) that the terms "cholesterol free," "low cholesterol," and "reduced cholesterol," respectively, be allowed only when the food product contains 2 g or less of saturated fatty acids per serving. A similar requirement is proposed for comparative cholesterol claims in § 101.62(d)(5)(i)(B) and (d)(5)(ii)(B).

As a result of this 2 g saturated fat threshold above which cholesterol claims may not be used, FDA tentatively concludes that it is not necessary to propose a requirement, based on section 403(r)(2)(A)(iii)(II) of the act, that the saturated fat content be disclosed adjacent to a cholesterol claim whenever the amount of saturated fat exceeds a set value. As discussed in the companion document on descriptor claims published elsewhere in this issue of the **Federal Register**, FDA is proposing in § 101.13(h) that the disclosure level for saturated fat be 4 g per serving or per 100 g. This value is 15

percent of the proposed DRV for saturated fat and is proposed as the level of saturated fat "that increases to persons in the general population the risk of disease or a health related condition which is diet related" as required by section 403(r)(2)(A)(iii) of the act. Because the agency is proposing that it would be misleading to make a cholesterol claim on a food exceeding 2 g of saturated fat, disclosure of levels of 4 g and above have no application to cholesterol claims.

c. *Fat thresholds.* Many comments to the tentative final rule (55 FR 29456) were opposed to the use of a total fat threshold that would prohibit cholesterol claims on foods that contain more than 5 g fat per serving and more than 20 percent fat on a dry weight basis. Some of these comments argued that current scientific knowledge does not support an association between the intake of total fat and high blood cholesterol as it does with saturated fatty acid intake, and therefore that a limit on total fat does not pass scientific scrutiny. Comments also asserted that such a threshold would condone the "good food/bad food" concept by requiring individual foods (and even ingredients of foods), rather than the total diet, to meet dietary guidelines of less than 30 percent of calories from fat.

A few comments pointed out that FDA surveys show that many consumers believe that cholesterol is found in all fats and oils, and that this finding demonstrates that there is a need for consumer education (which could include declarative statements adjacent to claims informing consumers of the total fat content of the product) rather than removal of truthful claims. Comments also stated that a total fat threshold would be a disincentive to the food industry to formulate low cholesterol and low fat foods, which would hinder the achievement of the "Healthy People 2000" objectives (Ref. 24). Comments also pointed out that such a threshold would interfere with harmonization between the U.S. and Canada, because Canada only restricts the saturated fatty acid content of foods making cholesterol claims.

FDA does not agree that a threshold for disallowing a descriptor supports a "good food/bad food" concept. The agency believes that such a threshold merely restricts the use of nutrient content claims to those foods on which they will not be misleading. However, FDA is persuaded by the comments that a cholesterol claim is not inherently misleading on a food that is high in total fat but contains 2 g or less of saturated fatty acids per serving.

The agency notes that Congress in the 1990 amendments appears to have considered that, in appropriate circumstances, cholesterol claims could be made on foods that contain significant levels of fat (see 21 U.S.C. 343(r)(2)(A)(iii)). For example, House Report 101-538 (Ref. 34, p. 20) states that a "no cholesterol" claim may be allowed on margarine, a food that is largely fat, under certain conditions. Accordingly, the agency is deleting the total fat thresholds.

d. *Conditions for use of cholesterol claims on foods exceeding disclosure levels of fat.* A cholesterol claim represents and suggests that the product provides a health benefit, and the level of fat in the food has a material bearing on this claim. This position is supported by section 403(r)(2)(A)(iii) of the act, which states that if a food contains fat or saturated fat in an amount that increases the risk for persons in the general population of developing a diet-related disease or health condition, it may not make a claim with respect to cholesterol unless it meets certain requirements and discloses the amount of total fat or saturated fat in immediate proximity to such claims.

Section 403(r)(2)(B)(ii) of the act provides similar language for nutrient content claims with the requirement that any nutrient in a food at a level that increases risk of diet related disease or health condition shall prominently disclose that nutrient on the label or in labeling in immediate proximity to the claim. FDA is referring to this level as a "disclosure level." The act goes even further with respect to health claims. In section 403(r)(3)(A)(ii), the act prohibits, except in special circumstances, health claims for a food if any nutrient is present in the food in an amount that increases the risk of diet-related disease or health condition. FDA will refer to this level as a "disqualifying level." The statutory language defining a disclosure level for a nutrient in conjunction with a nutrient content claim is the same as that for a disqualifying level for the nutrient for a health claim. Consequently, FDA is proposing the same levels for the individual nutrients for both types of claims.

The disclosure level for fat is proposed in § 101.13(h) of the companion document on nutrient content claims as an amount that is more than 11.5 g per serving or per 100 g of food. The identical amount is proposed in § 101.14(a)(5) of the proposed rule on health claims published elsewhere in this issue of the **Federal Register** as the disqualifying level for fat for health claims. In the proposed rule on health claims, the agency discusses how it arrived at the proposed disclosure and disqualifying levels.

Briefly, in setting such levels, FDA considered that there are no generally recognized levels at which nutrients such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease. Therefore, if FDA were to attempt to set these levels on an individual food basis, it would not be possible to do so. However, sections 403(r)(2)(B)(ii) and 403(r)(3)(A)(ii) of the act require that the agency take into account the significance of the food in the total daily diet. The intake of nutrients such as fat, saturated fat, and cholesterol in the total day's diet in excess of dietary recommendations increases the risk of diet-related disease. Therefore, because the agency's proposed DRV's for total fat, saturated fat, cholesterol, and sodium are based on recommended dietary intake levels, the agency tentatively decided to tie the disclosure and disqualifying levels to the DRV's.

To determine the appropriate disclosure/disqualifier levels, FDA used an approach based on the number of servings of food in a day and available information on food composition. As described in the health claims proposal, the agency has tentatively found that an appropriate disclosure/disqualifying level for individual foods is between 10 and 20 percent of the DRV. The agency made this tentative finding by looking at the food supply. It noted that the nutrients fat, saturated fat, cholesterol, and sodium are present in roughly one-half of the general USDA food categories. Therefore, if approximately 20 foods/beverages are consumed in a day and half of the foods consumed contain the nutrient at a level of 10 percent of the DRV (on average), then the total daily intake of the nutrient would be 100 percent of the DRV. This level of intake would not constitute a risk for chronic disease. On the other hand, if the same number of foods are consumed and half the foods contain on average 20 percent of the DRV, then the total daily intake of the nutrient would be 200 percent of the DRV, a level of intake that would increase the risk for diet-related disease. The agency then used food composition data to evaluate the effect of establishing various disclosure/disqualifying levels between 10 and 20 percent and tentatively concluded that a level of 15 percent of the DRV was most appropriate. If one-half of the foods consumed during the day contains on average this amount, the total daily intake of the nutrient

would exceed the DRV but without the risks inherent at higher levels. Yet, if this criterion is used, a significant number of foods would not be disqualified. Thus, FDA is proposing to establish disclosure/disqualifying levels for total fat, saturated fat, cholesterol, and sodium, and that these levels be 15 percent of the DRV per serving and per 100-g of food. These levels are 11.5 g for total fat, 4.0 g for saturated fat, 45 mg for cholesterol, and 360 mg for sodium. FDA is proposing that the disclosure/disqualifying levels apply on a 100-g basis as well as on a serving size basis to prevent nutrient-dense foods (i.e., those foods that contain relatively high concentrations on a caloric basis of one or more of the subject nutrients) that are consumed in small servings from being promoted for increased use in a diet through the use of health claims or nutrient content claims.

Accordingly, to implement section 403(r)(2)(A)(iii) of the act, FDA is proposing in § 101.62(d)(1)(ii)(C), (d)(2)(ii)(C), (d)(4)(ii)(C), and (d)(5)(ii)(C) that a "cholesterol free," "low cholesterol," "reduced cholesterol," or a comparative claim, respectively, may be made on foods containing more than 11.5 g of fat per serving or per 100 g of food only if, in addition to meeting the requisite cholesterol and saturated fat levels, the food label or labeling discloses the level of total fat in a serving of the food as labeled. The agency believes this requirement, if adopted, will prevent consumers from being misled about the health benefits of the product by the cholesterol claim.

In accordance with section 403(r)(2)(A)(iii)(II) of the act, FDA is also proposing in these paragraphs that the disclosure of fat must appear in immediate proximity to such claim and with appropriate prominence, that is in type that is no less than 1/2 the size of the type used for such claim. Because the level of fat has a material bearing on the claim, FDA is proposing that the disclosure of fat come immediately after the claim and before the referral statement required by § 101.13(g) (i.e., "See [*appropriate panel*] for nutrition information"). To limit unnecessary duplication of information, FDA is also proposing that if the claim appears on more than one panel, the requirement of the act will be met if the fat content is disclosed adjacent to the claim on each panel except for the panel that bears nutrition labeling, where it will not be required. Likewise, if the claim appears more than once on a panel, the requirement of the act will be met if the fat content is disclosed adjacent to the claim that is printed in the largest type on that panel. This proposal is similar to that proposed in § 101.13(g) of the companion document on nutrient content claims regarding the referral statement.

In addition to requiring that total fat levels be disclosed in immediate proximity to any cholesterol claims made on labels of foods that have more than 11.5 g of fat, section 403(r)(2)(A)(iii) of the act identifies two other conditions for use of cholesterol claims on such foods. These conditions are: (1) "the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share," or (2) "the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and the regulation requires that the statement disclose that cholesterol is not usually present in the food" (21 U.S.C. 343(r)(2)(A)(iii)(I)).

i. *Substantially less.* In regard to the first condition, FDA is proposing in § 101.62(d)(1)(ii)(E) and (d)(2)(ii)(E) to permit "free" and "low" cholesterol claims to be made on foods that contain more than 11.5 g of total fat if the foods meet the required cholesterol levels for the claim as a result of special processing, alteration, formulation, or reformulation that caused them to contain "substantially less" cholesterol than the reference foods.

The agency is proposing in § 101.62(d)(1)(ii)(E) and (d)(2)(ii)(E) to define "substantially less" in a way that is consistent with the requirements of § 101.62(d)(5)(i)(A) for a comparative claim using the term "less." Proposed § 101.62(d)(5)(i)(A) provides that to make a comparative claim, a food must contain at least 25 percent less cholesterol, with a minimum reduction of more than 20 mg of cholesterol per serving, than the reference food. The 25 percent reduction is consistent with the agency's position that a 25 percent or greater reduction in a nutrient for which excess consumption is a public health concern is consequential (that is, substantial) because it will assist persons attempting to limit their consumption of the nutrient to meet dietary recommendations. This position is the basis for comparative claims for sodium (49 FR 15510 at 15521, April 18, 1984) and for cholesterol as proposed in § 101.25(a)(2)(iv) of the tentative final rule. It also corresponds with USDA guidelines that permit comparative fat claims for meat and poultry products when fat is reduced by 25 percent.

FDA is proposing, as the second criterion for "substantially less," a minimum reduction of more than 20 mg of cholesterol per serving to preclude manufacturers from making inconsequential changes in a product, which, because of the initial low level of the nutrient, results in considerable reductions in terms of percent but not in terms of absolute amounts. The level of more than 20 mg cholesterol is that amount which exceeds the level proposed for a "low cholesterol" claim. FDA has tentatively concluded in its companion document on nutrient content claims that if a food is to make a consequential as well as a measurable reduction in a nutrient, the absolute reduction should not be less than that amount which is considered to be "low."

In reference to the requirement in section 403(r)(2)(A)(iii)(I) of the act that the level of cholesterol be less than the level usually present in the food "or in a food which substitutes for the food," the agency is proposing in § 101.62(d)(1)(ii)(E), (d)(2)(ii)(E), (d)(4)(ii)(A), and (d)(5)(ii)(A) for "cholesterol free," "low cholesterol," "reduced cholesterol," and comparative cholesterol claims, respectively, that the substitute food meet the requirements for a substitute food proposed in § 101.13(d) of the companion document on nutrient content claims. Proposed § 101.13(d) states that a substitute food is a food that organoleptically, physically, and functionally resembles the food for which it substitutes, that may be used interchangeably with such food, and that is not nutritionally inferior (as defined in current § 101.3(e)(4)). For example, vegetable oil margarine resembles butter in its performance characteristics (i.e., organoleptic properties, physical attributes, and functional properties), is used interchangeably with butter, and is not nutritionally inferior to butter. Therefore, a "cholesterol free" claim would be allowed for vegetable oil margarine on the basis that it substitutes for butter and contains substantially less cholesterol than butter.

Section 403(r)(2)(A)(iii)(I) of the act also requires that the substitute food discussed in the preceding paragraph have a "significant market share." FDA is proposing to find that a food has a significant market share if it has a market share of 5 percent or more of the sales of that category of foods according to an authoritative marketing data base. Examples of national data bases of food sales include those developed by The A.C. Nielsen Co. and Information

Resources, Inc. The agency is proposing to define "significant market share" as 5 percent or more because, for most categories of foods, products with less than this amount are not likely to remain on the market. Many retailers will not carry products with less than 5 percent of the market, and manufacturers find it uneconomical to continue to produce and market such products (Ref. 35). Therefore, in proposed § 101.62(d)(1)(ii)(E), (d)(2)(ii)(E), (d)(4)(ii)(A), and (d)(5)(ii)(A) for "cholesterol free," "low cholesterol," "reduced cholesterol," and comparative cholesterol claims, respectively, FDA is proposing to parenthetically define "significant market share" as a market share of 5 percent or more.

The agency is also proposing in § 101.62(d)(1)(ii)(E) and (d)(2)(ii)(E) that foods containing more than 11.5 g of fat per serving or per 100 g of food that make "free" and "low" cholesterol claims on the basis of containing "substantially less" amounts than another food be labeled in accordance with proposed § 101.13(j)(2) for all relative claims. Similar requirements exist in § 101.62(d)(4)(i)(C) and (d)(4)(ii)(D) for foods making "reduced cholesterol" claims and in § 101.62(d)(5)(i)(C) and (d)(5)(ii)(D) for foods making comparative cholesterol claims. Thus, if the agency adopts these requirements, the label or labeling would have to bear, in immediate proximity to the claim, a statement of the percent of reduction, identification of the reference food, and quantitative information comparing the product's per serving cholesterol content with that of the reference food (e.g., "Cholesterol free margarine, contains 100 percent less cholesterol than butter (0 mg of cholesterol compared with 30 mg in one serving of butter). Contains 11 grams of fat per serving."). (Note: Even though margarine contains less than 11.5 g per serving, it contains more than 11.5 g per 100 g, and therefore a "cholesterol free" claim on this food must disclose the amount of total fat.)

ii. *Absence claims.* The second condition in section 403(r)(2)(A)(iii) of the act for allowing cholesterol claims on foods that have more than 11.5 g of fat is that absence (i.e., "free") claims may be permitted on the basis of a finding that while cholesterol is not usually present in the food, such a claim would assist consumers in maintaining healthy dietary practices, and the claim discloses that cholesterol is not usually present in the food.

Consistent with the discussion on claims for foods that are inherently free of fat, FDA believes it is helpful to consumers to highlight "cholesterol free" foods useful in maintaining healthy dietary practices whether the food is inherently free of cholesterol or is processed to be that way. Several FDA surveys have shown that consumers want and use descriptor claims to identify foods having positive nutritional attributes (Refs. 19 through 21). These survey results, in conjunction with comments to the 1989 ANPRM, have persuaded FDA that the definitions established in this proposed rule respond to consumers' needs and help to educate consumers on the intrinsic properties of foods. Therefore, FDA has tentatively concluded that it is not necessary to limit "cholesterol free" claims to foods in which cholesterol is usually present or that substitute for foods that usually contain cholesterol.

However, the agency is concerned that unrestricted use of "free" claims on foods that are inherently free of cholesterol can be misleading since the claim could imply that the particular brand of food bearing the claim is different from other foods of the same type. Accordingly, FDA is proposing in § 101.62(d)(1)(ii)(D) to require that if a food is inherently free of cholesterol (i.e., it has not been processed, altered, formulated, or reformulated to remove cholesterol) it may make a cholesterol claim only if the claim refers to all foods of that type and not merely to the particular brand to which the labeling is attached (e.g., "Canola oil, a cholesterol-free food"). Such claims are subject to additional disclosure requirements in § 101.62 and § 101.13 (e.g., "Contains 14 g fat per serving" and "See [*appropriate panel*] for information on fat and other nutrients"). (Note: The agency does not consider margarines to be inherently free of cholesterol since the standard of identity for margarine allows for the use of animal fats.)

This requirement is consistent with the general policy on "free" and "low" nutrient content claims stated in rulemaking for sodium (49 FR 15510 at 15517) and cholesterol descriptor claims (51 FR 42584 at 42589 and 55 FR 29456 at 29465) and set forth in current § 105.66(c)(2) for "low calorie" claims. The agency has taken the position that foods inherently free of, or low in, a nutrient should not be labeled with a claim such as "cholesterol free," or "low cholesterol," immediately preceding the name of the food because such terminology would imply that the food has been altered to remove the nutrient as compared to other foods of the same type. Thus, FDA is proposing in § 101.62(d)(2)(i)(C) and (d)(2)(ii)(D) that foods that inherently contain 20 mg or less of cholesterol may be labeled as "low cholesterol" as long as the label makes clear that all foods of that type, and not merely the brand to which the label attaches, are low in cholesterol (e.g., "lowfat cottage cheese, a low cholesterol food").

For the same reasons, FDA is proposing in § 101.62(d)(1)(i)(C) to reflect the statutory language of section 403(r)(2)(A)(ii)(II) of the act by proposing to require that foods that contain less than the disclosure level of fat and that are inherently free of cholesterol must disclose that cholesterol is not usually present if they make a "cholesterol free" claim (e.g., applesauce, a cholesterol free food"). Foods that contain less than the disclosure level of fat and that have been processed to contain less than 2 mg of the cholesterol that is usually present in the food, or that have substitutes that contain cholesterol, can bear a "cholesterol free" claim under section 403(r)(2)(A)(ii)(I) of the act and proposed § 101.62(d)(1)(i)(A).

e. *Application of saturated fat thresholds to "reduced cholesterol" foods.* Comments were mixed on whether the fat and saturated fat thresholds should apply to "reduced cholesterol" claims. Several comments expressed the belief that reduced claims should adhere to the same thresholds as "free" or "low" cholesterol claims to be consistent and, thereby, to avoid consumer confusion and to provide "a level playing field." One such comment expressed the opinion that any cholesterol claim will convey to consumers the impression that a food is a healthy choice, and, therefore, a "reduced cholesterol" claim would be misleading if it did not have the same thresholds as "free" and "low" claims. Opposing comments supported the proposed position of not applying threshold levels to foods making "reduced" claims, stating that the use of thresholds would prevent some foods from making claims, thereby depriving consumers of useful information and the selection of foods with significant reductions in cholesterol.

The agency is convinced by the comments and the scientific evidence that cholesterol content claims can be misleading to consumers if the product contains amounts of saturated fat that contribute to high blood cholesterol levels. As stated above, a cholesterol claim represents and suggests that the product provides a health benefit, and that benefit is missing if the product contains high levels of saturated fat. Therefore, under section 403(r)(2)(A)(vi) of the act, which prohibits a claim if the claim is misleading in light of the level

of another nutrient, the agency is proposing to apply the saturated fat threshold to "reduced" as well as to free" and "low" cholesterol claims. Accordingly, FDA is modifying proposed § 101.25(a)(iii) in the tentative final rule (redesignated as § 101.62(d)(4) in this document) to require that "reduced cholesterol" claims only be used on labels or in labeling of foods that contain less than 2 g of saturated fat per serving. For these reasons, the agency is also including a similar requirement in proposed § 101.62(d)(5) for comparative claims.

2. "Cholesterol Free"

a. *Definition.* FDA first proposed that a "cholesterol free" food be defined as one containing less than 2 mg of cholesterol per serving in its proposed rule of November 25, 1986 (51 FR 42584). The agency selected a cutoff of less than 2 mg of cholesterol because that level is biologically and nutritionally insignificant. Moreover, analytical precision below that limit is not possible (51 FR 42584 at 42588). This quantitative amount was carried forward in the agency's tentative final rule on cholesterol nutrient content claims (55 FR 29456). In the tentative final rule, the agency rejected comments to the 1986 proposal that suggested that the level used in defining "cholesterol free" should be changed. Differing comments had recommended both lowering the defined amount to absolute zero and raising it to 5 mg per serving. FDA responded that a zero level could not be detected with analytical certainty, and that raising the level up to 5 mg could result in consumption of dietarily significant amounts of cholesterol when only "cholesterol free" foods were consumed.

A few comments on the 1990 tentative final rule reiterated comments received on the 1986 proposed rule on cholesterol nutrient content claims (51 FR 42584) that the level used in defining "cholesterol free" should be modified. Comments again recommended lowering the defined amount to zero and raising it to 5 mg per serving. However, none of these comments presented any information that the agency had not already received in response to the 1986 proposal and considered in drafting the tentative final rule.

In its tentative final rule, FDA advised that it considered that document to contain the final determination of the agency on all substantive issues other than on the threshold levels of fat and saturated fatty acids, and that a comment would have to be very significant to cause the agency to make any changes in the rule other than to the threshold levels. Therefore, not being presented with any new evidence, FDA has not revised the level of cholesterol in the definition for "cholesterol free" in proposed § 101.25(a)(2)(i), redesignated in this document as § 101.62(d)(1).

FDA is not proposing a second criterion based on the amount of cholesterol per 100 g for the definition of "free" because the first proposed criterion for "cholesterol free" requires that the food contain such a trivial level of cholesterol from a public health perspective that even frequent consumption in large amounts of food that bear a claim would not affect in any meaningful way the overall cholesterol level in the diet.

b. *Synonyms.* In accordance with the discussion on synonyms in the companion document on nutrient content claims, the agency is proposing in § 101.62(d)(1) to add the term "zero cholesterol," "trivial source of cholesterol," "negligible source of cholesterol," and "dietary insignificant source of cholesterol" as a synonym for "cholesterol free," "free of cholesterol," and "no cholesterol." As suggested in the IOM report on nutrition labeling (Ref. 4), the use of consistent and targeted nutrient content claims increases consumers' confidence in the validity of the claim. The agency requests comments on whether consumers commonly understand the other synonyms to have the same meaning as "free."

3. "Low Cholesterol"

a. *Definition.* In its proposed rule of November 25, 1986 (51 FR 42584), FDA proposed to allow the term "low cholesterol" on the label or in labeling of foods that contain less than 20 mg of cholesterol per serving. The agency found that foods containing less than 20 mg of cholesterol per serving were generally those that had been identified as useful to persons who want to control or moderate their cholesterol intakes or to maintain their cholesterol intakes at relatively low levels.

Comments submitted to the proposed rule persuaded FDA to modify the proposed definition in its tentative final rule: (1) To change the definition from "less than 20 mg per serving" to "20 mg or less per serving," and (2) to add a second criterion based on density, namely that the food contain 0.2 mg or less of cholesterol per g of food. FDA made the first change to be consistent with the agency's other definitions for "low," for calories (§ 105.66(c)(1)(i)) and for sodium (§ 101.13(a)(3)), that include the integer in the definition.

FDA made the second change to prevent "low cholesterol" label claims from conveying a misleading impression about the cholesterol content of certain foods. Comments pointed out that a single criterion based on serving size could result in widely recognized "high cholesterol" foods with small serving sizes (e.g., butter, lard, and some processed cheese foods) being labeled as "low cholesterol." These comments stressed that despite their small serving sizes, such foods actually may be consumed frequently and in large amounts, resulting in a substantial total daily intake of cholesterol. In addition, the comments were concerned that a "low cholesterol" claim on such foods could encourage increased consumption of the food, significantly adding to an individual's total cholesterol intake.

The comments to the tentative final rule fully supported the first criterion for "low cholesterol" claims (i.e., that the food should contain 20 mg or less cholesterol per serving). However, several comments requested the second criterion based on cholesterol density (i.e., 0.2 mg per g) be eliminated. These comments argued that promulgation of a regulation specifying serving sizes would negate the need for the second criterion.

As explained in the companion document on nutrient content claims, the agency has determined that, for the reasons discussed above, there continues to be a need for a second criterion for "low" claims even when FDA's rulemaking on serving sizes is completed (Ref. 36). The agency is proposing in that document to base the second criterion on the amount of the nutrient per 100 g of food.

Accordingly, FDA is proposing to keep the second criterion for the definition of "low cholesterol." However, the agency is modifying proposed § 101.25(a)(ii), redesignated as § 101.62(d)(2), to specify the second criterion as 20 mg per 100 g of food rather than 0.2 mg per g, an identical amount.

This definition is in accordance with the general approach described in the companion document on nutrient content claims for arriving at a definition for "low." This approach is described above in the discussions of the definitions of "low fat" and "low in saturated fat." Under that approach, the definition of "low" for a nutrient that is ubiquitous in the food supply, such as calories, is 2 percent of the DRV. If the nutrient is not ubiquitous but is found in more than a few food categories, such as fat, FDA has proposed to define "low" as two times the level that is 2 percent of the DRV. If the nutrient is found at measurable levels in the foods in only a few food categories, the agency has

proposed to define "low" as three times 2 percent of the DRV. Cholesterol, which is found only in foods of animal origin, is in the latter group. The DRV for cholesterol is 300 mg, 2 percent of which is 6 mg. Therefore, the definition of "low" is 18 mg (three times 6 mg). Rounded to the nearest 5 mg increment as is required in current and proposed nutrition labeling regulations, the proposed level is 20 mg per 100 g of food.

FDA is also proposing in § 101.62(d)(2) to allow the use of the synonymous terms, "contains a small amount of cholesterol" in accordance with the discussion on synonyms in the proposed rule on nutrient content claims.

b. *Definition of "low cholesterol" meal-type product.* As discussed in the companion document on nutrient content claims and above for "low fat" claims for meal type products, the agency has received many comments requesting that FDA provide for the use of nutrient content claims on these products. In recognition of the increasing role that meal-type products have in the marketplace, the agency believes that it is important to establish nutrient content claims that will help consumers to identify positive nutritional characteristics of such products. Accordingly, FDA is proposing in § 101.62(d)(3) that a "low cholesterol" claim may be made for a meal-type product that contains 20 mg or less of cholesterol per 100 g of the product. This value is the same as that suggested by GMA (Ref. 22) and uses the same quantitative amount of cholesterol used to define "low cholesterol" for individual foods. As noted above, FDA finds merit in setting nutrient content claims for meal type products on the basis of the amount of a nutrient per 100 g rather than on the basis of the amount per serving and per 100 g as is done for most "low" claims for individual foods. FDA anticipates that people will not consume more than one or two meal-type products per day, rather than the average of 16 to 20 servings of individual foods (Refs. 15 through 17). Therefore, FDA tentatively concludes that it is not reasonable to expect meal-type products to meet the same per serving criteria as individual foods.

For the same reason, FDA is proposing that the saturated fat threshold in § 101.62(d)(2)(i)(B) and (d)(2)(ii)(B) be modified from 2 g or less per serving to 2 g or less per 100 g. This proposed level would allow a 10 ounce meal that meets the requisite cholesterol levels to make a "low cholesterol" claim if it contained less than 5.5 g of saturated fat, a value that is approximately ⅕ of the DRV for saturated fat. FDA is proposing to make a similar modification in the fat level in § 101.62(d)(2)(i) and (d)(2)(ii). Thus, under proposed § 101.62(d)(3), the determination as to whether § 101.62(d)(2)(i) or (d)(2)(ii) applies will be made on the basis of whether the product contains 11.5 g or less of fat per 100 g of food.

4. "Reduced Cholesterol"

In its proposal of November 25, 1986 (51 FR 42584), FDA proposed to allow a "reduced cholesterol" claim on a food that had been specially formulated or processed to reduce its cholesterol content by 75 percent. The 75 percent criterion reflected FDA's concern about the many foods that contain relatively large amounts of cholesterol, and the possibility that products with relatively high levels of cholesterol could easily claim to have reduced cholesterol content if the agency permitted a lesser reduction.

Comments on the proposed rule requested that the percent reduction be lowered to 30 or 50 percent because the 75 percent requirement was unrealistic and technologically infeasible. FDA was not persuaded that cholesterol levels could not be reduced by 75 percent in many foods, and, in accordance with the agency's intent that the "reduced cholesterol" claim be reserved for those products that accomplished a very substantial reduction in the level of cholesterol, it did not change the requirement in the tentative final rule (55 FR 29456).

Comments to the tentative final rule requested that the agency reevaluate its position on the definition of "reduced cholesterol," suggesting that the definition be lowered from 75 percent to 25 or 33 percent. The comments pointed out that consumption surveys reflect a decrease in consumption of cholesterol over the past two decades, and these comments argued that too stringent a requirement for "reduced cholesterol" would limit the incentive for industry to develop "reduced cholesterol" foods to further this trend.

The agency has reviewed the use of "reduced" claims for cholesterol in light of the general criteria for "reduced" nutrient content claims set out in the companion document on nutrient content claims. These general criteria take into consideration the level of reduction that would result in substantial reductions in the nutrient content of foods, the need for consistency of terms, the technological feasibility of reducing levels of nutrients in foods, and the need for dietary changes relative to current intakes of nutrients.

The basis for defining a substantial reduction of a nutrient in food should include consideration of the distribution of the nutrient within the food supply and the amount of reduction that is necessary to produce a substantial reduction in the amount of the nutrient in the diets of individuals. Dietary cholesterol is not ubiquitous in the food supply. It is found only in foods of animal origin. Accordingly, if dietary intake levels of cholesterol are to be reduced substantially, it is important to make substantial reductions in individual foods that are major sources of cholesterol. FDA has reevaluated what level of reduction constitutes a substantial reduction in cholesterol content for several reasons.

First, FDA's 1988 Food Labeling and Package Survey (FLAPS) did not encounter any foods that made "reduced cholesterol" claims (Ref. 37). A few foods that had removed all of their cholesterol content (i.e., egg substitutes) properly bore "cholesterol free" rather than "reduced cholesterol" claims. These results of the FLAPS survey, in addition to earlier comments about the technological unfeasibility of a 75 percent reduction, are significant.

Moreover, comments indicate that lowering the defined level of reduction for "reduced cholesterol" claims from 75 percent to 50 percent would give industry greater incentive to develop new foods that meet the criterion through special processing or reformulation. In addition, this change would allow for greater consistency in the definitions of "reduced" foods because the agency is proposing that "reduced" claims for sodium, fat, and saturated fat be defined as a 50 percent reduction. The importance of such consistency of terms for consumer education purposes was emphasized at the 1989 public hearings and in comments to the ANPRM.

FDA has also examined the need for dietary change in light of dietary recommendations. In the case of dietary cholesterol, NAS's "Diet and Health" report (Ref. 6) and the NCEP report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction (Ref. 9) recommend consumption of less than 300 mg of cholesterol per day. The agency compared these values to current intake levels reported in a recent food consumption survey and estimates that a reduction in cholesterol intake of 20 percent is needed to lower the cholesterol content of the American diet to amounts recommended in dietary

guidance (Ref. 27). Since substantial reductions in cholesterol can only be made in a few food categories, it is reasonable to triple this value, as was done in calculations above for defining "low cholesterol" foods, to bring the percent change needed to 60 percent, a value that could appropriately be rounded down to 50 percent to maintain consistency with the proposed definitions for "reduced fat," "reduced saturated fat," and "reduced sodium." FDA is persuaded by the comments that a 75 percent reduction, as originally proposed for "reduced cholesterol" claims in 1986 (51 FR 42584) and carried forward in the tentative final rule (55 FR 29456), is not necessary. The factors discussed above, in addition to recent food consumption survey data showing a decrease in cholesterol intake levels, have convinced the agency that the earlier proposed requirement for a 75 percent reduction is not necessary to evoke a sufficient change in the food supply to allow the public to meet current dietary recommendations. Accordingly, the agency is proposing in § 101.62(d)(4)(i)(A) and (d)(4)(ii)(A) that the term "reduced cholesterol" may be used on foods that have been formulated or processed to reduce their cholesterol content by 50 percent.

However, to ensure that a 50 percent reduction amounts to more than an inconsequential reduction in cholesterol content, the agency is also proposing in § 101.62(d)(4)(i)(A) and (d)(4)(ii)(A) to add a second criterion that there be a minimum reduction of more than 20 mg per serving from the reference food. This criterion is consistent with the second criterion for other "reduced" nutrient content claims discussed above and represents an absolute reduction that is no less than the amount which is considered "low."

As proposed in § 101.13(j)(1) of the companion document on nutrient content claims, the reference foods against which "reduced cholesterol" claims are to be measured are either an industry-wide norm or the manufacturer's regular product. These reference points are defined and discussed above in the section on "reduced fat" claims.

The agency is proposing in § 101.62(d)(4)(i)(C) and (d)(4)(ii)(D) that the food that bears a "reduced cholesterol" claim be labeled in compliance with § 101.13(j)(2) as proposed in the companion document on nutrient content claims. This proposed section requires information in immediate proximity to the most prominent use of the claim of the extent (percent or fraction) that the cholesterol is reduced, the identity of the reference food to which it is compared, and the quantitative information comparing the actual amount of cholesterol in a serving of the food to the amount in the reference food.

5. Comparative Claims

Consistent with the earlier discussion of comparative claims describing the fat content of foods, FDA is proposing in § 101.62(d)(5) to allow the use of comparative claims using the term "less" for foods that have been reformulated, altered, or processed in a way that has resulted in a reduction of cholesterol. Proposed § 101.62(d)(5)(i)(A) and (d)(5)(ii)(A) would require a reduction of 25 percent or more in cholesterol and a minimum reduction of more than 20 mg of cholesterol per serving from a reference food. The agency believes that a reduction of 25 percent or more is necessary to ensure that consumers are not misled by claims for reductions that are inconsequential, i.e., that the products will serve a useful role in the diet of those individuals who are attempting to limit their consumption of cholesterol. Additionally, consistent with other relative claims, FDA believes it is important to provide for an absolute reduction that is not less than the amount that is defined as "low" (i.e., more than 20 mg of cholesterol per serving).

As discussed with respect to comparative claims for fat, FDA is proposing in § 101.13(j)(1) in the companion document on nutrient content claims that for comparative claims, the reference food may be an industry-wide norm, the manufacturer's regular product, or, if the comparison is to a class of similar foods, a current, valid data base such as USDA's Handbook No. 8, "Composition of Foods, Raw, Processed, Prepared."

Additionally, the labeling requirements proposed in § 101.62(d)(5)(i)(C) and (d)(5)(ii)(D) are identical to those in proposed § 101.13(j)(2) for all other relative claims. They require, in immediate proximity to the most prominent use of the claim, the percent or fraction that the cholesterol is reduced, the identity of the reference food to which it is compared, and the quantitative information comparing the actual amount of cholesterol in a serving of the food to the amount in the reference food.

IV. Conditions of Use of Defined Terms

A. Foods for Children

In § 101.13(a) of the companion document on nutrient content claims, the agency is proposing to prohibit the use of nutrient content claims, including claims about the fat, fatty acid, or cholesterol content on foods that are specifically intended for infants and toddlers less than 2 years of age. This provision is consistent with the agency's proposed exclusion of the use of claims about cholesterol and fatty acid content in such foods in proposed § 101.25(a)(1)(ii) and (b)(2), respectively, of the tentative final rule on cholesterol nutrient content claims (55 FR 29456).

The agency proposed this provision (55 FR 29456) based on comments to its 1986 proposal on cholesterol nutrient content claims (51 FR 42584). These comments stated that changing the diet of these children toward a more restrictive dietary pattern should await demonstration that such dietary restriction is needed and would support adequate growth and development. The agency agreed with these comments and proposed to exclude the use of nutrient content claims and quantitative cholesterol and fatty acid labeling on foods specifically intended for use by infants and toddlers. The agency tentatively concludes that this exclusion should also apply to fat nutrient content claims because the issue of a suitable dietary pattern for infants and toddlers includes the issue of the total fat content of their diet. There is agreement among the American Academy of Pediatrics, the American Heart Association, the National Institutes of Health's Consensus Conference on Lowering Blood Cholesterol, and the NCEP that fat and cholesterol should not be restricted in the diets of infants (Ref. 38).

Until the agency has information that a more restrictive dietary pattern (as might be encouraged by the use of these nutrient content claims) is appropriate for these children and would support adequate growth and development, the agency is proposing to bar the use of these nutrient content claims on food products that are specifically intended for infants and toddlers.

B. Use of Defined Terms in Conjunction with Statement of Identity

Comments on the 1989 ANPRM addressed the issue of how claims that describe the fat content of foods should be used with the names of standardized foods. Some of the comments suggested that these terms be allowed in conjunction with the names of standardized foods, even when the resulting food no longer complies with the standard.

This is an important issue that has ramifications for all nutrient content claims. Accordingly, FDA has prepared

a separate document on this issue. It is published elsewhere in this issue of the **Federal Register.**

C. Misbranding

Proposed § 101.25(g), which was numbered as § 101.25(d) in the cholesterol tentative final rule (55 FR 29456), states that any label or labeling that is not in conformity with this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act. The agency is proposing to retain this provision, redesignated as § 101.62(e) and modified to include authority under section 403(r) of the act.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register.** The agency requests comments on the RIA.

VII. Effective Date

FDA notes, however, that in section 10(a)(3)(B) of the 1990 amendments, Congress provides that if the Secretary of Health and Human Services (the Secretary), and by delegation FDA, finds that requiring compliance with section 403(q) of the act, on mandatory nutrition labeling, or with section 403(r)(2) of the act, on nutrient content claims, 6 months after publication of the final rules in the **Federal Register** would cause undue economic hardship, the Secretary may delay the application of these sections for no more than 1 year. In light of the agency's tentative findings in its regulatory impact analysis that compliance with the 1990 amendments by May 8, 1993, will cost $1.5 billion, and that 6 month and 1 year extensions of that compliance date will result in savings that arguably outweigh the lost benefits, FDA believes that the question of whether it can and should provide for an extension of the effective date of sections 403(q) and (r)(2) of the act is squarely raised.

FDA has carefully studied the language of section 10(a)(3)(B) of the 1990 amendments and sees a number of questions that need to be addressed. The first question is the meaning of "undue economic hardship." FDA recognizes that the costs of compliance with the new law are high, but those costs derive in large measure from the great number of labels and firms involved. The agency questions whether the costs reflected in the aggregate number represent "undue economic hardship." Therefore, FDA requests comments on how it should assess "undue economic hardship." Should it assess this question on a firm-by-firm basis, as was provided in the bill that passed the House Committee on Energy and Commerce (H. Rept. 101–538, 101st Cong., 2d sess., 24 (1990)), an industry-by-industry basis, or should it assess this question on an aggregate basis? If the agency should take the latter approach, comments should provide evidence that would permit the agency to make a determination that there is "undue economic hardship" for most companies. FDA also points out that assessing hardship on a firm-by-firm basis would likely be extremely burdensome because of the likely number of requests.

FDA will consider the question of the meaning and appropriate application of section 10(a)(3)(B) of the 1990 amendments as soon as possible after the comment period closes. The agency intends to publish a notice in advance of any final rule announcing how it will implement this section to assist firms in planning how they will comply with the act. The early publication of this notice is to assist firms in avoiding any unnecessary expenses that could be incurred by trying to comply with a compliance date that may cause "undue economic hardship."

VIII. Comments

Interested persons may, on or before February 25, 1991, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with section 3(b)(1)(B) of the 1990 amendments, FDA must issue by November 8, 1992, final regulations permitting nutrient content claims for fat and cholesterol. If the agency does not promulgate final regulations by November 8, 1992, section 3(b)(2) of the 1990 amendments provides that the regulations proposed in this document shall be considered as the final regulations. The agency has determined that 90 days is the maximum time that it can provide for the submission of comments and still meet this statutory timeframe for the issuance of final regulations. Thus, the agency is advising that it will not consider any requests under 21 CFR 10.40(b) for extension of the comment period beyond February 25, 1992. The agency must limit the comment period to no more than 90 days to assure sufficient time to develop a final rule based on this proposal and the comments it receives.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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2. Vanderveen, J. E., letter to Stop and Shop Supermarket Co., October 11, 1985.

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15. Interagency memorandum from Connie Marie Dresser, National Center for Health Statistics, to Marilyn Stephenson, Food and Drug Administration, December 3, 1981.

16. Human Nutrition Information Service, "Nationwide Food Consumption Survey—1986," NFCS, Continuing Survey of Food Intakes by Individuals, Report No. 86-3, U.S. Department of Agriculture, Hyattsville, MD, September 1988, p. 168.

17. Buzzard, I. M., Letter to Virginia Wilkening, February 12, 1991.

18. Humphrey, H.H., III, letter to Commissioner James Benson, July 11, 1990.

19. Heimbach, J.T., "Public Understanding of Food Label Information," FDA (HFF-240), 200 C St. SW., Washington, DC, May 1982.

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22. Gardner, S., and Guarino, E.T., Letter to Fred R. Shank, May 10, 1991.

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24. U.S. Department of Health and Human Services, Public Health Service, "Healthy People 2000: National Health Promotion and Disease Prevention Objectives," DHHS (PHS) Publication No. 91-50213, U.S. Department of Health, and Human Services, Washington, DC, 1991, pp. 33 and 39.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

§ 101.25 [Removed]

2. Section 101.25 *Labeling of foods in relation to fat and fatty acid and cholesterol content* is removed.

3. Section 101.62 is added to subpart D to read as follows:

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a food may only be made on the label and in the labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or, where applicable, § 101.36.

(b) *Fat content claims.* (1) The terms "fat free," "free of fat," "no fat," "zero fat," "nonfat" "trivial source of fat," "negligible source of fat," or "dietarily insignificant source of fat" may be used on the label or in labeling of a food provided that:

(i) The food contains less than 0.5 gram of fat per reference amount customarily consumed and per labeled serving size;

(ii) The food contains no added ingredient that is a fat or oil; and

(iii) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to disclose that fat is not usually present in the food (e.g., "broccoli, a fat-free food").

(2) The terms "low fat," "low in fat," "contains a small amount of fat," "low source of fat," or "little fat" may be used on the label or in labeling of foods, except meal-type products as defined in § 101.13(l), provided that:

(i) The food contains 3 grams or less of fat per reference amount customarily consumed, per labeled serving size, and per 100 grams of food; and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "frozen perch, a low fat food").

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 101.13(l) that:

(i) The product contains 3 grams or less of fat per 100 grams; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms "reduced fat," "reduced in fat," or "fat reduced" may be used on the label or in labeling of a food, except meal-type products as defined in § 101.13(l), provided that:

(i) The food has been specifically formulated, altered, or processed to reduce its fat content by 50 percent or more, with a minimum reduction of more than 3 grams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 101.13 (j)(1)(i) and (j)(1)(ii); and

(ii) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the fat has been reduced; the identity of the reference food; and quantitative information comparing the level of fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., "Reduced fat—50 percent less fat than our regular brownie. Fat content has been reduced from 8 grams to 4 grams per serving").

(5) A comparative claim using the term "less" may be used on the label or in labeling of a food, including meal-type products as defined in § 101.13(l), provided that:

(i) The food contains at least 25 percent less fat, with a minimum reduction of more than 3 grams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 101.13 (j)(1)(i), (j)(1)(ii), and (j)(1)(iii); and

(ii) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the fat has been reduced; the identity of the reference food; and quantitative information comparing the level of fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g. "This pound cake contains 40 percent less fat than our regular pound cake. Fat content has been lowered from 10 grams to 6 grams per serving.").

(6) The term "____ percent fat free" may be used on the label or in labeling of a food provided that:

(i) The food meets the criteria for "low fat" in paragraph (b)(2) or (b)(3) of this section.

(ii) The label or labeling discloses the amount of total fat per serving (as declared on the label) of the food expressed to the nearest 1/2 gram. When the total fat content is less than 0.5 grams per serving, the amount may be declared as "0." Such disclosure shall appear in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) and in type size that shall be no less than one half the size of the type used for such claim.

(iii) The percent of reduction and the words "fat free" are in uniform type size.

(iv) A claim for "100 percent fat free" meets all criteria for "fat free" in paragraph (b)(1) of this section.

(c) *Fatty acid content claims.* The label or labeling of foods that bear claims with respect to the level of saturated fat shall disclose the level of total fat and cholesterol in the food in immediate proximity to such claim each time the claim is made and in type that shall be no less than one-half the size of the type used for the claim with respect to the level of saturated fat. Declaration of cholesterol content may be omitted when the food contains less than 2 milligrams of cholesterol per labeled serving size.

(1) The terms "low in saturated fat," "low saturated fat," "contains a small amount of saturated fat," "low source of saturated fat," or "a little saturated fat" may be used on the label or in labeling of a food, except meal type products as defined in § 101.13(l), provided that:

(i) The food contains 1 gram or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and not more than 15 percent of calories from saturated fatty acids.

(ii) If a food meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "raspberries, a low saturated fat food").

(2) The terms defined in paragraph (c)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 101.13(1) provided that:

(i) The product contains 1 gram or less of saturated fatty acids per 100 grams of food; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(3) The terms "reduced saturated fat," "reduced in saturated fat," or "saturated fat reduced" may be used on the label or in labeling of a food, except meal-type products as defined in § 101.13(1), provided that:

(i) The food has been specifically formulated, altered, or processed to reduce its saturated fatty acid content by 50 percent or more, with a minimum reduction of more than 1 gram per reference amount customarily consumed and per labeled serving size from the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i) and (j)(1)(ii); and

(ii) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the saturated fat was reduced; the identity of the reference food; and quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., "Reduced saturated fat. Contains 50 percent less saturated fat than the national average for nondairy creamers. Saturated fat reduced from 3 grams to 1.5 grams per serving").

(4) A comparative claim using the term "less" may be used on the label or in labeling of a food, including meal-type products as defined in § 101.13(l), provided that:

(i) The food contains at least 25 percent less saturated fat with a minimum reduction of more than 1 gram per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii); and

(ii) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the saturated fat was reduced; the identity of the reference food; and quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., "Brand Y crackers contains 40 percent less saturated fat than our regular Brand X crackers. Brand Y contains 6 grams saturated fat; Brand X contains 10 grams saturated fat.").

(d) *Cholesterol content claims.* (1) The terms "cholesterol free," "free of cholesterol," "zero cholesterol," "no cholesterol," "trivial source of cholesterol," "negligible source of cholesterol," or "dietarily insignificant source of cholesterol" may be used on the label or in labeling of a food provided that:

(i) For foods that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams of food:

(A) The food contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size;

(B) The food contains 2 grams or less of saturated fat per reference amount customarily consumed and per labeled serving size;

(C) As required in § 101.13(e), if the food contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the food (e.g., "applesauce, a cholesterol-free food").

(ii) For foods that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of food:

(A) The food contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size;

(B) The food contains 2 grams or less of saturated fat per reference amount customarily consumed and per labeled serving size;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim appears more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(e), if the food contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the food (e.g., "Canola oil, a cholesterol-free food, contains 14 grams of fat/serving"); or

(E) If the food contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(5)(i)(A) of this section) than the food for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more) market share. As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the cholesterol was reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., Cholesterol free margarine, contains 100 percent less cholesterol than butter. Contains no cholesterol compared with 30 milligrams in one serving of butter. Contains 11 grams of fat per serving.")

(2) The terms "low in cholesterol," "low cholesterol," "contains a small amount of cholesterol," "low source of cholesterol," or "little cholesterol" may be used on the label or in labeling of a food, except meal type products as defined in § 101.13(1), provided that:

(i) For foods that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams of food:

(A) The food contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of food;

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size;

(C) As required in § 101.13(e), if the food contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of food without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., "lowfat cottage cheese, a low cholesterol food").

(ii) For foods that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of food:

(A) The food contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of food;

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(e)(2), the food contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of food without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches; or

(E) If the food contains 20 milligrams or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(5)(i)(A) of this section) than the food for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more) market share. As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the cholesterol has been reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., "Low cholesterol peanut butter sandwich crackers, contains 83 percent less cholesterol than our regular peanut butter sandwich crackers. Cholesterol lowered from 30 milligrams to 5 milligrams per serving, contains 13 grams of fat per serving.").

(3) The terms listed in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 101.13(1) provided that the product meets the requirements of paragraph (d)(2) of this section except that the determination as to whether paragraph (d)(2)(i) or (d)(2)(ii) of this section applies to the product will be made only on the basis of whether the product contains 11.5 grams or less of fat per 100 grams of food, the

requirement in paragraphs (d)(2)(i)(A) and (d)(2)(ii)(A) of this section shall be limited to 20 milligrams of cholesterol per 100 grams, and the requirement in paragraphs (d)(2)(i)(B) and (d)(2)(ii)(B) of this section shall be modified to require that the food contain 2 grams or less of saturated fat per 100 grams rather than per reference amount customarily consumed and per labeled serving size.

(4) The terms "reduced cholesterol," "reduced in cholesterol" or "cholesterol reduced" may be used on the label or in labeling of a food or a food that substitutes for that food as specified in § 101.13(d), except meal type products as defined in § 101.13(l), provided that:

(i) For foods that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams:

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol content by 50 percent or more, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size from the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i) and (j)(1)(ii);

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) As required in § 101.13(j)(2) for relative claims, the percent that the cholesterol has been reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii).

(ii) For foods that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of food:

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol content by 50 percent or more, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food (as defined in § 101.13(j)(1)(i) and (j)(1)(ii)) that it resembles and for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more) market share;

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the cholesterol has been reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii).

(5) A comparative claim using the term "less" may be used on the label or in labeling of a food or a food that substitutes for that food as specified in § 101.13(d), including meal-type products as defined in § 101.13(1), provided that:

(i) For foods that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams:

(A) The food contains at least 25 percent less cholesterol, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii);

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) As required in § 101.13(j)(2) for relative claims, the percent that the cholesterol was reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii).

(ii) For foods that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of food:

(A) The food contains at least 25 percent less cholesterol, with a minimum reduction of 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food as defined in § 101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii) that it resembles and for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more) market share;

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear each time the claim is made, in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the cholesterol was reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., "This pound cake contains 30 percent less cholesterol than our regular pound cake. Cholesterol lowered from 45 milligrams to 30 milligrams per serving. Contains 12 grams of fat per serving.").

(e) *Misbranding.* Any label or labeling containing any statement concerning fat, fatty acids, or cholesterol that is not in conformity with this section shall be deemed to be misbranded under sections 201(n), 403(a), and 403(r) of the Federal Food, Drug, and Cosmetic Act.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27159 Filed 11-26-91; 8:45 am]

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21 CFR Part 101

[Docket No. 84N-153A]

RIN 0905-AD08

Food Labeling: "Cholesterol Free," "Low Cholesterol," and "____ Percent Fat Free" Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its food labeling regulations to define "cholesterol free" and "low cholesterol" and to provide for the proper use of these terms and the term "____ percent fat free." The proposed rule is intended to ensure that these terms are not used in a manner that is misleading to consumers. In this document, FDA is also responding to the comments that it received in response to its tentative final rule on cholesterol claims (55 FR 29456, July 19, 1990) that pertain to use of the terms "cholesterol free" (including "no cholesterol" and "free of cholesterol") and "low cholesterol."

DATES: Written comments by January 27, 1992. The agency is proposing that any final rule that may be issued based upon this proposal become effective 30 days following its publication.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Virginia L. Wilkening, Center for Food Safety and Applied Nutrition (HFF-204), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1561.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has had a long interest in the proper labeling of foods with information on fat and cholesterol content. FDA's policies have reflected contemporary knowledge on the effect of these food components on health.

Because there was a lack of agreement on the relationship between fat and cholesterol and good health at the time the agency's current regulations were adopted, FDA limited the amount of information that could be provided on the food label about these food components. The relevant regulations are 21 CFR 101.9(c)(6) (formerly 21 CFR 1.17), which requires that the fat content of a food be included in the nutrition label (38 FR 2132, January 19, 1973; and amended at 38 FR 6951, March 14, 1973), and 21 CFR 101.25 (formerly 21 CFR 1.18) (42 FR 14302, March 15, 1977), which provides for the voluntary listing of cholesterol and fatty acid content as part of the food's nutrition label. No other information on fat or cholesterol content is permitted.

In 1986, however, with the emergence of a consensus that limiting dietary cholesterol would contribute to good health, FDA published a proposal to define terms that describe the cholesterol content of foods, including "cholesterol free" and "low cholesterol" (51 FR 42584, November 25, 1986). FDA also proposed to require that whenever these or other terms describing cholesterol content are used on the label, the cholesterol and fatty acid content of the food must be declared in the nutrition label.

As part of the Secretary of the Department of Health and Human Services' food labeling initiative, FDA issued a tentative final rule on cholesterol labeling on July 19, 1990 (55 FR 29456). In announcing that FDA would publish this document, Secretary Louis W. Sullivan stated: "All of us have been frustrated by the misuse of these terms, and only clear, standardized definitions will help us eliminate misleading claims." (Ref. 1.)

In the document FDA addressed the comments that it had received on the 1986 proposal. Many of the comments requested that FDA limit the amount of fat and saturated fatty acids that could be present in foods on which cholesterol claims are made. FDA agreed with these comments and, in the tentative final rule (55 FR 29456), the agency proposed to limit the fat and saturated fatty acid content of foods bearing such claims.

FDA proposed to limit the use of "cholesterol free" and "low cholesterol" to foods that, in addition to containing the requisite cholesterol levels, contain not more than 5 grams (g) of fat and not more than 2 g of saturated fatty acids per serving. On a dry weight basis, these foods could contain not more than 20 percent fat and not more than 6 percent saturated fatty acids. The agency did not propose to change the requisite cholesterol level for "cholesterol free" foods from the 1986 proposal. However, in the case of "low cholesterol" foods, FDA proposed to change the amount of cholesterol per serving from "less than 20 mg" to "20 mg or less" and to add a second criterion, 0.2 mg or less cholesterol per g of food.

On November 8, 1990, the President signed the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). The 1990 amendments made the most significant changes in food labeling law since the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (the act). The 1990 amendments strengthen the Secretary's food labeling initiative by clarifying FDA's legal authority to require nutrition labeling on foods and by defining the circumstances under which claims may be made about the nutrients in foods. Specifically, the 1990 amendments add section 403(r), which deals with claims on foods, to the act. Section 403(r)(1)(A) of the act states that a food is misbranded if a claim is made on the label or labeling that characterizes the level of any nutrient of the type required to be declared in nutrition labeling unless the claim conforms to the specific requirements of the act.

The 1990 amendments directly affect FDA's July 19, 1990 tentative final rule on cholesterol claims. Because of the magnitude of changes needed in the tentative final rule to bring it into conformity with requirements of the 1990 amendments, the agency is issuing a new proposed rule on cholesterol descriptors elsewhere in this issue of the **Federal Register**. The agency is including in that proposal definitions for fat and fatty acid descriptors because of the interrelationship of these food components and cholesterol in the etiology of cardiovascular disease. The 1990 amendments require that FDA propose new regulations by November 8, 1991, and issue final regulations by November 8, 1992. These regulations will go into effect in May of 1993.

As the rulemaking on cholesterol labeling has proceeded, however, FDA has grown progressively more concerned about the "cholesterol free" ("no cholesterol" or "free of cholesterol"), "low cholesterol," and ____ percent fat free" claims that have appeared in the marketplace. The agency's concerns culminated in May of 1991 in an FDA decision to advise a number of companies that the "no cholesterol" claims that they made on their products were misleading (Refs. 1a through 6). Each of the manufacturers that FDA contacted made a product that, while containing no cholesterol, was high in total fat and bore a picture of a heart or some other representation that implied that the food was particularly good for the heart. FDA advised the firms that their products were misbranded under sections 201(n) and 403(a) of the act (21 U.S.C. 321(n) and 343(a)) because their labels failed to reveal that dietary factors other than cholesterol content play a necessary role in achieving a healthy heart, and that the products were high in fat, and excess fat in the diet is a general health

risk. All of the firms that received letters from FDA agreed to modify their labels.

On June 6, 1991, in a speech given at the 20th Anniversary Conference sponsored by the Center for Science in the Public Interest, the Commissioner of FDA outlined the agency's concerns about "____ percent fat free" claims:

> The high number—often 90 percent, 93 percent, and even 97 percent—linked with a desirable characteristic—"fat free"—leads people to conclude that the food itself promotes good health. It can also lead people to conclude that they can eat as much of it as they want. * * * We believe that this kind of assertion confuses and misleads consumers. Foods that derive a high percentage of their calories from fat should not be making low fat claims.
> (Ref. 7)

The Commissioner called on industry to remove these claims from their products.

In response to FDA's actions, the food industry has expressed concern about what it perceives as a lack of rules regarding cholesterol and "____ percent fat free" claims. Industry has argued that fairness suggests that FDA should provide a set of rules under which such claims may or may not be made before the agency institutes enforcement actions. FDA is addressing these concerns in this proposal.

The agency intends to act on this proposal in an expeditious manner. The agency intends to publish a final rule in this proceeding as quickly as possible, and that that final rule will establish interim rules until the final rule implementing the 1990 amendments is promulgated.

II. Basis for Action

FDA has decided that manufacturers should not be permitted to continue to make misleading "cholesterol free" (including "no cholesterol" and "free of cholesterol"), "low cholesterol," and "____ percent fat free" claims while the rulemaking under the 1990 amendments goes forward. The agency has focused on these claims because of the wide industry use of them, and because of the significant effect that they can have on the public health if misused. Therefore, the agency has tentatively decided to adopt interim regulations that lay out the circumstances in which these claims may be made on the food label. Although "reduced cholesterol" and comparative claims were also proposed in the tentative final rule, they are not being addressed in this document because they are rarely found in the marketplace and have not been identified as a source of misleading claims.

The agency is not proposing these rules because it believes that such rules are a necessary prerequisite to enforcement actions against products that misuse "free" and "low cholesterol" and "____ percent fat free" claims. FDA can and will take actions against products that are misbranded at any time.

FDA is issuing these proposed regulations under sections 201(n), 403(a), and 701(a) of the act, and not under the new sections added by the 1990 amendments. FDA believes that these three provisions provide ample authority for the regulations that it is proposing. Section 403(a) of the act states that a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act states that labeling may be misleading not only because of representations made on or in the labeling, but also to the extent that the labeling fails to bear facts material in light of the representations made or material with respect to the consequences that may result from use of the article. Finally, section 701(a) of the act authorizes the agency to adopt regulations for the efficient enforcement of the act.

Although the agency is not relying on the 1990 amendments for legal authority to adopt these proposed interim regulations (in fact, the regulations that will be adopted under the 1990 amendments will supersede these proposed regulations if they are adopted by the agency), the agency has reviewed this proposal in light of the 1990 amendments. The agency recognizes that these proposed interim regulations do not exactly track the 1990 amendments. However, because the purpose of these proposed regulations, like that of the 1990 amendments, is to assure that certain cholesterol and fat claims are not made in a misleading manner, the agency is satisfied that these proposed regulations are not inconsistent with the 1990 amendments.

As stated above, elsewhere in this issue of the **Federal Register**, FDA is publishing a document on fat, saturated fat, and cholesterol nutrient content claims under the 1990 amendments. FDA plans to publish, if possible, the final rule in that proceeding so that comprehensive rules on nutrient content claims for these nutrients are in place at the same time.

III. The Proposed Regulations

A. Modifications of Section 101.25

FDA is proposing to remove § 101.25(a), (b)(2)(ii), (b)(2)(iii), (c)(1), (c)(2)(i), (c)(2)(iii), (d), and (g) because they are out of date. The agency had proposed to delete these provisions of § 101.25 in its proposed rule on cholesterol descriptors (51 FR 42584). The only comments received on these deletions addressed the deletion of percent of calories from fat in § 101.25(c)(2)(i). FDA responded to these comments in the tentative final rule on cholesterol descriptors (55 FR 29456 at 29469).

FDA is also proposing to revise § 101.25(b), (c), and (h) to reflect these deletions and to add a new paragraph (d) as described below.

B. Cholesterol Claims

FDA is proposing to permit "cholesterol free" and "low cholesterol" claims on foods that meet specific requirements that will ensure that these claims are not used in a misleading manner. These requirements, as proposed in § 101.25(d)(1) and (d)(2), are:

(1) That the food must contain no more than the requisite levels of cholesterol;

(2) That the food must contain 2 g or less of saturated fat per serving;

(3) That the label or labeling must disclose the amount of fat per serving in conjunction with the cholesterol claim; and

(4) That, if a food is inherently free of, or low in, cholesterol, the food must be labeled to refer to all foods of that type and not to a particular brand.

1. Definition

a. *"Cholesterol free"*. FDA first proposed that a "cholesterol free" food be defined as one containing less than 2 mg of cholesterol per serving in its proposed rule of November 25, 1986 (51 FR 42584). That discussion is included herein by reference. The agency selected the cutoff of less than 2 mg of cholesterol because that level is biologically and nutritionally insignificant. Moreover, analytical precision below that limit is not possible (51 FR 42584 at 42588). This quantitative amount was carried forward in the agency's tentative final rule on cholesterol descriptors (55 FR 29456). In the tentative final rule, the agency rejected comments to the 1986 proposal suggesting that the level used in defining "cholesterol free" should be changed. Differing comments had recommended both lowering the defined amount to absolute zero and raising it to 5 mg per serving. FDA responded that a zero level could not be detected with analytical certainty, and that raising the level to 5 mg could result in consumption of dietarily significant amounts of

cholesterol when only "cholesterol free" foods were consumed.

In its tentative final rule, FDA advised that it considered that document to contain the final determination of the agency on all substantive issues other than on the threshold levels of fat and saturated fatty acids above which a "cholesterol free" claim would be misleading, and that a comment would need to be very significant to cause the agency to make any changes in the rule other than to the threshold levels. No new evidence on this issue was presented in comments on the tentative final rule. Therefore, FDA has not revised the definition for "cholesterol free."

This rule applies to all the phrases that mean the product has no cholesterol, such as "cholesterol free," "free of cholesterol," "no cholesterol," and "does not have any cholesterol." It is not possible to list here all descriptive phrases that would lead consumers to believe the product had no cholesterol. This regulation is designed to govern all such phrases.

b. *"Low cholesterol".* In its proposed rule of November 25, 1986 (51 FR 42584), FDA proposed to allow the term "low cholesterol" on the label or labeling of foods that contain less than 20 mg of cholesterol per serving. That discussion is included herein by reference. The agency found that foods containing les than 20 mg of cholesterol per serving were generally those that had been identified as useful to persons who want to control or moderate their cholesterol intakes or to maintain their cholesterol intakes at relatively low levels.

Comments submitted to the proposed rule persuaded FDA to modify the proposed definition in its tentative final rule: (1) To change the definition from "less than 20 mg per serving" to "20 mg or less per serving," and (2) to add a second criterion based on density, namely that the food contain 0.2 mg or less of cholesterol per g of food. The first change was made to be consistent with FDA's other definitions for "low," for calories (§ 105.66(c)(1)(i)) and for sodium (§ 101.13(a)(3)), that include the integer in the definition.

FDA made the second change to prevent "low cholesterol" label claims from conveying a misleading impression about the cholesterol content of certain foods. Comments pointed out that a single criterion based on serving size could result in widely recognized "high cholesterol" foods with small serving sizes (e.g., butter, lard, and some processed cheese foods) being labeled as "low cholesterol." These comments stressed that despite their small serving sizes, such foods actually may be consumed frequently and in large amounts, resulting in a substantial total daily intake of cholesterol. In addition, the comments were concerned that a "low cholesterol" claim on such foods could encourage increased consumption of the food, significantly adding to an individual's total cholesterol intake.

The comments to the tentative final rule fully supported the first criterion for "low cholesterol" claims (i.e., that the food should contain 20 mg or less cholesterol per serving). However, several comments requested that the second criterion (i.e., 0.2 milligram per gram (mg/g)) be eliminated. These comments argued that promulgation of a regulation specifying serving sizes would negate the need for the second criterion.

Based on a review of the impact of the agency's proposed rule on serving sizes (55 FR 29517) on content descriptors, the agency has tentatively determined that there continues to be a need for a second criterion based on nutrient density even when FDA's rulemaking on serving sizes is completed (Ref. 8). Accordingly, FDA is carrying forward the second criterion for the definition of "low cholesterol." However, the agency is modifying proposed § 101.25(a)(2)(ii), redesignated as § 101.25(d)(2)(i), to specify the second criterion as 20 mg/100 g of food rather than 0.2 mg/g, an identical amount. The agency believes that expressing the second criterion as per 100 g, rather than as per g, is simpler because it eliminates decimals and makes the amount per serving and per weight identical (i.e., 20 mg of cholesterol per serving and per 100 g).

2. Saturated Fat Thresholds

Several comments to the tentative final rule (55 FR 29456) objected to the saturated fat threshold as well as to the total fat threshold for cholesterol claims. Many of these comments asserted that FDA did not have the legal authority to prohibit truthful claims. They stressed the need for consumer education rather than prohibition of claims. One comment argued that scientific evidence does not show that following dietary guidelines to reduce fat and saturated fat intake will decrease the risk of cardiovascular disease.

FDA believes there is convincing evidence that dietary intake of saturated fatty acids is related to the risk of cardiovascular disease, the reduction of which is one purpose behind this rulemaking to define cholesterol content claims. This belief is supported by the "Surgeon General's Report on Nutrition and Health" which states: "Excessive saturated fat consumption is the major dietary contributor to total blood cholesterol levels" (Ref. 9, p. 11), and by the National Research Council's "Diet and Health" report which found a strong relationship between blood cholesterol levels and the prevalence and incidence of atherosclerotic cardiovascular disease (Ref. 10). Accordingly, the agency believes that it would be misleading for a food that contains a significant amount of saturated fatty acids to make a cholesterol claim and, thereby, to encourage consumers to buy the product for the purpose of reducing their risk of heart disease.

The agency agrees that consumer education programs are necessary to explain the relationship between saturated fat intake and the risk of cardiovascular disease. However, FDA is not persuaded that such programs can effectively reach and be understood by all consumers. A recent FDA consumer survey found that 40 percent of respondents thought that a "cholesterol free" food would also be low in saturated fat, and another 20 percent were not sure what the claim implies about saturated fat content (Ref. 11). The survey found that consumers are interested in cholesterol content claims because they believe that eating foods with no or low cholesterol will have a significant effect on their blood cholesterol levels and on their chances of developing heart disease (Ref. 11). These findings lead FDA to conclude that a significant number of consumers are likely to perceive that a food that bears a cholesterol content claim will help to lower blood cholesterol levels and to reduce the risk of heart disease. In point of fact, foods containing little or no cholesterol can contain saturated fats at levels that can contribute to high blood cholesterol which, in turn, can contribute to atherosclerotic cardiovascular disease (Refs. 9 and 10). Accordingly, FDA continues to believe that to ensure that cholesterol content claims do not mislead consumers, it is necessary to permit their use only when the foods also contain levels of saturated fats that are below a specified threshold level.

The agency, therefore, is proposing in § 101.25(d)(1)(ii) and (d)(2)(ii) to prohibit the use of "cholesterol free" and "low cholesterol" claims, respectively, on foods that contain more than 2 g of saturated fatty acids.

3. Threshold Level for Saturated Fat

Many comments suggested changing the threshold levels for saturated fatty acids. The agency had proposed levels of 2 g or less per serving and 6 percent or less saturated fat on a dry weight basis. These values were based on

calculations of the maximum amount of saturated fat that could be present in foods bearing cholesterol claims if a person consuming a typical diet of 16 servings of food per day ate only such foods and was to stay within dietary guidelines of less than 10 percent of calories from saturated fat. Most of the comments were opposed to the percent dry weight criterion. They argued that a dry weight limit would discourage the development of new food products with lower fat and cholesterol contents where water is substituted, in part, for fat. Comments stated that the development of new food technologies to develop more healthful foods would be hampered, and that the dry weight criterion was unnecessary and would unfairly penalize foods that have a high moisture content. A few comments also objected to the 2 g criterion and suggested lower levels, generally related to suggested changes in the definition of "saturated fatty acids."

The agency is persuaded by the arguments contained in the comments that the dry weight criterion is not necessary and is possibly counterproductive to the "Healthy People 2000" objective of increasing the availability of processed food products that are reduced in fat and saturated fat content (Ref. 12). Accordingly, FDA is deleting the dry weight criterion and proposing the 2 g criterion as the sole threshold level for foods bearing a "cholesterol free" or "low cholesterol" claim.

In regard to the definition for "saturated fatty acids," the agency noted in the tentative final rule (55 FR 29469) that the definition was the subject of another rulemaking, namely the proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision." FDA recognizes the relationship between the definition of "saturated fatty acids" (i.e., the particular fatty acids that are included in the definition) and the numerical value associated with this threshold level (as well as the values defining "low" and "reduced" saturated fat) and will make adjustments in the proposed threshold level as necessary if it modifies the definition in the nutrition labeling rulemaking. However, for now, FDA is proposing to carry forward the definition of saturated fatty acids in § 101.25(c)(2)(ii) and to adopt a saturated fat threshold of 2 g per serving for "cholesterol free". and "low cholesterol" claims.

4. Total Fat Threshold

Many comments to the tentative final rule (55 FR 29456) were opposed to the use of a total fat threshold that would prohibit cholesterol claims on foods that contain more than 5 g fat per serving and more than 20 percent fat on a dry weight basis. Some of these comments argued that current scientific knowledge does not support an association between the intake of fat and high blood cholesterol, as it does with saturated fatty acid intake, and that therefore a limit on total fat does not pass scientific scrutiny. Comments also asserted that such a threshold would condone the "good food/bad food" concept by requiring individual foods (and even ingredients of foods), rather than the total diet, to meet dietary guidelines of less than 30 percent of calories from fat.

A few comments argued that even though FDA surveys show that many consumers believe that cholesterol is found in all fats and oils, these findings demonstrate a need for consumer education rather than removal of truthful claims. Such education, the comments suggested, could include declarative statements adjacent to claims informing consumers of the total fat content of the product. Comments also stated that a total fat threshold would be a disincentive to the food industry to formulate low cholesterol and low fat foods, which would hinder the achievement of the "Healthy People 2000" objectives (Ref. 12), as well as international harmonization between the U.S. and Canada. The comments pointed out that Canada only restricts the saturated fatty acid content of foods making cholesterol claims.

FDA does not agree that a threshold for allowing a descriptor supports a "good food/bad food" concept. The agency believes that such a threshold merely restricts the use of descriptors to those foods on which they will not be misleading. However, FDA is persuaded by the comments that a cholesterol claim is not inherently misleading on a food that is high in total fat but low in saturated fatty acids. Accordingly, the agency is deleting the total fat threshold.

5. Disclosure of Fat Content

A "cholesterol free" or "low cholesterol" claim, however, represents and suggests that the product provides a health benefit, and the level of fat in the food has a material bearing on this claim. Excess fat in a food increases the likelihood of cancer, other chronic diseases, and obesity. Thus, a "cholesterol free" or "low cholesterol" claim would be misleading under sections 201(n) and 403(a) of the act if the number of grams of fat in a serving of the food is not presented. Moreover, information on another panel of the food labeling would generally not correct this problem. See *United States* v. *An Article of Food * * * "Manischewitz * * * Diet Thins,"* 377 F. Supp. 746, 749 (E.D.N.Y. 1974).

Therefore, in § 101.25(d)(1)(iii) and (d)(2)(iii), FDA is proposing to require that the amount of total fat in a serving of food appear in immediate proximity to a "cholesterol free" or "low cholesterol" claim, respectively. "Immediate proximity" is defined as immediately adjacent to the claim and with no intervening material. FDA is proposing that if the food contains less than 0.5 g of fat per serving, the amount of fat may be declared as "0." The agency believes that less than 0.5 g is a negligible amount of fat.

6. Foods Inherently Cholesterol Free of, or Low in, Cholesterol

FDA is proposing in § 101.25(d)(1)(iv) to carry forward that part of proposed § 101.25(a)(2)(i) (55 FR 29456) that requires that if a manufacturer wishes to make a "cholesterol free" claim on a food that contains less than 2 mg of cholesterol per serving without the benefit of special processing or reformulation to alter cholesterol content, the food must be labeled as "____, a cholesterol free food" (e.g., "applesauce, a cholesterol free food"). The agency believes that this requirement is necessary to make clear that all foods of that type, and not merely the particular brand to which the labeling attaches, do not contain cholesterol. Placement of the term "cholesterol free" immediately before the name of the food (e.g., "cholesterol free applesauce.) would imply that the food has been altered to reduce cholesterol as compared to other foods of the same type. Such an implication would be false and misleading.

For the same reasons, FDA is proposing a similar provision in § 101.25(d)(2)(iv), based on proposed § 101.25(a)(2)(ii) (55 FR 29456) for "low cholesterol" claims. Under this provision foods that are inherently low in cholesterol will have to be labeled as "____, a low cholesterol food" (e.g., "lowfat cottage cheese, a low cholesterol food").

C. "____ Percent Fat Free" Claims

As stated above, FDA has significant concerns about " percent fat free" claims, and these concerns are reinforced by the comments that FDA has received that suggest that many consumers do not understand this type of claim. Therefore the agency is proposing to prohibit the use of this claim in those circumstances in which it

would be misleading and thus would misbrand the product.

Claims for "____ percent fat free. emphasize how close a food is to being free of fat, that is, to containing no fat. They imply that the food has a very small amount of fat in it, and that the food is useful in structuring a diet that is low in fat. The impression that the claim gives is misleading, however, if the food, despite the percentage calculation, contains a significant amount of fat.

Thus, to ensure that, as the claim implies, the food does in fact contain only a small amount of fat, FDA is proposing to require that such claims can only be made on foods that contain 3 g or less of fat per serving and per 100 g of food. FDA also believes that this level would provide an appropriate basis on which to describe a food as "low fat" or "low in fat." The agency urges that any use of the term "low fat" in labeling be in accordance with these levels. In determining this amount, FDA's starting point was § 101.3(e)(4)(ii), in which FDA defines a measurable amount of an essential nutrient as 2 percent of the U.S. Recommended Daily Allowance (RDA). Although there is no U.S. RDA for fat, most dietary guidance (Refs. 10 and 13) suggests that no more than 30 percent of calories should come from fat. Assuming that the average American consumes 2,350 calories a day (55 FR 29476), the average diet should contain no more than 75 g of fat. Two percent of 75 g is 1.5 g.

The agency is not proposing 1.5 g as the cut off for allowing "____ percent fat free" claims, however, because it believes that to do so would unduly restrict the type of foods that could make such a claim. The agency looked at the distribution of fat in the food supply and found that fat is not ubiquitous. Several food categories, including fruits, vegetables, and grains, are mostly free of fat. To account for this fact, FDA believes that it is reasonable to double the measurable amount of fat to arrive at a content level at which it would be misleading to make a "____ percent fat free" claim. Thus, in § 101.25(d)(3)(i), FDA is proposing to permit such claims only on foods that contain 3 g or less of fat per serving.

The agency believes that in addition to a criterion based on the amount of fat in a serving, a criterion based on density (amount in a given weight of food) is needed to control claims on fat-dense foods that have small serving sizes. Such foods may be consumed frequently resulting in a substantial total daily intake of fat. For example, some powdered coffee whiteners contain less than 3 g of fat per serving but contain 35 g of fat per 100 g of food. In addition, the agency is concerned that "____ percent fat free" claims on such foods could encourage consumers to consume the food in larger amounts and more frequently, significantly adding to the total fat intake in an individual's diet.

A density criterion is consistent with the definition for "low calorie" foods in § 105.66(c)(1)(ii) and the proposed definition discussed above for "low cholesterol" claims. In each of these cases, the second criterion is an amount per 100 g equivalent to the amount per serving. For example, "low calorie" is defined as 40 calories per serving and 0.4 calories per gram. The value of 0.4 calories per gram equals 40 calories per 100 g. Therefore, the definition is also 40 calories per serving and per 100 g. The agency considers this consistency to be helpful to consumers and health professionals in being able to recall and use the definitions. Accordingly, FDA is proposing in § 101.25(d)(3)(i) that "____ percent fat free" claims be permitted on food containing 3 g or less fat per serving and per 100 g.

Finally, a "____ percent fat free" declaration would be misleading if the number of grams of fat in a serving of the food was not presented in conjunction with the claim. As discussed with respect to the "cholesterol free" claim, under section 201(n) of the act, a food label is misleading if it fails to reveal facts material in light of the representations that are made on the label. Clearly, the actual amount of fat in a food is a material fact when a "____ percent fat free" claim is made. Moreover, that information generally must be presented on the same label panel as the claim. *United States* v. *An Article of Food * * * "Manischewitz * * * Diet Thins," supra.* Therefore, in § 101.25(d)(3)(ii), FDA is proposing to require that the disclosure of the amount of total fat in a serving of food appear in immediate proximity to a "____ percent fat free" claim. FDA is proposing that if the food contains less than 0.5 g of fat per serving, the amount of fat may be declared as "0." The agency believes that less than 0.5 g is a negligible amount of fat.

IV. References

The following information has been placed on display in the Dockets Management Branch (address above), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Sullivan, Louis W., M.D., remarks given to USDA/FDA Journalists' Conference, Washington, DC, June 26, 1990.

1a. Lake, Robert L., letter to Robert Cillespie, May 14, 1991.

2. Lake, Robert L., letter to Robert M. Harris, May 14, 1991.

3. Lake, Robert L., letter to Edwin L. Artzt, May 14, 1991.

4. Lake, Robert L., letter to Albert J. Crosson, May 17, 1991.

5. Lake, Robert L., letter to James Bell, May 17, 1991.

6. Lake, Robert L., letter to Robert M. Harris, May 24, 1991.

7. Kessler, David A., M.D., remarks given to 20th Anniversary Conference, Center for Science in the Public Interest, Washington, DC, June 6, 1991.

8. Park, Youngmeek, Memorandum to Director, Office of Nutrition and Food Services, February 13, 1991.

9. U.S. Department of Health and Human Services, "The Surgeon General's Report on Nutrition and Health," DHHS(PHS) Publication No. 88-50210 (GPO Stock No. 017-001-00465), U.S. Government Printing Office, Washington, DC, 1988.

10. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Diet and Health, Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.

11. Levy, A. S. et al., "Recent Trends in Beliefs about Diet/Disease Relationships: Results of the 1979-1988 FDA Health and Diet Surveys," presented at FDA/USDA Food Editors Conference, December 1 and 2, 1988.

12. U.S. Department of Health and Human Services, Public Health Service, "Healthy People 2000, Health Promotion and Disease Prevention Objectives," DHHS Pub. No. (PHS) 91-50213, U.S. Government Printing Office, Washington, D.C., 1991.

13. U.S. Department of Agriculture and U.S. Department of Health and Human Services, "Nutrition and Your Health, Dietary Guidelines for Americans," Home and Garden Bulletin No. 232, 3d Ed., U.S. Government Printing Office, Washington, DC, 1990.

V. Economic Impact

This proposal defines the terms "cholesterol free" and "low cholesterol" and provides for the proper use of these terms and for the use of "____ percent fat free" claims in the labeling of foods. The costs resulting from this proposed rule are those borne by firms currently using these terms but not as provided for by this proposal. The agency estimates that 3500 labels may need to be redesigned in order to comply with this proposed regulation for an estimated one-time incremental cost of $25 million. Therefore, in accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal and has determined that the final rule, if promulgated, will not be a major rule as defined by that Order.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal

would have on small entities including small businesses and has determined that, in accordance with section 605(b) of the Regulatory Flexibility Act, that there will be no significant economic impact on a substantial number of small entities.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Comment Period

Interested persons may, on or before January 27, 1992, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.25 is amended by revising the section heading, and paragraphs (b), (c), (d), and (h) and by removing and reserving paragraphs (a) and (g) and (h) to read as follows:

§ 101.25 Labeling of food in relation to fat, fatty acid, and cholesterol content.

(a) [Reserved]

(b) A food label or labeling may include a statement of the cholesterol content of the food: *Provided*, That it meets the following conditions:

(1) The food is labeled in accordance with the provisions of § 101.9; and

(2) The cholesterol content, stated to the nearest 5-milligram increment per serving, is declared in nutrition labeling in accordance with the provisions of § 101.9(c)(6)(ii).

(c) A food label or labeling may include information on the fatty acid content of the food: *Provided*, That it meets the following conditions:

(1) The food is labeled in accordance with the provisions of § 101.9; and

(2) The amount of fatty acids, calculated as the triglycerides and stated in grams per serving to the nearest gram, is declared in nutrition labeling in accordance with the provisions of § 101.9(c)(6)(ii). Fatty acids shall be declared in the following two categories, stated with the following headings, in the following order, and displayed with equal prominence:

(i) *Cis, cis*-methylene-interrupted polyunsaturated fatty acids, stated as "Polyunsaturated", and

(ii) The sum of lauric, myristic, palmitic, and stearic acids, stated as "Saturated".

(d) *Descriptors.* (1) The terms "cholesterol free," "free of cholesterol," or "no cholesterol" or phrases that mean the same thing may be used to describe a food provided that:

(i) The food contains less than 2 milligrams of cholesterol per serving;

(ii) The food contains 2 grams or less of saturated fat per serving;

(iii) The label or labeling discloses the amount of total fat per serving of the food expressed to the nearest gram. When the total fat content is less than 0.5 grams per serving, the amount may be declared as "0." Such disclosure shall appear in immediate proximity to such claim; and

(iv) If the food inherently contains less than 2 milligrams of cholesterol per serving without the benefit of special processing or reformulation to lower cholesterol content, it shall be labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., "applesauce, a cholesterol free food").

(2) The terms "low cholesterol" or "low in cholesterol" may be used to describe a food provided that:

(i) The food contains 20 milligrams or less of cholesterol per serving and per 100 grams;

(ii) The food contains 2 grams or less of saturated fat per serving;

(iii) The label or labeling discloses the amount of total fat per serving of the food expressed to the nearest gram. When the total fat content is less than 0.5 grams per serving, the amount may be declared as "0." Such disclosure shall appear in immediate proximity to such claim; and

(iv) If the food inherently contains 20 milligrams or less of cholesterol per serving and per 100 grams without the benefit of special processing or reformulation to lower cholesterol content, it shall be labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., "lowfat cottage cheese, a low cholesterol food").

(3) The term "____ percent fat free" may be used to describe a food provided that:

(i) The food contains 3 grams or less fat per serving and per 100 grams, and

(ii) The label or labeling discloses the amount of total fat per serving of the food expressed to the nearest gram. When the total fat content is less than 0.5 grams per serving, the amount may be declared as "0." Such disclosure shall appear in immediate proximity to such claim.

* * * * *

(g) [Reserved]

(h) Any food bearing a label or having labeling containing any statement concerning cholesterol, fat, or fatty acids which is not in conformity with this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the Federal Food, Drug, and Cosmetic Act.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27156 Filed 11-26-91; 8:45 am]

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21 CFR Part 130

[Docket No. 91N-0317 et al.]

RIN 0905-AD08

Food Standards: Requirements for Substitute Foods Named by Use of a Nutrient Content Claim and a Standardized Term

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the General Provisions for food standards to prescribe a general definition and standard of identity for substitute foods named by use of a nutrient content claim defined in 21 CFR part 101 (such as "fat free," "low calorie," and "light") in conjunction with a traditional standardized name (for example "reduced-fat sour cream"). FDA is proposing this action in recognition of current national nutrition

goals and the resulting need to allow modified versions of certain standardized foods to bear descriptive names that are meaningful to the consumer. FDA believes that the action proposed herein will promote honesty and fair dealing in the interest of consumers. This proposal applies only to standards of identity and not to standards of fill or quality.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may be issued based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0112.

SUPPLEMENTARY INFORMATION:

I. Introduction

One of the main purposes of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) was to establish the circumstances in which claims could be made that describe the nutrient content of food. In response to the 1990 amendments, elsewhere in this issue of the **Federal Register**, FDA is proposing definitions for such nutrient content claims together with general principles and procedures governing their use. A use of nutrient content claims in which there is a great deal of both industry and consumer interest, but that is not addressed in the nutrient content claims document, is as part of the statement of identity of substitutes for standardized foods.

Foods that are subject to food standards, or that substitute for foods that are subject to food standards, make up a substantial portion of the nation's food supply. There is a strong desire among consumers for substitute foods that have been modified to reduce their fat, saturated fat, cholesterol, or sodium levels below those that are required, or that would occur, under existing food standards. This desire has been voiced in consumer comments in related FDA rulemakings and in statements made at public hearings held by the agency in recent years.

Manufacturers have responded to this consumer desire by placing statements on food labels, including the labels of foods that are subject to standards of identity, that describe the products as "reduced fat" or "light." FDA has been concerned about these actions for two reasons. First, as a general matter, because no uniform set of definitions exists for these nutrient content claims, they are being used in an inconsistent manner, which can result in consumers being confused and misled. Second, FDA is concerned because these nutrient content claims are being used in a manner that is not provided for in the standards of identity. Thus, the use of these nutrient content claims has had the effect of undermining confidence in the labeling of standardized foods, and FDA has taken regulatory action against some of these uses.

FDA's objective, however, is to facilitate, not to hinder, consumer's selection of healthful alternative foods. As Congress recognized in adopting the 1990 amendments (see section II. G. of this document), this objective can be fostered by the use of statements regarding the level of certain nutrients in foods. The agency also recognizes that for foods subject to standards of identity, this objective requires action to provide for the use of accurate, easily understood statements of identity that inform consumers about the nutritional characteristics of substitute products. Finally, FDA believes that such action is necessary to ensure that the substitute products are equivalent to the standardized foods that they replace with respect to nutritional quality and similar to them with respect to essential performance and organoleptic characteristics.

Therefore, FDA tentatively concludes that it is appropriate in addressing the use of nutrient content claims in foods in general, to specifically address the naming of foods that substitute for standardized products using nutrient content claims with standardized terms. That is what the agency intends to do in this document.

II. Background on Food Standards and Food Names

A. The Federal Food, Drug and Cosmetic Act of 1938

Congress provided for the establishment of definitions and standards of identity for particular foods in section 401 of the Federal Food, Drug, and Cosmetic Act (the act) of 1938. Congress' original concept of food standards was that there are certain traditional foods that everyone knows, such as bread, milk, and cheese, and that when consumers buy these foods, they should get the foods that they are expecting. Thus, the definitions and standards of identity fixed the content of the food that could be called by a particular name. For example, any food called "bread" has to comply with the definition and standard for that food. Many of the food standards established by FDA were in the form of restrictive recipes that defined the composition of these foods in great detail. As a result, many food manufacturers argued that food standards suppressed competition and stifled innovation.

FDA has promulgated approximately 300 standards of identity under section 401 of the act. These standards are codified in 21 CFR parts 131 through 169. Under the misbranding provisions of section 403 of the act, if a food resembles a standardized food but does not comply with the standard, that food must be labeled as an "imitation."

B. Formal Rulemaking Keeps Standards Behind Technology

Because of the elaborate, formal rulemaking procedures specified for food standards in section 701(e) of the act, many months or years were often required to adopt a standard or to amend one once it had been adopted. As a result, FDA found it almost impossible to keep food standards up-to-date with advances in food technology and nutrition.

C. Food Additive Provisions and the "Safe and Suitable" Policy

Before enactment of the Food Additives Amendment of 1958 and the Color Additive Amendments of 1960, virtually all ingredients of standardized foods were prescribed individually by name. These amendments, however, included requirements for the premarket approval of new food and color additives and, thus, eliminated questions of safety from the development of food standards.

As a result, FDA felt that it could depart from the strict recipe approach to food standards. In the standard for frozen raw breaded shrimp, which was issued in 1961 (now codified at 21 CFR 161.175), instead of specifying each individual ingredient allowed in the breading, FDA simply provided for "safe and suitable" batter and breading ingredients.

FDA defined "safe and suitable" in 21 CFR 130.3(d) to mean regulated food additives, color additives, generally recognized as safe substances (GRAS), and other functional ingredients used in conformance with provisions of the act at levels no higher than necessary to achieve the intended functional effect. A number of current standards of identity permit the use of "safe and suitable" ingredients.

D. The 1973 "Common or Usual Names" Policy

In the **Federal Register** of March 14, 1973 (38 FR 6964), FDA promulgated regulations governing the establishment of "common or usual names" for nonstandardized foods. FDA advised in the proposed rule of June 22, 1972 (37 FR 12327), that new food standards need not be issued if, for certain foods, appropriate labeling would be sufficient to protect the interest of consumers. In such cases, in lieu of a full food standard, the agency would rely instead on the establishment of the common or usual name of the food.

One of the principal benefits of this regulation (now codified at 21 CFR part 102) was that new products and names for them could be adopted by informal notice-and-comment procedures, rather than by the costly and time-consuming process of formal rulemaking under section 701(e) of the act. The new regulation did not prove to be widely applicable, however, because many foods (e.g., ice cream, cheese) are defined not only by ingredient content but also by technical descriptions of methods of manufacture, processing, or storage, which are much more amenable to presentation in a standard of identity.

E. The 1973 "Imitation" Policy

In a further attempt to provide for advances in food technology and thus to give manufacturers relief from the dilemma of either complying with an outdated standard or having to label their new products as "imitation," FDA sought in 1973 to narrow the scope of food standards by adopting the so-called "imitation" policy. Until 1973, there were no objective criteria for the use of the term "imitation." In the **Federal Register** of August 2, 1973 (38 FR 20702), FDA promulgated 21 CFR 101.3(e), which provides that only nutritionally inferior substitute foods are required to be labeled "imitation."

In its proposed rule of January 19, 1973 (38 FR 2138), FDA noted that vast strides in food technology had been made since the act was enacted in 1938, and that "there are now on the market many new wholesome and nutritious food products, some of which resemble and are substitutes for other, traditional foods. Significantly, it is no longer the case that 'such products are necessarily inferior to the traditional foods for which they may be substituted."

In addressing the nutritional properties of substitute foods in which fat and calories are reduced, FDA stated that since a reduction in fat content or caloric content may well be desirable, such a reduction should not be regarded as nutritional inferiority.

The regulation defined "nutritional inferiority" as any reduction in the content of an essential nutrient that is present at a level of 2 percent or more of the U.S. Recommended Daily Allowance (U.S. RDA), as established in 21 CFR 101.9(c)(7). It also provided that a substitute food would not be deemed to be an imitation if, in addition to not being nutritionally inferior, its label bears a common or usual name that complies with 21 CFR 102.5, or it bears "an appropriately descriptive term that is not false or misleading."

Under this policy, FDA took the position that an appropriately descriptive term included not only a description of the change from the standardized food (for example "reduced fat") but also the fact that the food was a substitute or alternative to a standardized food. FDA felt that it was necessary to include the latter fact to ensure that the consumer was not misled into believing that he or she was buying the traditional food. Thus, a cheddar cheese product in which the fat was reduced (FDA's informal view was that fat had to be reduced by 50 percent for it to be "reduced") had to be called "reduced fat cheddar cheese substitute." Many manufacturers, however, felt that terms such as "substitute" or "alternative" have a derogatory meaning and imply to the consumer that the products are of inferior quality, or that they are less nutritious than the respective standardized foods. The manufacturers felt that consumers would consequently be unwilling to accept and purchase the substitute products.

FDA also took the position that if such a product were labeled without the use of the term "substitute" or "alternative," the product would purport to be the standardized food. Thus, the manufacturer could seek to amend the standards of identity to provide for the modified food. However, if the manufacturers marketed the food without doing so, the product was subject to regulatory action as a misbranded food.

F. The 1989 Advance Notice of Proposed Rulemaking

In the **Federal Register** of August 8, 1989 (54 FR 32610), FDA published an advance notice of proposed rulemaking (ANPRM) concerning food labeling. The agency requested public comments on several matters, including "whether to formally define commonly used food nutrient content claims and/or reconsider the use of standards of identity for foods." The notice stated that because of the growing public interest in eating healthy foods, manufacturers had begun to place statements on their labels that described their products in such ways as "low in _____." and "reduced _____." FDA had found, however, that these nutrient content claims were not always used in honest or consistent ways. To bring some order to the marketplace and to ensure that consumers are not misled, FDA stated that it was developing a series of nutrient content claims for use on the labels of foods.

G. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). The 1990 amendments make the most significant changes in food labeling and food standards law since passage of the act in 1938. The effect of this legislation is to clarify and strengthen FDA's legal authority to require nutrition labeling on foods and to establish the circumstances under which claims may be made about nutrients in foods. Several provisions of the 1990 amendments relate to the proposal discussed below.

Section 3(a) of the 1990 amendments revised the act by, among other things, adding new paragraph 403(r)(1)(A). This provision states that a food is misbranded if it bears a claim in the label or labeling that either expressly or by implication characterizes the level of any nutrient of the type required by nutrition labeling (i.e., amounts of saturated fat, total fat, cholesterol, sodium, complex carbohydrates, total carbohydrates, sugars, total calories derived from any source and derived from total fat, and various vitamins and minerals), unless such claim has been specifically defined (or otherwise exempted) by regulation, as required by section 403(r)(2)(A)(i) of the act.

Section 3(a) of the 1990 amendments also added new section 403(r)(5)(C) to the act, which states that nutrient content claims that are made with respect to a food because the claim is required by a standard of identity issued under section 401 of the act are not subject to section 403(r)(2)(A)(i). Thus, a nutrient content claim that is part of the name of a standardized food may continue to be used even if the use of the term in the standardized name is not consistent with the definition for the term that FDA adopts, or even if FDA has not defined the term. This exemption was necessary to protect the status of existing standards having names that make a nutrient content claim (such as "low-fat milk"). The

legislative history of the 1990 amendments (Ref. 1, p. 22) reveals that Congress was aware, however, that the Secretary and, by delegation, FDA have the authority to correct this problem by amending the portions of the standards of identity pertaining to food labels to conform with the regulations issued under new section 403(r) of the act.

Section 3(b)(1)(A)(iii) of the 1990 amendments requires that the Secretary issue regulations to define the following terms (unless the Secretary finds that the use of any such terms would be misleading): "Free," "low," "light"/ "lite," "reduced," "less," and "high."

Section 7(1) of the 1990 amendments amended 403(i) of the act by striking out the provision that exempted standardized foods from the requirement for full ingredient labeling. Under the pre-1990 amendment provisions of paragraph 403(i) of the act, only those components of standardized foods classified as "optional" had to be declared by their common or usual name on the label, and then only when specifically required by FDA.

Section 8 of the 1990 amendments removed section 401 of the act from the coverage of section 701(e). Thus, FDA may now use informal notice-and-comment rulemaking, rather than formal rulemaking, in adopting new food standards and in amending or repealing existing standards, except for the existing standards for dairy products and maple syrup.

III. Existing Regulations Employing Nutrient Content Claims

FDA has adopted several regulations prescribing nutrient content claims. For example, the regulation on sodium labeling (current 21 CFR 101.13) defines various levels of sodium on a per serving basis as follows: "Sodium free" (less than 5 milligrams), "very low sodium" (35 milligrams or less), "low sodium" (140 milligrams or less), and "reduced sodium" (75 percent reduction for the food as a whole). The agency has also defined "low calorie" and "reduced calorie" foods relating to usefulness in reducing or maintaining caloric intake or body weight (current 21 CFR 105.66), as well as terms such as "sugar free," "sugarless," and "no sugar" (current 21 CFR 105.66(f)).

A number of standards of identity have been established that incorporate the terms "light," "low," "non," or "reduced" in the names of the standards, including: lowfat dry milk (§ 131.123), nonfat dry milk (§ 131.125), nonfat dry milk fortified with vitamins A and D (§ 131.127), lowfat milk (§ 131.135), acidified lowfat milk (§ 131.136), cultured lowfat milk (§ 131.138), light cream (§ 131.155), light whipping cream (§ 131.157), lowfat yogurt (§ 131.203), nonfat yogurt (§ 131.206), low sodium cheddar cheese (§ 133.116), low sodium colby cheese (§ 133.121), lowfat cottage cheese (§ 133.131), nonfat milk macaroni products (139.121), and low-fat cocoa (§ 163.114).

In addition, FDA has issued many temporary marketing permits (TMP's) under terms of § 130.17 for various low-, reduced- and non-fat alternative foods such as light eggnog, nonfat cottage cheese, and light sour cream. By issuing a TMP, FDA expresses its willingness to refrain from instituting regulatory action against a product on the grounds that it does not conform to the applicable standard while market tests are conducted to measure consumer acceptance of the product, identify mass production problems, assess commercial feasibility, and determine whether the standards of identity should be amended to provide for the new food.

IV. The Current Situation

In the August 1989 ANPRM (54 FR 32610), FDA stated that it was aware that manufacturers were using nutrient content claims such as "low in _____" or "reduced _____" on a wide variety of food labels, and that, in the absence of definitions provided by FDA, the nutrient content claims were being used in an inconsistent manner, so that consumers were likely confused or being misled.

The agency is also aware that these nutrient content claims are being applied to products that substitute for foods for which FDA has published standards of identity, particularly dairy products defined in 21 CFR Part 131 (Milk and cream), Part 133 (Cheese and related cheese products), and Part 135 (Frozen desserts), as well as mayonnaise and salad dressings defined in 21 CFR Part 169 (Food dressings and flavorings). By use of nutrient content claims such as "low fat," "reduced fat," or "no fat," these products are represented as containing levels of fat that are below the minimum levels required by the respective standards of identity for the foods for which the products substitute.

As discussed above, the formal rulemaking procedures specified for food standards in section 701(e) of the act have made it difficult to update the many existing food standards. Consequently, certain food standards do not reflect advances in food technology or current knowledge regarding nutrition and health. The most immediate problem is with fat, which was considered to be an economically and nutritionally valuable component of food when the act was enacted in 1938 and which is the basic characterizing ingredient in many foods for which standards have been adopted over the last 50 years, primarily dairy products.

Today, high dietary levels of cholesterol and fat/fatty acids are implicated as significant risk factors in the development of cardiovascular and other chronic diseases. Both "The Surgeon General's Report on Nutrition and Health" (Ref. 2) and the National Academy of Science's report on "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 3) focus on fat consumption by Americans as the primary diet-related risk factor for cardiovascular disease.

Technological developments have brought about new products having a reasonable degree of consumer acceptance that are low or reduced in fat and cholesterol. The inflexibility of the traditional standards system, however, places these and similar products at a disadvantage when they attempt to enter the market because they cannot legally be called by a name that is easily recognized or desired by consumers. For instance, a product called "sour cream" must contain a minimum of 18 percent milkfat, as required by the standard of identity, § 131.160, even though lower fat products are now available.

FDA is aware that the issues discussed in this document, including suggestions for improvements in the food standards system, have been addressed repeatedly for many years by experts and observers both inside and outside the agency (Refs. 4 through 15). The role of food standards was assessed by a committee of the Food and Nutrition Board of the National Academy of Sciences' Institute of Medicine (IOM) as part of a recent study supported by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture. In its report entitled "Nutrition Labeling, Issues and Directions for the 1990's" (Ref. 16), the committee observed that: "In 1990, less skepticism exists about consumers' abilities, aided by informative labeling, to protect themselves against debased or diluted products * * *. Attention is now focused on the consumption of too much fat rather than the possibility that some products will be made using less of an ingredient than was historically considered a valuable constituent. Accordingly, it seems clear to the [IOM] Committee that any system that significantly impedes the marketing of reduced-, low-, and non- or no-fat

substitutes should be examined and, presumably, changed." FDA believes that this is a fair assessment of the current situation.

V. Pending Petitions

The Milk Industry Foundation (MIF), Washington, DC 20006, a trade association representing manufacturers and distributors of dairy products, filed a petition, dated September 12, 1988 (Docket No. 88P-0329), to establish a standard of identity for "light sour cream." MIF believes that establishing a standard of identity for "light sour cream" would promote public health, satisfy consumer demand, and would assure that "light sour cream" has an appropriate reduction in fat content. Since the MIF petition was filed, FDA has received a number of applications from companies desiring to market test "light (or lite) sour cream," and the agency has issued 19 TMP's for the product. FDA received two additional petitions to establish a standard for "light sour cream" from H. P. Hood, Inc. (Docket No. 89P-0105), and Crowley Foods, Inc. (Docket No. 89P-0403), at the time these manufacturers submitted applications to extend their TMP's.

MIF also filed a petition, dated September 16, 1988 (Docket No. 88P-0334), to establish a standard of identity for "light eggnog." MIF stated in its petition that establishing a standard of identity for light eggnog would promote public health, satisfy consumer demand, and would assure that light eggnog products have a significant reduction in fat content. Since the MIF petition was filed, FDA has received a number of applications from companies desiring to market test "light (or lite) eggnog." The agency has issued 33 TMP's for the product. H. P. Hood, Inc., submitted a petition (Docket No. 89P-0329) to establish a standard for "light eggnog" at the time they applied to extend their TMP for this product.

FDA has received a number of letters from firms indicating that they desire to participate in the extended market tests for "light sour cream" and "light eggnog," and FDA has issued letters of approval for participation in the extensions.

The International Ice Cream Association (IICA), Washington, DC 20006, a trade association representing manufacturers and distributors of ice cream and other frozen desserts, and the Public Voice for Food and Health Policy (Public Voice), Washington, DC 20036, a national nonprofit consumer research, education, and advocacy organization, submitted petitions dated February 23 and March 30, 1990, respectively, asking FDA to amend the standard of identity for ice milk to change the name of the food to "reduced fat ice cream" and to establish standards of identity for products designated as "lowfat ice cream" and "nonfat ice cream." The Public Voice petition would, in addition, reduce the maximum milkfat content in the standard of identity for ice milk from 7 percent to 5 percent.

Kraft General Foods, Inc. (KGF), Philadelphia, PA 19103, a manufacturer and distributor of a broad range of food products within the United States, also submitted a petition, on March 14, 1990, to establish a standard of identity for "nonfat ice cream." The Calorie Control Council (CCC), Atlanta, GA 30342, an international association of manufacturers of low-calorie and diet foods and beverages, including manufacturers of a variety of sweeteners and other low-calorie ingredients, submitted a petition, dated March 5, 1990, to add a provision to each of the IICA proposed standards (i.e., "reduced fat ice cream," "lowfat ice cream," and "nonfat ice cream") to permit the use of any safe and suitable sweeteners, including saccharin, aspartame, and acesulfame potassium (acesulfame K), in the foods. IICA submitted another petition, dated March 29, 1990, to expand its February 23, 1990, petition to include a provision in the standard of identity for ice cream (§ 135.110) and in each of its proposed standards to permit the use of safe and suitable sweeteners, as provided in the CCC petition.

On January 22, 1991, FDA published an advanced notice of proposed rulemaking (56 FR 2149) concerning the filing of these petitions to amend the standards for ice cream and ice milk and to establish standards for reduced fat, lowfat, and nonfat ice creams.

FDA is responding to the above petitions in this proposal although FDA will also respond to some portions of the petitions to amend the standards for ice cream and ice milk in a separate proposal to be published at a future date. FDA encourages these petitioners and all interested persons to comment on this proposal and on the other nutrient content claim proposals published elsewhere in this issue of the **Federal Register**.

VI. Rationale and Legal Issues

A. Appropriateness of the Proposed Action

Questions concerning the naming of foods that are substitutes for standardized foods and concerning the use of standardized terms with nutrient content claims to describe products that substitute for standardized foods have confronted the agency for almost 20 years. In response to FDA's proposed rule on the "imitation" policy published in the **Federal Register** of January 19, 1973 (38 FR 2138), one comment recommended that the "imitation" regulation should preclude the use of a standardized name in connection with the name of a nonstandardized product (38 FR 20702, 20703). FDA rejected this suggestion, however, on the grounds that it may be necessary to include a standardized name in the name of a substitute food in order to provide the consumer with accurate, descriptive, and fully informative labeling. The agency confirmed this interpretation in the **Federal Register** of January 19, 1979 (44 FR 3964), stating that the existence of a standard of identity for a particular food does not necessarily preclude the use of the standardized name in connection with the name of a nonstandardized food.

In further commenting on the use of standardized names for substitute foods in the **Federal Register** of August 19, 1983 (48 FR 37666), FDA again advised that in some cases, it may be reasonable and appropriate to include the name of a standardized food or other traditional food in the name of a substitute food in order to provide the consumer with an accurate description. The agency stated that when this is done, the name of the food must be modified such that the nature of the substitute food is clearly described and is clearly distinguished from the food that it resembles and for which it is intended to substitute. The agency stated that the modification of the traditional or standardized food's name must be descriptive of all differences that are not apparent to the consumer. Thus, the agency concluded, the procedure for naming these foods will depend on the nature of the substitute food and the manner and extent to which it differs from the food it simulates.

As discussed in section III of this document, a number of standards of identity have been established that incorporate the terms "light," "low," "non," or "reduced" in the names of the standards. Thus, the use of nutrient content claims (similar to those discussed herein) in connection with standardized terms is neither new nor unusual.

However, FDA did not have available a uniform set of defined nutrient content claims that could be referenced in a regulation of that provided for their use in a generic sense in connection with standardized terms, nor did it have a mandate from Congress to provide statements regarding the level of these

nutrients in foods "in a manner that facilitates the public's understanding" (Ref. 1, p. 18). New section 403(r) (1) of the act (added by section 3 of the 1990 amendments) provides for the establishment of FDA-defined nutrient content claims on food labels to accurately and truthfully inform consumers about the nutritional content of products complying with the definitions. FDA believes that this section together with section 401 of the act, which gives the agency authority to promulgate definitions and standards of identity if such action will promote honesty and fair dealing in the interest of consumers, and the amendment of section 701(e), which makes it possible to adopt new standards by notice and comment rulemaking, provide the agency with the authority and the means to adopt the new generic standard in proposed § 130.10.

FDA believes that this proposed action is reasonable and appropriate, and that it is needed to provide the consumer with accurate, descriptive, and fully informative labeling that will not only promote honesty and fair dealing in the interest of consumers but will also facilitate achievement of the national nutritional goals. The agency invites comments with respect to the appropriateness and need for the action proposed in this document.

B. Departure From Traditional Policy

FDA is aware that the regulatory approach in proposed § 130.10 represents a departure from the agency's traditional policy with respect to the naming of substitute foods. FDA notes, however, that its policies have always evolved, even in the absence of significant legislative amendments to the act.

For example, in 1953 FDA held that the nondairy product "Chil-Zert" was misbranded under section 403(c) of the act because it was a substitute for ice cream (which was not standardized at the time) but was not labeled as "imitation," even though the package was conspicuously labeled "Not an Ice Cream" and "Contains No Milk or Milk Fat." By 1973, however, when FDA instituted the "imitation" policy, the agency had decided that a nutritionally equivalent substitute for a standardized food need not be labeled "imitation" provided its label bore a common or usual name, or an appropriately descriptive name, that was not misleading. Moreover, FDA also decided that "since a reduction in fat content or calorie content may well be desirable, such a reduction should not be regarded as nutritional inferiority" (38 FR 2138).

FDA believes that recent developments make further changes in FDA's policies appropriate. Through the 1990 amendments, Congress has given FDA the authority to ensure that consumers are given information about the ingredient and nutrient content of virtually all foods and to establish the circumstances under which claims may be made about the levels of nutrients in foods. Thus, the agency can now rely more on labeling requirements, and less on restrictive recipes, in carrying out its mandate to ensure that consumers get the products they expect, and that the nutritional and health-related properties of foods are properly conveyed to the consumer.

VII. FDA Proposal

A. Generic Standard

FDA recognizes that valuable and helpful information concerning the nutrient content of food could be conveyed to consumers if defined nutrient content claims could be used in a consistent and responsible manner in the names of certain substitute foods. A substitute food as defined in proposed § 101.13(d) in the general proposal on nutrient content claims, published elsewhere in this issue of the **Federal Register**, is one that may be used interchangeably with another food that resembles, i.e., organoleptically, physically, and functionally similar to, that food, and is not nutritionally inferior to that food unless labeled as an "imitation."

The agency is also defining in that proposal the terms "free," "low," "light" or "lite," "reduced," and "high." In addition, FDA is proposing to define the terms "very low" (for sodium only) and "source" and to make provision for the use of comparative statements using the terms "less," "fewer," and "more" because the agency has tentatively concluded that they would be useful in helping consumers choose a healthy diet. FDA is also defining the term "modified" in proposed § 101.13(k) to be used in the statement of identity of a food that bears a comparative claim in conformity with the requirements of 21 CFR part 101.

Given these developments and the other developments discussed in this proposal, FDA believes that it is now appropriate for it to set forth general requirements governing the establishment of standards of identity for certain nutritionally equivalent alternate foods. The proposed general requirements in § 130.10 specify the conditions under which aspects of traditional standards and appropriate nutrient content claims may be used to define new standardized foods.

The establishment of individual new standards may be necessary for certain foods, but, in general, the promulgation of a large number of individual regulations would be time-consuming and unnecessarily wasteful of the agency's resources. Consequently, FDA believes that a generic standard applicable to the vast majority of alternate foods offers the most reasonable and effective approach. Proposed § 130.10 describes the conditions under which a variety of substitute foods may use nutrient content claims and standardized names.

B. Existing Standards Using Nutrient Content Claims Not Affected

Currently there are a number of standards, such as lowfat cottage cheese (§ 133.131) in which a nutrient content claim ("lowfat") is already part of the name of the food. The names of such foods would remain unchanged by the regulation proposed in this document. In recognition of the fact that various nutrient content claims have already been incorporated in the names of a number of standardized foods (see listing of such foods in section III of this document), Congress exempted these foods from compliance with the nutrient content claim-provisions of the 1990 amendments (section 403(r)(5)(CC) of the act). FDA points out, however, that these existing standards are subject to amendment to make them consistent with the nutrient content claim definitions that are being proposed in a document published elsewhere in this issue of the **Federal Register**.

C. Substitute Foods Defined by This Proposal

1. Nutrient Content Claims

FDA is proposing in § 130.10 a generic standard of identity that prescribes the conditions under which substitute foods (as defined in proposed § 101.13(d)) that do not comply with a standard of identity defined in 21 CFR parts 131 through 169 because of a deviation that is described by a nutrient content claim, but that do comply with the standard in most other respects, may be named using a nutrient content claim and the standardized term. In § 130.10(a), FDA is proposing that the use of the nutrient content claim to name the new food must comply with the requirements of § 101.13 and with the requirements of the regulations in 21 CFR part 101 that define the particular nutrient content claim that is used.

Proposed § 101.13, which is published elsewhere in this issue of the **Federal Register**, prescribes the general circumstances in which claims that characterize the level of a nutrient in a food may be made on a food label or in labeling. Proposed § 101.13(b) limits the claims that can be used, expressly or by implication, to characterize the level of a nutrient (nutrient content claim) of the type required to be declared in nutrition labeling pursuant to § 101.9 to those that have been defined by FDA regulation.

Moreover, the substitute food must meet the definition for the nutrient content claim that FDA has adopted. For example, to use a "reduced fat" nutrient content claim as part of the statement of identity for a cheddar cheese product, it will not be enough for the product to have slightly less than the minimum milkfat content required by the standard of identity for cheddar cheese (§ 133.113). Rather the product will have to have a significant fat reduction. Proposed § 101.62(b)(4)(i) requires that a food must be specifically formulated, altered, or processed to reduce its fat content by 50 percent or more, with a minimum reduction of more than 3 grams per label serving size and per reference amount customarily consumed, from the reference food that it resembles and for which it substitutes to bear such a claim. Regular cheddar cheese contains 10 grams fat per 30 gram serving. Therefore, if this proposal is adopted, "reduced fat cheddar cheese" will have to contain 5 grams or less fat per serving to comply with these requirements and with § 130.10.

Proposed § 130.10(a) requires that the food comply with the traditional standard in all respect except as described by the nutrient content claim and as provided in paragraphs (b) and (d) of the regulation. These exceptions are discussed below.

A number of the standards in 21 CFR parts 131 through 169 contain several requirements for the standardized foods. FDA realizes that some alternate foods using nutrient content claims may deviate from the standard in more than one aspect. For example, eggnog, as defined in § 131.170, must contain not less than 6 percent milkfat and one or more of the optional egg yolk containing ingredients specified in § 131.170(c), such that the egg yolk solids content is not less than 1 percent by weight of the finished food. A product such as nonfat eggnog would deviate from the standard in that it would contain less than 6 percent milkfat and less than the required amount of egg yolk solids content. FDA is requesting comment concerning how far a product may deviate from a standard and still qualify for use of the standardized name.

2. Serving Size

Elsewhere in this issue of the **Federal Register**, FDA is publishing a reproposal of its serving size regulations (first proposed July 19, 1990 (55 FR 29517)) as part of its food labeling initiative to implement the provisions of the 1990 amendments. To prevent consumer deception as a result of a manufacturer reducing the serving size and thereby the calorie, fat, or sodium content per serving, FDA is proposing in § 101.12, which is published elsewhere in this issue of the **Federal Register**, that the serving size of a substitute product, such as a "low calorie" version of the food, must be based on the same reference amount customarily consumed as that of the regular counterpart food. Thus, any change in the characteristics of the food will be the result of changes in the food and not of changes in the serving size.

3. Presentation of Information

To avoid consumer confusion, FDA believes that the principal display panel of the label should clearly describe the difference between the traditional standardized product and the modified substitute product bearing the standardized term, and that the product should be labeled in accordance with proposed nutrient content claim regulations in proposed § 101.13 and other regulations in part 101 (proposed elsewhere in this issue of the **Federal Register**).

For example, for a reduced fat product to comply with §§ 101.13 and 101.62, a truthful comparative statement must appear in immediate proximity to the most prominent use of the fat claim, stating the percentage difference in fat between the modified product and the traditional standardized product. Proposed § 101.62 also requires the declaration of quantitative information comparing the actual amount of fat in a serving of a reduced fat product as compared to the amount in the traditional standardized product. Thus, the principal display panel of the label of a product such as "reduced fat sour cream" that contains 50 percent less fat than regular sour cream will have to include the statement "contains 50 percent less fat than regular sour cream, fat content has been reduced from 6 grams to 3 grams per serving" in immediate proximity to the most prominent (as defined in § 101.62(b)(2)(ii)) statement of identity.

D. Nutritional Inferiority

FDA is proposing to specifically require in § 130.10(b) that a substitute food named by use of a nutrient content claim and a standardized term not be nutritionally inferior, as defined in § 101.3(e)(4), to the traditional standardized food. For example, a cheddar cheese product containing 33 percent less milkfat than regular cheddar cheese that is nutritionally inferior to cheddar cheese under § 101.3(e) would be subject to the requirements of section 403(c) of the act and thus properly labeled as "imitation cheddar cheese."

In § 101.3(e)(4)(i), FDA defines nutritional inferiority as any reduction in the content of an essential nutrient that is present in the food in a measurable amount. FDA has defined measurable amount of an essential nutrient in a food in § 101.3(e)(4)(ii) as 2 percent or more of the U.S. RDA of protein or any vitamin or mineral listed under current § 101.9(c)(7)(iv) per average or usual serving, or where the food is customarily not consumed directly, per average or usual portion, as established in § 101.9. FDA is proposing in the document on Mandatory Nutrition Labeling, published elsewhere in this issue of the **Federal Register**, to establish Reference Daily Intakes (RDI's) for use in declaring nutrient content in nutrition labeling and to replace the current U.S. RDA's with the RDI's. If FDA adopts that proposal, nutritional equivalence will be based on the established RDI.

Dairy products typically contain a significant quantity of fat-soluble vitamins, such as vitamin A, in the milkfat portion. For example, one serving (30 grams) of cheddar cheese provides 8 percent of the U.S. RDA for vitamin A. A 33-percent reduction in the amount of milkfat in "modified cheddar cheese" also reduces the amount of vitamin A and other fat-soluble vitamins per serving. Therefore, FDA believes that vitamin A and other essential nutrients must be added to restore nutrients to products to ensure that the substitute food is not nutritionally inferior to the standardized food. FDA is proposing to provide for that addition in § 130.10(b). Under this proposal, the addition of nutrients will be reflected in the ingredient statement.

E. Performance Characteristics of Food

FDA believes that consumers expect that a product bearing a standardized name will not only resemble the traditional standardized food but will perform like the traditional standardized food. Consumers may assume that the substitute product can be used interchangeably with the traditional standardized food in all applications.

Therefore, in order not to mislead consumers, FDA is proposing in § 130.10(c) to require that a product bearing the standardized name have similar performance characteristics to the standardized food. FDA is proposing that the performance characteristics on which the substitute food is judged include physical properties (e.g., texture, melting point, freezing point), flavor characteristics (e.g., aroma and taste), functional properties (e.g., body, spreadability), and shelf life.

FDA recognizes, however, that it may not be possible or practical to produce substitute products that perform similarly to the traditional standardized food in all respects. As discussed in section IV of this proposal, many existing standards require certain levels of fat because fat was considered to be a valuable component of food when these standards were established. Reduced fat substitute foods, under proposed § 101.62 (b)(4), must have at least 50 percent of the fat removed. The fat is replaced by one or more other ingredients. Many manufacturers "agree that successful fat reduction typically extends beyond the abilities of one single ingredient. It requires a firm understanding of what fat does in a product, and how those functions can be replicated with nonfat ingredients. This understanding covers three primary arenas: Mouthfeel/textural characteristics, flavor characteristics and functionality/ processing concerns" (Ref. 17, p. 28).

Fats exhibit unique physical properties in a food. The fatty acid composition, crystal formation, melting and solidifying properties, and association with aqueous components of the food are important regarding the various textural properties fat imparts. For example, milkfat is important in ice cream because it inhibits the formation of large ice crystals and provides a smooth texture to the food.

Fats are important carriers for flavor because most food flavors, both natural and artificial, whether inherent in a food or added to a food, are fat soluble. Fats are also major contributors to flavor compound precursors and to functional characteristics. For example, a cheddar cheese substitute "made from milk with increased polyunsaturated fatty acid content does not develop normal flavor or body characteristics" (Ref. 18, 337).

FDA believes that shelf life is another important performance characteristic because the moisture content of a food may increase significantly with the reduction of a component such as fat. The increase in moisture becomes a factor in the microbial stability of products. In a food such as "reduced fat ice cream," the increase in moisture also can lead to the formation of large ice crystals because the higher level of free moisture makes the product less freeze-thaw stable (Ref. 17, p. 40).

Therefore, to assure that consumers are not misled as to the characteristics of the modified product, FDA is also proposing in § 130.10(c) to require that if a product bearing a standardized term does not perform in the same way as the traditional standardized food, the label must include a statement informing the consumer of any significant differences. For example, a reduced fat margarine may not perform the same as margarine for use in frying, and if this proposal is adopted, a statement such as "not recommended for frying purposes" must appear on the label. Under 403(f) of the act, FDA believes that the statement must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use. FDA believes that the statement must appear in the same area of the label as the statement of identity for the modified product so that the consumer will know where to find such information. Therefore, FDA is proposing in § 130.10(c) to require that this statement appear on the principal display panel within the bottom 30 percent of the area of the label panel with appropriate prominence which shall be no less than one-half the size of the most prominent nutrient claim on the panel but no smaller than one-sixteenth of an inch.

The agency tentatively concludes that this information is a material fact under section 201(n) of the act because it bears on the consequence of the use of the article. Accordingly, this information must be communicated to the consumer on the product label or the labeling would be misleading, and the product would be misbranded under section 403(a) of the act. FDA is requesting comments concerning what differences in performance characteristics a modified standardized product may possess and still resemble the standardized food closely enough to be included in that product category.

F. Other Ingredients

1. Ingredients Provided For by Proposed Regulation

FDA believes that the ingredients used in the modified version of the standardized food should be those ingredients provided for by the traditional standard with only those deviations necessary to attain an acceptable finished product that meets the requirements of the nutrient content claim that is used. Therefore, FDA is proposing in § 130.10(d)(1) that ingredients used in the product be those ingredients provided for by the traditional standard except that, in addition, "safe and suitable" ingredients, as defined in 21 CFR 130.3(d), may be used to improve texture, add flavor, prevent syneresis, or extend shelf life so that the product is not inferior in performance characteristics to the traditional standardized food.

If flavors are added to a modified standardized product, the label must comply with § 101.22. According to § 101.22(i), if the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor, by word, vignette (e.g., depiction of a fruit), or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor. If the food contains any artificial flavor that simulates, resembles, or reinforces the characterizing flavor, under § 101.22(i), the name of the food on the principal display panel or panels of the label must be accompanied by the common or usual name of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food. In addition, the name of the characterizing flavor shall be accompanied by the word or words "artificial" or "artificially flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor. For example, the name of an artificially butter-flavored light margarine would be "light margarine, artificially flavored" if the labeling implies that the product has a buttery taste. Also, natural and artificial flavors must be declared in accordance with applicable sections of 21 CFR part 101 in the ingredient statement in accordance with proposed § 130.10(f).

2. Use of Similar Ingredients

The provision for the use of safe and suitable ingredients proposed in § 130.10(d)(1) is not intended to allow for the replacement or exchange of any required ingredient or component of a required ingredient in the standardized food with functionally similar ingredients from other sources not provided for by the standard. For example, the standard for sour cream (§ 131.160) states that sour cream contains not less than 18 percent

milkfat. FDA believes that replacing the milkfat in sour cream with vegetable oil to make a product labeled as "cholesterol free sour cream" would be misleading because consumers expect sour cream to be a dairy product. Therefore, FDA is proposing in § 130.10(d)(2) that a required ingredient or component of an ingredient that is specifically required by the traditional standard shall not be replaced or exchanged with a similar ingredient from another source unless the traditional standard provides for the use of such ingredient. Thus, a manufacturer who used vegetable oil to replace or substitute for the milkfat in a modified sour cream product would not be able to take advantage of § 130.10.

FDA realizes that many modified versions of standardized foods may contain a greater percentage of moisture than permitted under the traditional standard because of the water contributed by ingredients with a high water content, such as skim milk. For example, colby cheese as defined in § 133.118 may contain not more than 40 percent moisture. Modified colby cheese containing one-third less fat than regular colby cheese may exceed this moisture limit because less whey is drained from the product during processing. FDA is requesting comment from interested persons concerning the appropriateness of the addition of high moisture ingredients and water to foods as ingredients to replace fat and calories in substitute products. FDA is aware of the recent development of fat analogs and is also requesting comments from interested persons concerning the appropriateness of the use of approved fat analogs to replace the fat in substitutes for standardized foods.

3. Ingredients Prohibited by the Standard

The majority of standards of identity prescribe the ingredients that may be included in a standardized food. However, there are some standards of identity defined in 21 CFR Parts 131 through 169 that specifically prohibit the addition of certain ingredients. For example, the standard for milk chocolate, § 163.130, states that milk chocolate may be spiced, flavored, or otherwise seasoned with one or more of the optional ingredients specified in the standard, other than any such ingredient or combination of ingredients that imparts a flavor that imitates the flavor of chocolate, milk, or butter (§ 163.130(a)). FDA believes that ingredients specifically prohibited by the standard should not be used in a substitute food. Therefore, FDA is proposing in § 130.10(d)(3) that an ingredient or component of an ingredient that is prohibited by the standard as defined in 21 CFR Parts 131 through 169 shall not be added to a substitute food.

G. Nomenclature

1. How Foods Are to be Named

FDA is proposing in § 130.10(e) to provide that the name of a substitute food that complies with § 130.10 is the respective standardized term plus an appropriate defined nutrient content claim (e.g., reduced fat sour cream). If a food meets the requirements of § 130.10, it is itself a standardized food. Therefore, even though it does not meet the requirements of the standard underlying the term included in its name, its name need not include the term "substitute" or "alternate." It does not purport to be the traditional standardized food named by that term. It purports to be a food that satisfies the requirement of the standard in § 130.10. Thus, it is appropriately named by use of only the nutrient content claim and the standardized term.

2. Name That Is To Be Used

FDA believes that foods that comply with any standard in 21 CFR parts 131 through 169 must use that standardized name. For example, cream cheese is defined in 21 CFR 133.134 as a product containing at least 33 percent milkfat by weight of the cream cheese, and the maximum moisture content is 60 percent by weight. Neufchatel cheese (§ 133.162) is a product similar to cream cheese except that the milkfat content is not less than 20 percent but less than 33 percent by weight of the finished food, and the maximum moisture content is 65 percent by weight. A modified cream cheese containing 25 percent less fat than cream cheese complies with the standard for neufchatel cheese. The standardized name "neufchatel cheese" must appear on the principal display panel, but the comparative statement "contains 25 percent less fat than cream cheese" may also appear on the label. FDA believes that the use of comparative labeling in accordance with regulations in part 101 provides the consumer with useful information in the selection of a variety of foods.

H. Ingredient Labeling

FDA is proposing in § 130.10(f)(1) that each of the ingredients used in the food shall be declared on the label as required by applicable regulations in 21 CFR parts 101 and 130. Under § 101.4, all ingredients must be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel.

To assist the consumer in differentiating between the traditional standardized food and the modified version of the standardized food, FDA is proposing in § 130.10(f)(2) that all ingredients added under the "safe and suitable" provision, if not provided for by the traditional standard, as well as permitted ingredients added at levels in excess of those allowed by the traditional standard, must be appropriately identified as such with an asterisk in the ingredient statement. The statement "*Ingredients not in regular _____" (fill in name of the traditional standardized food), or "*Ingredients in excess of amount permitted in regular _____" (fill in name of the traditional standardized food), or both as appropriate, shall immediately follow the ingredient statement in the same type size.

FDA believes that the consumer may be misled to believe that ingredients added to restore nutrients are present in greater amounts than needed to obtain nutritional equivalency if these nutrients are identified with an asterisk in the ingredient statement. Therefore, the agency is proposing that nutrients added to restore nutrients shall not be identified by an asterisk in the ingredient statement.

FDA is requesting comments on the proposed approach to ingredient labeling and on other methods of identifying ingredients not provided for by the traditional standard of identity.

VIII. Noncharacterizing Changes in Standardized Foods

A. Foods Meeting the Requirements of the Standards

When an ingredient or component of an ingredient not specifically required by the standard is removed or reduced (e.g., reduced-cholesterol liquid eggs) or is added (e.g., bread with added oat bran) to a product, the food does not deviate from the established standard of identity. In the former example, the liquid eggs are standardized in § 160.115. The standard does not specifically state how much cholesterol must be present in the eggs, nor does cholesterol contribute any important characteristics to the eggs. Therefore, cholesterol is not a required component of the eggs.

In the latter example, oat bran may be added to bread as one of the optional ingredients included in the standard of identity for bread (§ 136.110). FDA traditionally has considered optional ingredients as nonmandatory ingredients of standardized foods,

unless the standard of identity specifies that one or more of a group of optional ingredients must be present in a food.

FDA specifically considered the issue of the use of nutrient content claims in conjunction with the names of standardized foods in its tentative final rule relating to cholesterol nutrient content claims (55 FR 29456 through 29466, July 19, 1990). In the tentative final rule, FDA stated that defined cholesterol nutrient content claims could be used in association with the names of standardized and nonstandardized foods (except for those foods that are inherently free of, or low in cholesterol). However, the agency noted that for most standardized foods, a change in cholesterol content does not in and of itself change the character and nature of the food such that the food is no longer the standardized food. Thus, the agency said, for most of these foods, the use of nutrient content claims in conjunction with their standardized names will not create common or usual names that will take the food out of the standard for the purposes of § 101.3(e). FDA said that for these foods, the nutrient content claim merely points out the special property (i.e., the cholesterol content) of the food.

FDA further stated in the cholesterol tentative final rule that the use of the same lettering for the nutrient content claim and for the standardized name may be misleading because it would imply that the food is not the standardized food, but a different food that does not meet the requirements of the standard. The agency said that therefore, when cholesterol content claims are used in conjunction with a standardized name, they should be distinguished from that name by type, color, style of lettering, or type size in order to clearly differentiate the identity of the food from the cholesterol claim. FDA received no comments either for or against this policy in response to the tentative final rule.

FDA recognizes that valuable and helpful information concerning the nutrient content of food could be conveyed to consumers if defined nutrient content claims could be used in a consistent and responsible manner in the names of standardized foods. The agency also recognizes that, for the first time, defined nutrient content claims will be available as required by the 1990 amendments.

Because the substitute foods discussed in this proposal may be labeled using nutrient content claims and standardized terms in the statement of identity under proposed § 130.10, the foregoing factors have led FDA to decide to change the position that it set out in the tentative final rule for cholesterol and to tentatively conclude that foods that qualify for the use of a defined nutrient content claim but that still comply with a traditional standard of identity should also be labeled using nutrient content claims and standardized terms in the statement of identity. FDA has been led to this view by two additional factors. First, FDA believes that using inconsistent methods of labeling foods would be confusing to the consumer. Second, FDA believes that this approach provides an additional way to highlight those foods in which the cholesterol level is substantially less than in a food that substitutes for the food (see section 403 (r)(2)(A)(ii)(I) and (r)(2)(A)(iii)(I) of the act and the discussion of those sections in the companion documents on descriptors). Therefore, FDA tentatively concludes that the use of the same lettering for defined nutrient content claims and for the standardized name would not be misleading to consumers.

Thus, under these circumstances, FDA believes that the use of defined nutrient content claims and standardized terms in the statement of identity of a food is appropriate even though the food still complies with the standard of identity. The ingredient statement would reflect any modification of any ingredient used in the food. All claims used must comply with the applicable regulations in 21 CFR part 101 (proposed in separate documents published elsewhere in this issue of the **Federal Register**).

B. Substitute Foods Not Meeting the Requirements of the Standards Because of the Restoration of Nutrients

FDA is advising that substitute foods that do not comply with a traditional standard because nutrients may have been removed coincidental with the removal of a component not required by the standard, and those nutrients are added back to the food to restore nutrients to the levels present in the traditional food, may use a nutrient content claim and the standardized term in association with the statement of identity of the product if the claim complies with the requirements of proposed § 101.13 and with the requirements of the regulations defining the nutrient content claim in 21 CFR part 101. FDA believes that naming foods in this manner will provide for the use of accurate, easily understood statements of identity that inform consumers about the nutrient content of the substitute product. FDA believes that this policy makes sense in light of current national nutritional goals.

FDA believes that the restoration of these nutrients to the food should not be highlighted on the principal display panel or in the statement of identity of the product. In FDA's fortification policy (§ 104.20), the agency stated that it is inappropriate to make any claim or statement on a label or in labeling, other than in a listing of the nutrient ingredients as part of the ingredient statement, that any vitamin, mineral, or protein has been added to a food that replaces a traditional food to avoid nutritional inferiority in accordance with § 101.3(e)(2).

For example, a product such as liquid eggs that has been processed to reduce the cholesterol content may be nutritionally inferior to traditional liquid eggs because some processes to remove cholesterol from a product may inadvertently remove significant quantities of nutrients such as vitamin A. The standard for liquid eggs (§ 160.115) does not provide for the addition of nutrients to the food to restore these nutrients. Without the addition of nutrients to the food, this product would be an imitation food and thus subject to the requirements of section 403(c) of the act in accordance with 21 CFR 101.3(e). FDA believes that a policy that would require such a result would make little sense in light of current dietary guidance. Therefore, FDA tentatively concludes that if nutrients that were inadvertently removed from the liquid eggs during the process to remove cholesterol have been added back to the food, the product may be called "reduced cholesterol liquid eggs" if it complies with nutrient content claim regulations in part 101. All nutrients added to the product would have to be listed in the ingredient statement.

IX. Request for Comment

The agency is requesting comments on the proposed regulation in general, and in particular with respect to the provision concerning the requirement that the performance characteristics of the new product must remain similar to those of the standardized food. FDA encourages the submission of technical data and other information pertaining to the identification and measurement of key performance characteristics for different types of substitute foods, as well as comments about performance properties that are of greatest importance to consumers.

X. Environmental Impact

FDA has determined under 21 CFR 25.24(a) (11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment

nor an environmental impact statement is required.

XI. Economic Impact

FDA has examined the economic implications of the proposed rule pertaining to part 101 requirements as required by Executive Orders 12291, 12612, and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking, and Executive Order 12612 requires federal agencies to ensure that federal solutions, rather than state or local solutions, are necessary. Finally, the Regulatory Flexibility Act requires regulatory relief for small businesses where feasible.

Because no marginal costs are expected to be incurred to comply with this proposed regulation, the agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub. L. 96-354), FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses. Finally, because this regulation is intended to regulate food for interstate trade and individual State regulations may hinder interstate trade, FDA finds that there is no substantial Federalism issue which would require an analysis under Executive Order 12612.

FDA is proposing a change that will provide for consistent use of nutrient content claims for foods that substitute for standardized foods found in 21 CFR parts 131 through 169. This action will codify terms that manufacturers are currently using with TMP's. By establishing a generic standard of identity for modified standardized foods, FDA will avoid having to issue new TMP's or, ultimately, establish individual new food standards. Thus, rather than raise costs to industry and consumers, this action will lower future costs of marketing standardized foods. Rather than addressing a market failure, this action remedies an existing public regulation problem. The benefits of this action include both a reduction of the administrative costs of TMP's and elimination of consumer confusion for terms used to describe standardized and nonstandardized foods.

Options considered include no action, which would cause the agency to continually issue TMP's for each new modified standardized food and, ultimately, to issue separate food standards for each modified food. The other option, which is not appropriate or practicable at this time, would be to eliminate many food standards. Formal rulemaking procedures specified in section 701(e) of the act still apply for amending or repealing food standards for dairy standards and maple syrup under the 1990 amendments. These procedures often require many months or years.

Under existing Federal laws, removal of Federal food standards would allow each state to establish their own standards, which could inhibit interstate trade. Congress, in section 6 of the 1990 amendments, specifically provided for preemption of State laws for foods that are subject to a standard of identity established under section 401 of the act, unless specific exemptions are granted by FDA. Congress' action should help the food industry to conduct its business in an efficient and cost-effective manner, although the agency remains open to consider individual situations.

As firms will not be required to change existing labels, FDA finds that there are no marginal costs of this regulation. This action is also expected to facilitate international trade by providing expanded markets for new products such as low cholesterol and low fat foods that are appropriately named.

XII. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. Comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XIII. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. House of Representatives Report 101-538 on the Nutrition Labeling and Education Act of 1990 (H.R. 3562), June 13, 1990.

2. "The Surgeon General's Report on Nutrition and Health," DHHS (PHS) Publication No. 88-50210 (GPO Stock No. 017-001-00465-1), U.S. Government Printing Office, Washington, DC, 1988.

3. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.

4. Merrill, Richard A. and Earl M. Collier, Jr., "'Like Mother Used to Make': An Analysis of FDA Food Standards of Identity," *Columbia Law Review*, 74:561-621, 1974.

5. Hutt, Peter B., "Regulatory Inaction vs. Regulatory Reform," *Food Chemical News/ Pesticide Chemical News Annual Yearbook*, pp. 84-88, 1982.

6. Stribling, Jess H., Jr., "Food Labeling: Who's Responsible * * * For Assuring Its Truthfulness?" *Food Drug Cosmetic Law Journal*, 37:251-256, 1982.

7. Vallowe, Joseph M., "Informing Consumers of the Existence and Significance of Food and Drug Administration Food Standards of Identity'," *Food Drug Cosmetic Law Journal*, 38:256-272, 1983.

8. Merrill, Richard A., "Food and Drug Administration Regulation: An Unnecessary Barrier to New Product Innovation," *Food Drug Cosmetic Law Journal*, 39:113-119, 1984.

9. Miller, Sanford A. and Karen Skinner, "The Nose of the Camel: The Paradox of Food Standards," *Food Drug Cosmetic Law Journal*, 39:99-108, 1984.

10. Board on Agriculture, National Research Council, "Designing Foods: Animal Product Opportunities in the Marketplace," National Academy Press, Washington, DC, 1988.

11. Center for Science in the Public Interest, "Food Labeling Chaos: The Case for Reform," Washington, DC, 1989.

12. Agar, John, "Generally Recognized as Sour Cream: Treating Standards of Food Identity as a Success," *Food Drug Cosmetic Law Journal*, 44:237-250, 1989.

13. Kessler, David A., "The Federal Regulation of Food Labeling: Promoting Food to Prevent Disease," *New England Journal of Medicine*, 321:717-725, 1989.

14. Degnan, Frederick H., "What is in a Name? The Legal Effect of Food Standards," *Food Drug Cosmetic Law Journal*, 45:263-272, 1990.

15. Lake, L. Robert and Raymond E. Newberry, "Current Labeling Issues Concerning Dairy Products," *Food Drug Cosmetic Law Journal*, 45:273-277, 1990.

16. Committee on Nutrition Components of Food Labeling, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, "Nutrition Labeling: Issues and Directions for the 1990's," National Academy Press, Washington, DC, 1990.

17. Hegenbart, Scott, "Beyond Fat Replacement: Making the System Work," *Food Product Design*, 1:28-40, 1991.

18. Lampert, Lincoln M., "Modern Dairy Products," Chemical Publishing Company, Inc., New York, 1975.

List of Subjects in 21 CFR Part 130

Food additives, Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 130 be amended as follows:

PART 130—FOOD STANDARDS: GENERAL

1. The authority citation for 21 CFR part 130 continues to read as follows:

Authority: Secs. 201, 306, 401, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 341, 343, 371).

2. Section 130.10 is added to subpart A to read as follows:

§ 130.10 Requirements for substitute foods named by use of a nutrient content claim and a standardized term.

(a) *Description.* The foods prescribed by this general definition and standard of identity are those foods that substitute (see § 101.13(d) of this chapter) for a standardized food defined in parts 131 through 169 of this chapter but that do not comply with the standard of identity because of a deviation that is described by a nutrient content claim that has been defined by FDA regulation. The nutrient content claim shall comply with the requirements of § 101.13 of this chapter and with the requirements of the regulations in part 101 of this chapter that define the particular nutrient content claim that is used. The food shall comply with the relevant standard in all other respects except as provided in paragraphs (b) and (d) of this section.

(b) *Nutrient addition.* Nutrients shall be added to the food to restore nutrient levels so that the product is not nutritionally inferior, as defined in § 101.3(e) (4) of this chapter, to the standardized food as defined in parts 131 through 169 of this chapter. The addition of nutrients shall be reflected in the ingredient statement.

(c) *Performance characteristics.* The performance characteristics (e.g., physical properties, flavor characteristics, functional properties, shelf life) of the food shall be similar to those of the standardized food as produced under parts 131 through 169 of this chapter, except that if there is a significant difference in performance characteristics, the label shall include a statement informing the consumer of such difference (e.g. if appropriate, "not recommended for cooking"). Such statement shall appear on the principal display panel within the bottom 30 percent of the area of the label panel with appropriate prominence, in type which shall be no less than onehalf the size of the type used in such claim but no smaller than one-sixteenth of an inch.

(d) *Other ingredients.* (1) Ingredients used in the product shall be those ingredients provided for by the standard as defined in parts 131 through 169 of this chapter and in paragraph (b) of this section, except that safe and suitable ingredients to improve texture, add flavor, prevent syneresis, or extend shelf life may be used so that the product is not inferior in performance characteristics to the standardized food defined in parts 131 through 169.

(2) An ingredient or component of an ingredient that is specifically required by the standard as defined in parts 131 through 169 of this chapter, shall not be replaced or exchanged with a similar ingredient from another source unless the standard, as defined in parts 131 through 169, provides for the addition of such ingredient (e.g., vegetable oil shall not replace milkfat in light sour cream).

(3) An ingredient or component of an ingredient that is specifically prohibited by the standard as defined in parts 131 through 169 of this chapter, shall not be added to a substitute food under this section.

(e) *Nomenclature.* The name of a substitute food that complies with all parts of this regulation is the appropriate nutrient content claim and the applicable standardized term.

(f) *Label declaration.* (1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(2) Ingredients not provided for, and ingredients used in excess of those provided for, by the standard as defined in parts 131 through 169 of this chapter, shall be identified as such with an asterisk in the ingredient statement, except that ingredients added to restore nutrients to the product as required in paragraph (b) of this section shall not be identified with an asterisk. The statement "*Ingredient(s) not in regular _____" (fill in name of the traditional standardized food) or "*Ingredient(s) in excess of amount permitted in regular _____" (fill in name of the traditional standardized food) or both as appropriate shall immediately follow the ingredient statement in the same type size.

David A. Kessler,
Commissioner of Food and Drugs.
Louis W. Sullivan,
Secretary of Health and Human Services.
Dated: November 4, 1991.

[FR Doc. 91-27170 Filed 11-26-91; 8:45 am]
BILLING CODE 4160-01-M

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21 CFR Part 101

[Docket No. 91N-0344]

RIN 0905-AD08

Food Labeling: Use of Nutrient Content Claims For Butter

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to adopt a regulation that will permit the use of nutrient content claims ("descriptors") that are defined by regulation in 21 CFR part 101 to be made for butter. This action is in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). FDA believes that the proposed regulation will provide the consumer with a selection of modified butter products that are informatively labeled and will promote honesty and fair dealing in the interest of consumers.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0112.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Situation With Respect to Butter—The Act of March 4, 1923—Sections 201a and 401 of the Federal Food, Drug, and Cosmetic Act

The Act of August 2, 1886 (24 Stat. 209), defined "butter" as:

> * * * the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter.

The Act of March 4, 1923 (21 U.S.C. 321a) amended the Act of August 2, 1886, by adding the requirement that butter must contain not less than 80 percent by weight of milkfat. FDA has not established any further standards of identity concerning butter because section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) specifically states that "no definition and standard of identity and no standard of quality shall be established for * * * butter."

B. Pending Petitions

Johanna Farms, Inc., Flemington, NJ 08822, submitted a citizen petition, dated April 9, 1990 (Docket No. 90P-0141), requesting that FDA establish, by regulation, a common or usual name for

"light butter." Johanna Farms, Inc., is engaged in the dairy business throughout the northeastern and mid-Atlantic United States. Johanna Farms, Inc., stated in its petition that a common or usual name definition for light butter would: (1) Further the public health interest in reduced fat consumption; (2) further the public interest in calorie reduction; (3) respond to consumer demand; (4) provide a term that is truthful, adequately informative, and not misleading; and (5) be consistent with the statutory definition of butter. Because this petition was filed before the passage of the 1990 amendments, FDA is responding to it in this proposal.

FDA published a notice in the **Federal Register** on March 14, 1991 (56 FR 10906) advising, in part, that it is likely to deny, without prejudice, any health claim or descriptor petition submitted under the 1990 amendments until the agency has promulgated final procedural regulations concerning the submission and content of such petitions. Therefore, FDA has not considered any of the petitions on modified butter products that have been submitted since the passage of the 1990 amendments in developing this proposal. FDA, however, encourages these petitioners and all interested persons to comment on this proposal and on the other descriptor proposals published elsewhere in this issue of the **Federal Register**.

C. The 1990 Amendments

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). Section 3(b)(1)(A) of the 1990 amendments requires that FDA issue regulations that define claims that characterize the level of nutrients that are of the type that are required to be declared in nutrition labeling. Specifically, FDA was directed to promulgate regulations prescribing the use of the terms "free," "low," "light" or "lite," "reduced," "less," and "high" to characterize the level of these nutrients, unless the Secretary finds that the use of any such term would be misleading (section 3(b)(1)(A)(iii) of the 1990 amendments). Regulations prescribing general requirements for the use of nutrient content claims and defining specific descriptors are proposed in other documents published elsewhere in this issue of the **Federal Register**. Section 3(b)(1)(A)(viii) of the 1990 amendments authorizes FDA to issue regulations to permit the use of nutrient content claims for butter.

The legislative history of the 1990 amendments, specifically the House of Representatives Report 101-538, 101st Cong., 2d sess. 22-23 (June 13, 1990), states that while the Committee on Energy and Commerce believed that FDA has authority under current law to permit nutrient content claims on butter products, the 1990 amendments "explicitly [permit] the Secretary to allow a claim described in section 403(r)(1)(A) of the act (such as 'light') to be made for butter." The House Report goes on to state that "[i]n issuing regulations for claims concerning fat, calories, and other nutrients in butter, the Secretary should consider arguments concerning the appropriate characteristics of butter." (*Id.*, at 23.) This proposal gives interested persons the opportunity to present their views on this issue.

II. The Proposal

A. Tentative Finding that Providing for the Use of Nutrient Content Claims for Butter Will Assist Consumers in Maintaining Healthy Dietary Practices

FDA believes that the use of nutrient content claims for butter will assist consumers in maintaining healthy dietary practices. "The Surgeon General's Report on Nutrition and Health" (Ref. 1) emphasizes the need for most people to reduce their consumption of fat, saturated fat, and cholesterol and to achieve and maintain a desirable body weight. It states that heart disease, cancer, and stroke are the three leading causes of death in the United States, and that diet plays a part in the development of these conditions as well as other chronic health problems, such as atherosclerosis, high blood pressure, diabetes mellitus, obesity, osteoporosis, dental diseases, and diverticular disease. A product that has been modified to have significantly lower levels of fat, saturated fat, sodium, or cholesterol so that it can bear nutrient content claims will, therefore, be of nutritional benefit to consumers.

FDA notes that there is consumer demand to purchase modified dairy products. Under 21 CFR 130.17, FDA has issued temporary marketing permits for light sour cream, light ice cream, nonfat cottage cheese, and light eggnog. FDA has also granted temporary marketing permit extensions for light sour cream and light eggnog. The manufacturers submitting the applications for the extensions included information gathered under their market tests that shows a high level of consumer acceptance of those products.

B. FDA's Traditional View of How Modified Butter Products Must Be Labeled and the Effect of the 1990 Amendments

Congress provided the definition for "butter" in section 201a of the act to protect consumers from butter-like products that were inferior to the butter that they expected to purchase. Consistent with this, one of the main purposes of the act is to protect consumers from economic deception. A product using the term "butter" must comply with the statutory definition of butter, or its labeling would be false, and it would be misbranded under section 403(a)(1) of the act (21 U.S.C. 343(a)(1)). A food sold under the name "butter" that does not comply with the statutory standard for butter also is in violation of section 403(b) of the act (21 U.S.C. 343(b)) in that it is sold under the name of another food. These provisions apply to all foods defined by a standard of identity.

Therefore, a food whose statement of identity includes a term that is defined by a food standard purports to be that standardized food and must comply with the applicable standard. The effect of this requirement, however, is that a product labeled as, for example, "light butter" because it contains less fat and calories than regular butter, or a product labeled as "light sour cream" because it contains less fat and calories than regular sour cream, would be misbranded because it does not meet the applicable standard.

The maker of the "light sour cream" product has had an alternative, however. It has been able to submit a petition for a new food standard that will define "light sour cream" as a different product than "sour cream." Moreover, it could obtain a temporary marketing permit, as several manufacturers have, that will allow it to market the product while it develops its petition, and the petition is reviewed by FDA.

The maker of the "light butter" product, however, has had no such option. As stated above, section 401 of the act prohibits FDA from establishing any new standards for foods that purport to be butter.

Consequently, modified butter products have been sold under a common or usual name such as "dairy spread," along with appropriate labeling that accurately informs the consumer as to what the product is but that does not represent it to be butter. Modified butter products that are nutritionally inferior (as defined in § 101.3(e) (21 CFR 101.3(e))) to butter are sold as "imitation butter."

To provide some relief in this situation, Congress passed section 3(b)(1)(A)(viii) of the 1990 amendments. While this section does not directly address the prohibition in section 401 of the act, it clearly evidences an intent by

Congress to permit nutrient content claims like "light" to be made for butter. This provision was discussed by Congressman Torricelli and Congressman Waxman, a sponsor of the bill that became the 1990 amendments.

Mr. Torricelli * * *

My inquiry is whether it would be within the authority of the FDA under the language we have been discussing to authorize the marketing of a product called lite butter that achieved * * * 35 to 40 percent milkfat, and with a third less calories as long as it were not nutritionally inferior and kept other characteristics of butter and were properly labeled * * *.

Mr. Waxman * * *

[I]t would be in the FDA's discretion to determine the characteristics of light butter. (Congressional Record, H5845, July 30, 1990.)

It is FDA's job to read section 3(b)(1)(A)(viii) of the 1990 amendments and section 401 of the act together and to develop an interpretation that gives effect to both provisions. Thus, proposed § 101.67 focuses not on the ingredients that may be used in a butter product, as a standard would, but rather, as section 3(b)(1)(A)(viii) of the 1990 amendments does, on the circumstances in which nutrient content claims may be used. While the proposed regulation, in § 101.67(a)(2), does list the ingredients of the food, this list is essentially the same as that in section 201a of the act, with two small additions that reflect Congress's intent in passing the 1990 amendments and that do not represent a change from the statutory standard. FDA believes that its proposed approach harmonizes section 3(b)(1)(A)(viii) of the 1990 amendments and section 401 of the act. The agency requests comments on its approach.

C. FDA's Proposed Regulation

In response to section (3)(b)(1)(a)(viii) of the 1990 amendments, FDA is proposing to permit nutrient content claims to be made for butter. Under proposed § 101.67(a), such claims may be made if the product meets the applicable definition of the nutrient content claims, it complies with certain content requirements that assure that it can fairly be characterized as "butter," and it is not nutritionally inferior to butter as butter would be produced under section 201a of the act. In addition, FDA is proposing to require that the product that bears the nutrient content claims have similar performance characteristics to butter, and that to the extent it does not, this fact is disclosed with appropriate prominence in the labeling. Each of these proposed requirements is discussed in more detail below.

1. The Nutrient Content Claim

Proposed § 101.67(a)(1) provides that a butter product may bear a nutrient content claim if it complies with both the general requirements for nutrient content claims in § 101.13 and the requirements for use of the particular nutrient content claim that is to be applied to the product.

Section 101.13, as proposed elsewhere in this issue of the **Federal Register**, prescribes the circumstances in which claims that characterize the level of a nutrient in a food may be made on a food label or in labeling. Proposed § 101.13(b) limits the claims that can be used to expressly or by implication characterize the level of a nutrient (nutrient content claim) of the type required to be declared in nutrition labeling pursuant to § 101.9 to those that have been defined by FDA by regulation.

To prevent consumer deception as a result of a manufacturer reducing the serving size and, thereby, the milkfat content per serving, FDA is proposing that the serving size for butter that is to bear a nutrient content claim must be the same as that established for regular butter. (See proposed § 101.12(g).) On July 19, 1990 (55 FR 29517), FDA published a proposal to establish serving sizes for 159 food product categories and proposed the standard serving size for butter and modified versions of butter as 1 tablespoon. FDA is retaining these amounts in its reproposal of its serving size regulations published elsewhere in this issue of the **Federal Register** as part of its food labeling initiative to implement the provisions of the 1990 amendments.

The agency is defining in proposals published elsewhere in this issue of the **Federal Register** the terms "free,. "low," "light" or "lite," "reduced," and "high." In addition, FDA is proposing to define the terms "very low" (for sodium only) and "source" and to make provision for the use of comparative statements using the terms "less," "fewer," and "more" because the agency has tentatively concluded that they would be useful in helping consumers choose a healthy diet.

For example, under proposed § 101.62 concerning fat claims, which is published elsewhere in this issue of the **Federal Register**, a product must be formulated to have a significant reduction in fat content (50 percent) to bear a "reduced fat" descriptor. A product that contains only slightly less (e.g., 10 percent) fat than the regular version of the product could not bear such a claim.

To avoid consumer confusion, FDA believes that the principal display panel of the label should clearly state the difference between butter as defined in section 201a of the act and the product that bears the nutrient content claim. Thus, in proposed § 101.67(a)(1), FDA is requiring, in accordance with proposed §§ 101.13 and 101.62(b)(4)(ii), that for example, if a .reduced fat" claim is made, a truthful comparative statement must appear in immediate proximity to the most prominent use of the claim (e.g., the statement of identity). The comparative statement would disclose the percentage difference between the level of milkfat in the product that bears the claim and 80 percent milkfat, which is the level specified for butter in section 201a of the act and which FDA is proposing, in § 101.67(a)(1), to use as the basis for calculating milkfat reductions. Proposed § 101.62 also requires that the comparative statement include quantitative information comparing the actual amount of fat in a serving of the butter for which the claim is made to the amount in regular butter. For example, a product that contains 40 percent milkfat could be labeled "reduced fat butter" and bear, in immediate proximity to the name, the statement: .Contains 50 percent less fat than regular butter. Fat content has been reduced from 12 grams to 6 grams per serving."

FDA advises that under proposed § 101.62(d)(4), which defines cholesterol claims, reducing the cholesterol content of butter will not justify a reduced cholesterol claim because of the high saturated fat content of butter. Comments on the impact of cholesterol claim restrictions on butter labeling should be directed to docket numbers 84N-0153 and 90N-0256 pertaining to the proposed descriptor regulations for fats and cholesterol published elsewhere in this issue of the **Federal Register**.

As provided in the statutory standard, salt is an optional ingredient in butter. Thus, under proposed § 101.67, sodium and salt content nutrient content claims that are truthful and in accordance with proposed §§ 101.13 and 101.61 may also be used for butter.

2. "Butter"

As a condition for the use of a nutrient content claim on butter, the product that is to bear the nutrient content claim must not only satisfy the requirements for the claim, it must also be fairly described as "butter." The characterizing component of butter is milkfat. Under section 201a of the act, "butter" must contain at least 80 percent milkfat.

The legislative history of the 1990 amendments makes clear, however, that Congress intended to authorize FDA to permit the use of nutrient content claims on butter products that contain less than 80 percent fat. (H. Rept. 101-538, 101st Cong., 2d sess. 23.) As stated above, in floor debate preceding passage of the 1990 amendments in the House, a Congressman asked one of the sponsors of the bill whether it would permit FDA to allow a product that contains 35 or 40 percent milkfat to be called "lite butter." The response was that it would. (Congressional Record H5844, July 30, 1990).

Therefore, in § 101.67(a)(2), FDA is proposing to permit the use of the term "butter" in conjunction with a nutrient content claim if the product that bears the nutrient content claim is made from the ingredients and constituents of the ingredients listed in section 201a of the act, but the agency is not proposing to require that the product contain a particular level of milkfat. FDA believes that this proposed action is consistent with congressional intent.

In the House Report, Congress directed FDA to consider arguments concerning the appropriate characteristics of butter. In a footnote, the Report continued:

> The Committee is aware that the dairy industry takes the position that products containing less than approximately 50 percent milkfat lose some of the characteristics of butter. In connection with the promulgation of the regulations, representatives of dairy interests and health experts will have the opportunity to present their views on the issue to the Secretary. (H. Rept. 101-538, 101st Cong., 2d sess. 23. n. 3.)

FDA requests comments on whether its tentative decision not to include a minimum milkfat level in § 101.67 is appropriate.

FDA is proposing to add two types of ingredients to the list of ingredients that derives from section 201a of the act. First, to ensure that a butter product that bears a nutrient content claim is not nutritionally inferior to butter that is produced under section 201a of the act, FDA is proposing to permit the addition of nutrients to the product. The legislative history makes clear that Congress anticipated that a butter product that bears a nutrient content claim would not be nutritionally inferior to butter. (Congressional Record H5845, July 30, 1990.)

Secondly, FDA is proposing to permit the use of safe and suitable bacterial cultures. The agency is doing so for two reasons. First, butter has historically been a cultured product. When the Act of August 2, 1886 was passed, milk and cream used in the manufacture of butter were permitted to sour spontaneously or by the addition of a starter of soured milk or cream prior to churning (Ref. 2). Thus, FDA is merely conforming proposed § 101.67 to the way that butter has traditionally been produced. Secondly, in the floor debate that preceded the House passage of the 1990 amendments, a sponsor of the bill in the House agreed that under the language of the bill, it would be within the FDA s authority to grant the Johanna Farms, Inc., petition. (Congressional Record H5844.) The petition specifically provides for the use of safe and suitable bacterial cultures.

FDA realizes that manufacturers may want to use ingredients that are not listed in § 101.67(a)(2) to yield an acceptable "butter" product. Therefore, FDA is requesting comment on whether it should provide for the use of safe and suitable nondairy ingredients to improve texture, prevent syneresis, add flavor, or extend the shelf life in § 101.67(a)(2). FDA is also requesting comment concerning the addition of water instead of skim milk, whey, or milk, as an ingredient in butter products to replace the milkfat. If comments support the use of safe and suitable nondairy ingredients and provide a substantial basis for their use, FDA may provide for the use of these ingredients in any final rule based on this proposal.

Under proposed § 101.67(c), each of the ingredients that is used in the butter for which a claim is made must be declared on the label as required by the applicable sections of 21 CFR part 101. According to § 101.4, all ingredients must be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel.

3. Nutritional Inferiority

FDA is proposing to specifically require in § 101.67(a)(3) that a product that bears a nutrient content claim not be nutritionally inferior to standardized butter. A modified butter product that is nutritionally inferior to butter would be an imitation food under § 101.3(e)(1) and thus subject to the requirements of section 403(c) of the act. In § 101.3(e)(4)(i), FDA defines nutritional inferiority as any reduction in the content of an essential nutrient that is present in the food imitated in a measurable amount. In § 101.3(e)(4)(ii), FDA has defined a measurable amount of an essential nutrient in a food as 2 percent or more of the U.S. Recommended Daily Allowance (U.S. RDA) of protein or any vitamin or mineral listed under current § 101.9(c)(7)(iv) per average or usual serving or, where the food is customarily not consumed directly, per average or usual portion, as established in § 101.9. FDA is proposing in the document on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register** to establish Reference Daily Intakes (RDI's) for use in declaring nutrient content in nutrition labeling and to replace the current U.S. RDA's with the RDI's. If FDA adopts that proposal, nutritional equivalence will be based on the established RDI.

Butter is a significant source (as defined in current § 101.9(c)(7)(v)) of fat soluble vitamins such as vitamin A. A 1-tablespoon serving of butter provides 10 percent of the U.S. RDA for vitamin A. Any reduction in the amount of milkfat also reduces the amount of vitamin A and other fat soluble vitamins per serving. Therefore, FDA believes that vitamin A and other essential nutrients must be added to restore nutrients to products using the term "butter" in their name. Given Congress's intent to provide for butter products with modified milkfat levels (Congressional Record H5844, July 30, 1990), FDA believes it is appropriate to provide for the addition of such nutrients, even though the statutory standard for butter does not provide for the addition of those ingredients.

4. Performance Characteristics

FDA believes that consumers expect that a product bearing the term "butter" will resemble butter and perform like butter. Therefore, in order to not mislead consumers, FDA believes that a product bearing the term "butter" in its identity statement should meet these expectations. The relevant performance characteristics include physical properties (e.g., melting point), organoleptic characteristics (e.g., texture, aroma, and taste), functional properties (e.g., spreadability), and shelf life.

FDA recognizes, however, that it may not be possible or practical to produce a product that meets the requirements for a fat claim and that performs similarly to butter in all respects. Therefore, to assure that consumers are not misled as to the characteristics of the product, FDA is proposing in § 101.67(b) to require that the label include a statement informing the consumer of any significant differences in performance characteristics between a product that bears a nutrient content claim and standardized butter.

For example, reduced fat butter may not perform the same as standardized butter when used as an ingredient in

baked goods, and if this proposal is adopted, a statement such as "not recommended for baking purposes" will have to appear on the label of the former product. Under 403(f) of the act, FDA believes that the statement must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use. FDA believes that the statement must appear in the same area of the label as the statement of identity for the product so that the consumer will know where to find such information. Therefore, FDA is proposing in § 101.67(b) to require that this statement appear on the principal display panel within the bottom 30 percent of the area of the label panel with appropriate prominence, that is, it shall be in type no less than one half the size of the type of the most prominent nutrient claim on the panel but no smaller than one-sixteenth of an inch.

The agency tentatively concludes that this information about the performance characteristics of the product is a material fact under section 201(n) of the act because it bears on the consequence of the use of the article. Accordingly, this information must be communicated to the consumer on the product label, or the labeling would be misleading, and the product would be misbranded under section 403(a) of the act. FDA is requesting comments concerning what performance characteristics butter that bears a claim may possess and still be considered to perform like standardized butter.

D. Conclusion

FDA believes that descriptors should be used to make available to the consumer informatively labeled products and to aid the consumer by providing a larger variety of products to meet nutritional goals. FDA is issuing this proposal in furtherance of these objectives as well as to implement section 3(b)(1)(A)(viii) of the 1990 amendments and to respond to the Johanna Farms, Inc., petition. FDA requests comments on the appropriateness of its approach and on alternative approaches that are more appropriate to attain these objectives.

III. Economic Impact

FDA has examined the economic implications of the proposed rule pertaining to 21 CFR Part 101 requirements as required by Executive Order 12291 and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking and the Regulatory Flexibility Act requires regulatory relief for small businesses where feasible.

FDA is proposing changes to the food label that will, for the most part, codify changes mandated by the 1990 amendments. The agency has prepared a regulatory impact analysis (RIA) to determine the economic effects of this and other proposed labeling rules which amend food labeling regulations under 21 CFR part 101. This proposed action will provide consumers with a selection of butter products that are informatively labeled.

Because there are no additional costs to manufacturers to comply with this proposed regulation, FDA concludes that this is not a major rule as defined by Executive Order 12291. In addition, FDA certifies that this action will not result in a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with section 3(b)(1)(B) of the 1990 amendments, FDA must issue by November 8, 1992, final regulations permitting nutrient content claims for butter. If the agency does not promulgate final regulations by November 8, 1992, section 3(b)(2) of the 1990 amendments provides that the regulations proposed in this document shall be considered as the final regulations. The agency has determined that 90 days is the maximum time that it can provide for the submission of comments and still meet this statutory timeframe for the issuance of final regulations. Thus, the agency is advising that it will not consider any requests under 21 CFR 10.40(b) for extension of the comment period beyond February 25, 1992. The agency must limit the comment period to no more than 90 days to assure sufficient time to develop a final rule based on this proposal and the comments it receives.

VI. References

The following information has been placed on display in the Dockets Management Branch (address above), and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. U.S. Department of Health and Human Services, Public Health Service, "The Surgeon General's Report on Nutrition and Health, "DHHS (PHS) Publication No. 88-50210 (GPO Stock No. 017-001-00465-1), U.S. Government Printing Office, Washington, DC, 1988.

2. U.S. Department of Justice opinion letter, from Harris M. Daugherty, U.S. Attorney General to the U.S. Secretary of the Treasury Department, August 12, 1921.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.67 is added to Subpart D to read as follows:

§ 101.67 Use of nutrient content claims for butter.

(a) Claims may be made to characterize the level of nutrients, including fat, in butter if:

(1) The claim complies with the requirements of § 101.13 and with the requirements of the regulations in this part that define the particular nutrient content claim that is used and how it is to be presented. In determining whether a claim is appropriate, the calculation of the percent fat reduction in milkfat shall be based on the 80 percent milkfat requirement provided by the statutory standard for butter (21 U.S.C. 321a);

(2) The product contains cream or milk, including milk constituents (including, but not limited to, whey, casein, modified whey, and salts of casein), or both, with or without added salt, with or without safe and suitable colorings, with or without nutrients

added to comply with paragraph (a)(3) of this section, and with or without safe and suitable bacterial cultures; and

(3) The product is not nutritionally inferior, as defined in § 101.3(e)(4), to butter as produced under 21 U.S.C. 321a.

(b) The performance characteristics (e.g., physical properties, organoleptic characteristics, functional properties, shelf life) of the product shall be similar to butter as produced under 21 U.S.C. 321a. If there is a significant difference in performance characteristics, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for baking purposes"). Such statement shall appear on the principal display panel within the bottom 30 percent of the area of the label panel in type that shall be no less than ½ the size of the type used for such claim but no smaller than 1/16 of an inch.

(c) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of this part.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27158 Filed 11-26-91; 8:45 am]

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21 CFR Part 100

[Docket No. 91N-0038]

RIN 0905-AD08

State Petitions Requesting Exemption From Federal Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to provide for petitions requesting exemption from preemption for certain State or local food standards and other labeling requirements that are preempted under the provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). The proposed regulations set out the procedures for the submission, and for agency review, of these petitions, and the information that the petitioner should supply. Petitions by State and local governments seeking exemption from specified preemptive Federal requirements are specifically authorized by the 1990 amendments.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective November 8, 1992, or 30 days after date of publication in the **Federal Register**, if earlier.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, 301-443-1751.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0229.

SUPPLEMENTARY INFORMATION:

I. Background

A. Federal Labeling Requirements Made Preemptive by the Nutrition Labeling and Education Act of 1990

The Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments) amends the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*) (the act) to provide, among other things, for Federal preemption of certain food standards and labeling requirements issued by a State or a political subdivision of a State (hereinafter referred to collectively as "State"). Section 6(a) of the 1990 amendments adds section 403A to the act (21 U.S.C. 343-1) which provides that after the effective date of the operative provisions (prescribed in section 10(b) of the 1990 amendments), no State may directly or indirectly establish under any authority, or continue in effect as to any food in interstate commerce, any of the following types of requirements:

1. Any requirement for a food that is the subject of a standard of identity established under section 401 of the act (21 U.S.C. 341) that is not identical to such standard of identity or that is not identical to the requirements of section 403(g) of the act (21 U.S.C. 343(g)). Section 403(g) of the act states that a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been established under section 401 of the act, unless it conforms to the definition and standard, and its label bears the name of the food specified in the definition and standard. Preemption of this type of requirement became effective on November 8, 1990, the date of enactment of the 1990 amendments (section 10(b)(1)(A) of the 1990 amendments).

2. Any requirement for the labeling of foods that relates to use of the term "imitation" that is not identical to the requirements of section 403(c) of the act; any requirement for label information identifying the manufacturer, packer, or distributor and the quantity of contents, that is not identical to the requirements of section 403(e) of the act; and any requirement concerning the listing on the label of ingredients that is not identical to the requirements of section 403(i)(2) of the act. Preemption of these types of requirements (section 403A(a)(2) of the act) will take effect on November 8, 1991, 1 year after the date of the enactment of the 1990 amendments (section 10(b)(1)(B) of the 1990 amendments).

3. Any requirement for the labeling of food that is offered for sale under the name of another food that is not identical to the requirements of section 403(b) of the act; any requirement concerning a container that is so made, formed, or filled as to be misleading that is not identical to the requirements of section 403(d) of the act; any requirement concerning the prominence of required information on the label that is not identical to the requirements of section 403(f) of the act; any requirement concerning the labeling of a food purporting to be or represented as a food for which a standard of quality or a standard of fill has been established under section 401 of the act that is not identical to the requirement of section 403(h) of the act; any requirement that the label of a food bear the common or usual name of the food that is not identical to the requirements of section 403(i)(1) of the act; and any requirement that the label states whether a food contains any artificial flavoring, artificial coloring, or a chemical preservative that is not identical to the requirements of section 403(k) of the act. Under section 6(b) of the 1990 amendments, these six provisions (section 403A(a)(3) of the act) do not become preemptive until FDA determines that each is being adequately implemented by Federal regulations (see section 403(A)(a) of the act and section 10(b)(1)(C) of 1990 amendments).

Whether there is adequate implementation of the State and Federal requirements of the type addressed in section 403A(a)(3) of the act is being studied by the Committee on State Food Labeling of the National Academy of Sciences (the committee), Institute of Medicine, Food and Nutrition Board (56 FR 21388, May 8, 1991 (and 56 FR 55130, October 24, 1991)). Although the 1990 amendments state that the contract shall provide for completion of the committee's study by May 8, 1991, completion of the study and the committee's report has been delayed by unforeseen circumstances (56 FR 21388,

May 8, 1991 and 56 FR 55130, October 24, 1991). The committee has informed the agency that the study report will take more time than initially anticipated because of the magnitude of the undertaking and its importance, as well as the complexity of the issues involved.

The agency believes that the committee's report is crucial to the agency's development of a proposed list of which of the six provisions listed in section 403A(a)(3) of the act are being adequately implemented and which are not. Thus, a delay in publication of a proposed list beyond the August 8, 1991 date specified in the 1990 amendments is justified. The agency still expects to issue its final list of the sections of the act that are, and that are not, being adequately implemented by the November 8, 1992 deadline set in the 1990 amendments. If the agency does not issue a final list, the proposed list, which FDA expects to publish in early 1992, is to be considered the final list, and preemption will become effective on November 8, 1992 for those sections found to be adequately implemented in the proposed list.

Under the amendments, FDA is to also propose revisions by November 8, 1992, and issue final revisions by May 8, 1993, to any regulations found to be inadequately implemented (sec. 6(b)(3) of the 1990 amendments). Preemption will become effective on the effective date of the final revisions to any regulations initially found to be inadequate. If the agency does not issue final revisions by May 8, 1993, the proposed revisions will be considered the final revisions under the 1990 amendments, and preemption will become effective on May 8, 1993.

4. Any requirement for nutrition labeling or for nutrient content or health claims on food labels that is not identical to the requirements of section 403 (q) and (r) of the act. The 1990 amendments amended section 403 of the act by adding paragraphs (q) and (r) pertaining to nutrition labeling and label claims (nutrient content and health claims), respectively. Preemption of nutrition labeling requirements and requirements for label claims (section 403A (a)(4) and (a)(5) of the act) will become effective when regulations to implement sections 403 (q) and (r) of the act take effect (section 10 (b)(1)(D) and (b)(1)(E) of the 1990 amendments).

However, section 10(b)(2) of the 1990 amendments creates an exception to the effective dates for preemption granted under section 403A (a)(3), (a)(4), and (a)(5) of the act. Under this exception, if a State submits a petition for exemption from Federal preemption under section 403A(b) of the act within 18 months of enactment, i.e., by May 8, 1992, the State requirement will not be preempted until 24 months after the date of enactment of the 1990 amendments (November 8, 1992), or until FDA acts on the petition, whichever is later.

B. State Petitions for Exemption From Federal Preemption

The 1990 amendments also add section 403A(b) of the act, which permits the States to petition FDA for an exemption from the Federal preemption granted by section 403A(a) of the act. Three criteria must be met for an exemption to be granted. The State must show through the petition that the State requirement: (1) Would not cause any food to be in violation of any applicable requirement under Federal law, (2) would not unduly burden interstate commerce, and (3) addresses a particular need for information not met by the requirements of Federal law.

In the **Federal Register** of March 14, 1991 (56 FR 10906), the agency announced that it was developing procedural regulations to govern the content, substance, and agency review of State petitions in addition to the other types of petitions (petitions for health claims and nutrient content claims) specifically authorized by the 1990 amendments. In the March 14, 1991 notice, the agency stated its belief that the issuance of procedural regulations is a necessary first step in providing the framework within which a petitioner can develop the petitions authorized by the 1990 amendments, and within which the agency can evaluate and act on such petitions. In the same notice, the agency also advised that it will deny or defer action on any petition requesting action under the 1990 amendments that is submitted before issuance of final procedural regulations for petitions. However, as noted above, the 1990 amendments give special standing to States that submit petitions by May 8, 1992, seeking exemption from the preemption provisions of section 403A(a)(3), (a)(4), and (a)(5) of the act (section 10(b)(2) of the 1990 amendments). It would, therefore, be improper to deny such petitions because procedural regulations for State petitions have not been issued. The agency thus stated in the March 14, 1991 notice that it is likely to defer action on, rather than to deny, State petitions given this special standing until after this proposed rule is finalized. The agency requested information and comments from interested persons on the March 14, 1991 notice. The agency is reflecting section 10(b)(2) of the 1990 amendments in proposed § 100.1(g).

C. Comments to Agency Notice on Procedural Regulations

Twelve comments were received from States, industry, industry trade associations, and consumer interest groups in response to the March 14, 1991 notice. The comments were considered, and many of the recommendations were incorporated, or otherwise used, in the development of this proposed rule.

One comment requested that FDA withdraw the March 14, 1991 notice and not develop procedural regulations for petitions authorized by the 1990 amendments. The comment characterized the development of procedural regulations as a waste of agency resources, and stated that the development of regulations could take years to complete.

The agency disagrees with this comment. The 1990 amendments contemplate that the agency may issue regulations prescribing the conditions under which a State requirement may be exempt from Federal preemption. Section 403A(b) of the act specifically authorizes the agency to grant such exemptions from preemption "under such conditions as may be prescribed by regulation." Furthermore, the agency believes that it is essential that a State provide the agency with the necessary information to facilitate the agency's review of these petitions and to enable it to make the findings required by section 403A(b) of the act. The agency believes that the development of procedural regulations that specify the format of State petitions and the information that should be included in such petitions: (1) Will result in the most efficient use of the agency's and the States resources, (2) will expedite the review and the decision-making process, and (3) will enable the agency to evaluate all petitions in a consistent manner.

Some comments recommended that petitions for exemption from preemption be submitted as citizens' petitions under § 10.30 (21 CFR 10.30).

The agency believes that § 10.30 alone does not provide adequate guidance to a State seeking exemption from preemption, especially with respect to the specific showings required of a petitioner by the 1990 amendments. However, some of the provisions of § 10.30 are applicable to State petitions and have been adopted in the proposed procedural regulation as described in the next section.

Other comments recommended that the petition procedure be modeled after the Consumer Product Safety Commission's (CPSC) regulations for the

exemption of State requirements from preemption by the provisions of the Flammable Fabrics Act (15 U.S.C. 1191 *et seq.*), the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*), the Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*), and the Poison Prevention Packaging Act (15 U.S.C. 1471 *et seq.*) (56 FR 3414, January 30, 1991). As is the case for the 1990 amendments, the preemption provisions of the four CPSC administered acts expressly bar differing State requirements unless exemption is granted by the Federal agency upon petition by a State.

An exemption may be granted by the CPSC only if it finds that compliance with the State requirement will not result in a violation of the applicable CPSC requirements; that the State requirement provides a substantially higher degree of protection than the CPSC requirement from the risk of illness or injury that they both address; and that the State requirement does not unduly burden interstate commerce. In 1977, the United States District Court for the District of Minnesota in *Cosmetic, Toiletry and Fragrance Association, Inc., et al.* v. *State of Minnesota et al.*, 440 F. Supp. 1216 (D. Minn. 1977), *affirmed* 575 F.2d 1256 (8th Cir. 1978), in examining the preemption provisions of the CPSC administered acts, described this approach as representing "the most appropriate response to the factors present in the modern regulatory process—legislative rulemaking on a national scale, state attempts to provide a greater degree of protection, and corresponding burdens on interstate commerce. As it also represents the most recent Congressional response, the court suspects that it would probably be adopted if Congress were once again to legislate with regards to food, drug, and cosmetic products." The 1990 amendments are a more recent congressional response, and Congress did adopt similar criteria.

The recommendation that the CPSC regulations serve as a model for this proposed rule has merit because the CPSC regulations and this proposed rule pertain to the same matter-exemption from preemption. Further, the agency finds the general format of the CPSC regulations to be useful and appropriate as a general format for the procedural regulations that the agency is proposing herein. The agency has therefore followed the same general format in its proposed regulation as is in the CPSC regulations in 16 CFR part 1061. However, many of the substantive elements of FDA's regulation differ from those of the CPSC regulation inasmuch as they address the substantive requirements of 1990 amendments.

Some comments requested that individuals or parties other than States be accorded the right to petition for exemption.

The agency believes that only States have legal standing to petition for exemption. The agency's opinion is based on the wording in the 1990 amendments that, "Upon petition of a State or a political subdivision of a State, the agency may exempt * * *." Thus, Congress did not authorize petitions from other parties.

Two comments indicated to the agency that preemption is not well understood. These comments stated that a State should be able to petition for an exemption from preemption when the State has labeling requirements that are not addressed directly or indirectly by Federal law, or when the State requirement is not preempted by any Federal law, either explicitly or implicitly.

The agency is not taking any action in response to these comments. If a State requirement is not preempted by a Federal law, it simply makes no sense to provide a mechanism by which a State can seek exemption from preemption for that requirement. An exemption is an immunity from a requirement. If the requirement does not apply, that is, the State requirement is not subject to preemption, there is no need for a mechanism by which the immunity may be sought.

Moreover, section 6(c)(1) of the 1990 amendments clearly manifests Congress's intention that the 1990 amendments "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Act." Section 403A of the act is only operative in matters where there is a Federal requirement applicable to the labeling addressed in the State requirement. If there is no applicable Federal requirement that has been given preemptive status by Congress, there is no competing claim of jurisdiction, and, therefore, no basis under the 1990 amendments for Federal preemption or grounds to justify the submission of a State petition for exemption. Therefore, FDA has no authority under the 1990 amendments to rule on State petitions for exemption where the 1990 amendments have not imposed such Federal requirements. Of course section 6(c)(3) of the 1990 amendments provides that the amendments shall not affect any preemption, expressed or implied, which arises under the Constitution or other provisions of Federal law or regulation.

Several examples of the types of State requirements that would not be subject to the preemption provisions of the 1990 amendments were given in the Congressional Record of July 30, 1990 (H5842). The examples included State laws pertaining to issues for which there is no national framework, such as open date labeling, unit price labeling, container deposit labeling, religious dietary labeling, and previously frozen labeling.

Comments from States and consumer interest groups advocated that the agency apply liberal criteria in establishing the types and degree of information necessary to sustain a State's burden of proof in a petition. Comments from the food industry advocated strict construction of the 1990 amendments, and thus a more exacting standard for information requirements for State petitions.

In construing the provisions for exemption from preemption, the agency is guided by the policy in Executive Order 12612 (E.O. 12612) of October 26, 1987 on federalism (52 FR 41685 at 41687, October 30, 1987) that preemption of State law shall be restricted to the minimum level necessary to achieve the objectives of the statute. A corollary of this policy is that exemption from preemption should be liberally granted to the extent that the statutory objectives are fulfilled. FDA will consider E.O. 12612 as part of its review of any petitions that it receives.

The agency therefore must determine what effect a grant of an exemption from preemption will have on the congressional objective of providing national uniformity for certain aspects of food labels and labeling. Congress noted that since the enactment of the act in 1938, major changes have taken place in the marketing of foods in the U.S. The last 50 years have seen a decline in the numbers of plants and companies that serve regional markets and an increase in the nationwide distribution and marketing of foods. As one of the Senate sponsors of the bill that became the 1990 amendments stated:

> Today, we have a single food supply. Therefore, we need a single, integrated, and coordinated system with an appropriate allocation of regulatory responsibility among the Federal, State, and local governments. And, we need this for a reason: We must have confidence in the safety of our national food supply; and we must have consumers who can make informed decisions so they can adopt sound dietary practices.

(Congressional Record, S16611, October 24, 1990.)

Congress included limited express preemption in the 1990 amendments

because, according to one of the managers of the bill in the House,

> * * * it was decided that the fairest way to expect the food industry to support a nutrition labeling bill, was to give them some types of preemption of burdensome State laws that interfered with their ability to do business in all 50 States. Therefore, the bill provides industry with uniformity of law in a number of important areas—such as standards of identity, imitation labeling, and ingredient labeling—that will permit them to conduct their business in an efficient and cost-effective manner.

(Congressional Record, H12954, October 26, 1990.)

Congress reserved to the States the option of putting into effect composition or labeling requirements that differ from, and are more stringent than, Federal requirements providing that the States can demonstrate that the statutory criteria for exemption from preemption are met. The agency has included in the proposed regulations set forth below the matters that it considers necessary for a State to address to justify an exemption. A more liberal and less exacting interpretation of the types and depth of information required to sustain a State's burden of proof in a petition would undermine the congressional objective of national uniformity in certain aspects of food labeling.

Several States suggested that an exemption be granted by an advisory opinion rather than by regulation.

Although the 1990 amendments do not require that the exemption be granted by regulation, the agency believes that exempting a State requirement from Federal preemption is a type of action that may significantly affect many parties, including industry and consumers, and as such, the agency is proposing that such exemption be granted by notice and comment rulemaking. The rulemaking process will provide interested parties with the opportunity to comment on a proposed regulation granting exemption. If the agency determines that exemption should be granted, codification of the exemption in the food labeling regulations will ensure that all of the relevant information concerning the exemption, including its scope and conditions, is readily accessible for examination by all affected parties.

II. Proposed Regulation

The proposed rule states in § 100.1(a) the scope and purpose of the procedural regulation and cites the statutory authority for the agency to act on State petitions requesting exemption from preemption. Proposed § 100.1(b) defines the terms used in the proposed regulation.

In proposed § 100.1(c), the regulation lists the prerequisites that must be met for the merits of the petition to be considered. The State requirement must have been enacted in its final form and must either be in effect or would be in effect but for the provisions of section 403A(a) of the act (proposed § 100.1(c)(1)).

Under proposed § 100.1(c)(2), the preemptive Federal regulation also must have the full force and effect of law. However, FDA is proposing that a petition seeking exemption from a Federal requirement that has been published as a final rule with a designated effective date may be submitted before the effective date of that final rule. Petitions seeking exemption from Federal requirements that are preemptive under sections 403A (a)(3) through (a)(5) of the act and that are submitted before May 8, 1992 will be considered timely even though the requirements for which exemption from preemption is requested may not actually be in effect on that date. This portion of proposed § 100.1(c)(2) reflects the special standing given these petitions under section 10(b)(2) of the 1990 amendments.

Proposed § 100.1(c)(3) requires that the petitioner must be an official of the State having authority to act for, or on behalf of, the State in applying for an exemption.

Proposed § 100.1(c)(4) reflects that a State requirement is subject to preemption under section 403A(a) of the act if it is not identical to the corresponding Federal requirement. In proposed § 100.1(c)(4), the agency advises that it interprets the term "not identical" to mean that the State imposes obligations or contains provisions that are not imposed by or contained in the applicable Federal law regulation, including a standard of identity, quality, or fill, or that differ from those imposed by or contained by the applicable Federal law or regulation. Therefore proposed § 100.1(c) defines "not identical" as follows:

> "Not identical" does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that: (1) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act, or (2) differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the Act.

The requirements for petitions under section 403A(b) of the act are proposed in the petition format requirements in § 100.1(d). The petitioner should identify and document the State requirement for which exemption is sought, identify the Federal requirement that is believed to preempt the State requirement, explain the rationale of the State requirement, and compare it to the Federal requirement. The petitioner should address with specificity the grounds for exemption from preemption stated in the 1990 amendments. In this regard, the State will be expected to show that the State requirement will not cause a food label to be in violation of any applicable requirement under Federal law. In a case where a State requirement would allow for the violation of any Federal requirement, the agency could not grant the petition. The State would be free, however, to submit a citizen petition to the agency under § 10.30 to amend the Federal requirement to the extent the agency could affect such an amendment by regulation. The State will also have to supply specific information on the effect that the granting of exemption will have on interstate commerce. This information will be used by the agency in reaching a finding as to whether granting the exemption will unduly burden interstate commerce. Finally, the petitioner should identify and discuss the particular information need that the State requirement is designed to meet that is not met by Federal law. In this context, any public health considerations will be relevant.

The proposal also states that the petition needs to include a claim for a categorical exclusion under 21 CFR 25.24 or an environmental assessment under 21 CFR 25.31. Finally, the proposal states that the petition should include the name and address of the person to be notified of the agency's action concerning the petition and a certification by the petitioner that to his best knowledge and belief, the petition includes all information and views on which it relies.

The proposed rule provides in § 100.1(e) that public disclosure of State petitions will be governed by the rules specified in § 10.20(j). Proposed § 100.1(f) details the procedures for the agency's consideration of State petitions. Section 100.1(f)(1) states that unless otherwise specified, all relevant provisions and requirements of 21 CFR Part 10—Administrative Practices and Procedures, Subpart B—General Administrative Procedures, are applicable to State petitions requesting exemption from Federal preemption under section 403A(b) of the act. Such provisions include the opportunity for an interested person to request

reconsideration of the agency's decision on a petition under § 10.33.

Proposed § 100.1(f)(2) provides that if a petition does not meet the prerequisite requirements of § 100.1(c), the agency will issue a letter to the petitioner denying the petition and stating in what respect the petition did not meet the prerequisite requirements. Proposed § 100.1(f)(3) states that if a petition appears to meet the prerequisite requirements in § 100.1(c), it will be filed by the Dockets Management Branch, stamped with the date of filing, and assigned a docket number to be used for all subsequent submissions relating to the petition. The filing of the petition is without prejudice concerning the agency's final action on the petition. Proposed § 100.1(f)(4) provides that any interested person may submit written comments on a filed petition as provided in § 10.30(d).

Proposed § 100.1(f)(5) provides that within 90 days of the date of filing, the agency will furnish a response to the petitioner. The response will either: (1) State that the agency has tentatively determined that the petition merits the granting of an exemption, and that FDA intends to publish in the **Federal Register** a proposal to grant the exemption through rulemaking, (2) deny the petition and state the reasons for such denial, or (3) provide a tentative response stating why the agency has been unable to reach a decision on the petition, e.g., because of other agency priorities or a need for additional information.

An exemption under this proposed regulation will be granted only to the petitioner State. Exemption from preemption is largely based on an evaluation of a unique situation within a State. Should a situation arise that is more national in scope, the agency would consider amending the Federal requirement because the action requested would be more universal than that envisioned by Congress in providing for exemption.

III. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the provisions of § 100.1 *Petitions requesting exemption from preemption for State or local requirements* relating to submission of petitions to FDA will be submitted for approval to the Office of Management and Budget (OMB). These provisions will not be effective until FDA obtains OMB approval. FDA will give notice of OMB approval of these requirements in the **Federal Register** as part of any final rule that is based on this proposal.

V. Economic Impact and Federalism Implications

FDA has examined the economic implications of the proposed rule pertaining to 21 CFR part 100 requirements as required by Executive Order 12291 and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking and the Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. As discussed in section I.C. of this document, FDA has fully considered the effect of Executive Order 12612.

This proposed regulation codifies procedures to be followed by a State or local government in petitioning the agency for an exemption from preemption by Federal food standards and labeling regulations. FDA has no information as to the cost to a State to prepare and submit the required petition to the agency; however, the petition process has been structured to minimize the paperwork burden on the State. If, for example, the required paperwork costs $100 per State action to prepare, it would take over 1 million enforcement actions to cause this proposed requirement to become a major rule, an unlikely event. Thus, FDA concludes that this proposed rule is not a major rule as defined by Executive Order 12291. In addition, FDA certifies that this action will not result in a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Effective Date

The agency intends to issue final regulations pertaining to the State enforcement provisions of the 1990 amendments by November 8, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective November 8, 1992, or 30 days after publication in the **Federal Register**, if earlier. The agency believes that November 8, 1992, is the appropriate effective date for these petition regulations because that is the date on which section 307 of the act becomes effective, under which States may bring enforcement actions in their own names in Federal courts for violations of Federal requirements having preemptive effect under the 1990 amendments. November 8, 1992, is also the date by which the agency is to have published final regulations implementing sections 403(q) and 403(r) (see sections 2(b) and 3(1)(B) of the 1990 amendments) as well as a list of sections adequately implementing the statutory requirements specified in section 403A(a)(3) (see section 6(b)(3)(B) of the 1990 amendments).

List of Subjects in 21 CFR Part 100

Administrative practice and procedure, Food labeling, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 100 be amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR part 100 continues to read as follows:

Authority: Secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. A new subpart A consisting of § 100.1 is added to read as follows:

Subpart A—State and Local Requirements

§ 100.1 Petitions requesting exemption from preemption for State or local requirements.

(a) *Scope and purpose.* (1) This subpart applies to the submission and consideration of petitions under section 403A(b) of the Federal Food, Drug and Cosmetic Act (the act), by a State or a political subdivision of a State, requesting exemption of a State requirement from preemption under section 403A(a) of the act.

(2) Section 403A(b) of the act provides that where a State requirement has been preempted under section 403A(a) of the act, the State may petition the agency

for an exemption. The agency may grant the exemption if the agency finds that the State requirement will not cause any food to be in violation of any applicable requirement under Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement.

(b) *Definitions.* (1) *Act* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

(2) *Agency* means the Food and Drug Administration.

(3) *Commissioner* means the Commissioner of Food and Drugs.

(4) *State* means a State as defined in section 201(a)(1) of the act (which includes a territory of the United States, the District of Columbia, and Puerto Rico) or any political subdivision of a State having authority to issue food standards and food labeling regulations having force of law.

(5) *State requirement* means any statute, standard, regulation, or other requirement that is issued by a State.

(c) *Prerequisites for petitions for exemption from preemption.* The Food and Drug Administration will consider a petition for exemption from preemption on its merits only if the petition demonstrates that:

(1) The State requirement was enacted or was issued as a final rule by an authorized official of the State and is in effect or would be in effect but for the provisions of section 403A of the act.

(2) The State requirement is subject to preemption under section 403A(a) of the act because of a statutory provision listed in that section or because of a Federal standard or other Federal regulation that is in effect, or that has been published as a final rule with a designated effective date, and that was issued under the authority of a statutory provision listed in that section. For the purposes of this subpart, all petitions seeking exemption from preemption under section 403A(a)(3) through (a)(5) of the act, if submitted before May 8, 1992, will be considered timely even though the applicable statutory provisions or regulations are not yet in effect.

(3) The petitioner is an official of a State having authority to act for, or on behalf of, the Government in applying for an exemption of State requirements from preemption.

(4) The State requirement is subject to preemption under section 403A(a) of the act because it is not identical to the requirement of the preemptive Federal statutory provision or regulation including a standard of identity, quantity, and fill. *Not identical* does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that:

(i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or

(ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act.

(d) *Form of Petition.* (1) All information included in the petition should meet the general requirements of § 10.20(c) of this chapter.

(2) Four copies of the petition for exemption from preemption for a State requirement shall be submitted to the Dockets Management Branch in the following form:

(Date)———————————

Dockets Management Branch, Food and Drug Adninistration, Department of Health and Human Services, Rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

Petition Requesting Exemption From Preemption for State Requirement

The undersigned submits this petition under section 403A(b) of the Federal Food, Drug, and Cosmetic Act to request that the Food and Drug Administration exempt a State requirement from preemption.

The undersigned has authority to act for, or on behalf of, the (*identify State or political subdivision of the State*) because (*document petitioner's authority to submit petition on behalf of the State*).

A. Action Requested

1. Identify and give the exact wording of the State requirement and give date it was enacted or issued in final form.

2. Identify the specific standard or regulation that is believed to preempt the State requirement and the section and paragraph of the act that the standard or regulation implements.

B. Documentation of State Requirement

Provide a copy of the State requirement that is the subject of the application. Where available, the application should also include copies of any legislative history or background materials used in issuing the requirement, including hearing reports or studies concerning the development or consideration of the requirement.

C. Statement of Grounds

A petition for an exemption from preemption should contain the following:

1. An explanation of the State requirement and its rationale, and a comparison of State and Federal requirements to show differences.

2. An explanation of why compliance with the State requirement would not cause a food to be in violation of any applicable requirement under Federal law.

3. Information on the effect that granting the State petition will have on interstate commerce. The petition should contain information on economic feasibility, i.e., whether the State and Federal requirements have significantly different effects on the production and distribution of the food product; comparison of the costs of compliance as shown by data or information on the actual or anticipated effect of the State and Federal requirements on the sale and price of the food product in interstate commerce; and the effect of the State requirement on the availability of the food product to consumers. To the extent possible, the petition should include information showing that it is practical and feasible for producers of food products to comply with the State requirement. Such information may be submitted in the form of statements from affected persons indicating their ability to comply.

4. Identification of a particular need for information that the State requirement is designed to meet, which need is not met by Federal law. The petition should describe the conditions that require the State to petition for an exemption, the information need that the State requirement fulfills, the inadequacy of the Federal requirement in addressing this need, and the geographical area or political subdivision in which such need exists.

D. Environmental Impact

The petition shall contain a claim for categorical exclusion under 21 CFR 25.24 or an environmental assessment under 21 CFR 25.31.

E. Notification

Provide name and address of person, branch, department, or other instrumentality of the State government that should be notified of the Commissioner's action concerning the petition.

F. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies.

(Signature) ———————————

(Name of petitioner) ———————————

(Mailing address) ———————————

(Telephone number) ———————————

(e) *Submission of petition for exemption; public disclosure.* The availability for public disclosure of a petition for exemption will be governed by the rules specified in § 10.20(j) of this chapter.

(f) *Agency consideration of petitions.* (1) Unless otherwise specified in this section, all relevant provisions and requirements of subpart B of part 10 of this chapter, are applicable to State petitions requesting exemption from Federal preemption under section 403A(b) of the act.

(2) If a petition does not meet the prerequisite requirements of paragraph (c) of this section, the agency will issue a letter to the petitioner denying the

petition and stating in what respect the petition does not meet these requirements.

(3) If a petition appears to meet the prerequisite requirements in paragraph (c) of this section, it will be filed by the Dockets Management Branch, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Dockets Management Branch for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. The Dockets Management Branch will promptly notify the petitioner in writing of the filing and docket number of a petition.

(4) Any interested person may submit written comments to the Dockets Management Branch on a filed petition as provided in § 10.30(d) of this chapter.

(5) Within 90 days of the date of filing the agency will furnish a response to the petitioner. The response will either:

(i) State that the agency has tentatively determined that the petition merits the granting of an exemption, and that it intends to publish in the **Federal Register** a proposal to grant the exemption through rulemaking;

(ii) Deny the petition and state the reasons for such denial; or

(iii) Provide a tentative response indicating why the agency has been unable to reach a decision on the petition, e.g., because of other agency priorities or a need for additional information.

(g) If a State submits a petition for exemption of a State requirement from preemption under section 403A(a)(3) through (a)(5) of the act before May 8, 1992, that State requirement will not be subject to preemption until:

(1) November 8, 1992; or

(2) Action on the petition, whichever occurs later.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27153 Filed 11-26-91; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 100

[Docket No. 91N-0343]

RIN 0905-AD08

State Enforcement Provisions of the Nutrition Labeling and Education Act of 1990

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to implement section 4 of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which provides for State enforcement of certain requirements of the Federal Food, Drug, and Cosmetic Act (the act), so long as the state provides 30 days notice of its intent to act and complies with other procedural requirements before taking any such enforcement action. The agency is proposing to adopt regulations that will provide the states with instructions on how to give the requisite 30-day notice. FDA has framed these instructions to ensure that this notification system functions efficiently. This proposal also describes relevant State and Federal obligations.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Janice F. Oliver, Center for Food Safety and Applied Nutrition (HFF-310), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-485-0187.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). The 1990 amendments make the most significant changes in food labeling law since the passage of the act in 1938. In this document, FDA is proposing to adopt procedures to implement section 4 of the 1990 amendments, which amended section 307 of the act (21 U.S.C. 337) to authorize states to enforce certain sections of the act in their own names.

Before the passage of the 1990 amendments, section 307 of the act required that all enforcement proceedings be by, and in the name of, the United States. A state could only use its own laws to bring enforcement action against food located in that state. Any enforcement of the act had to be undertaken by the Federal government.

Under the 1990 amendments, section 307(b)(1) of the act has been revised to authorize a state to bring in Federal court in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 401 (Definitions and Standards for Foods) and of the misbranding provisions of sections 403(b) (offered for sale under another name), 403(c) (imitation of another food), 403(d) (misleading containers), 403(e) (name and address of manufacturer and net weight), 403(f) (prominence of information on label), 403(g) (representation as to definition and standard of identity), 403(h) (representation as to standard of quality and fill of container), 403(i) (common or usual name and ingredient labeling of all fabricated food), 403(k) (artificial flavoring, artificial coloring, or chemical preservative), 403(q) (nutrition information), and 403(r) (claims) of the act (21 U.S.C. 341, 343(b) through (i), (k), (q), and (r)), if the food that is the subject of the proceeding is located within the state. This provision will enable the states to supplement FDA s enforcement capabilities. It is effective 24 months after date of enactment. See section 10(a)(1)(C) of the 1990 amendments.

Under section 307(b)(2) of the act, however, a state's ability to exercise this new authority to enforce Federal law is predicated on certain conditions:

(1) A proceeding may not be commenced unless the state has given notice to FDA that it intends to bring such proceeding; also, the state must wait 30 days after giving notice before instituting action.

(2) If after receiving such notice, FDA, within 30 days, commences an informal or formal enforcement action pertaining to the food in question, the state may not bring its proceeding until an additional 60 days have passed (90 days from the initial notice by the state).

(3) If FDA is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal enforcement action or the formal enforcement action pertaining to such food, the state may not institute a proceeding. Section 307(b)(2) of the act, however, does permit a state to intervene as a matter of right in any court proceeding that has been brought by FDA.

Although the statute and legislative history are silent as to what is meant by "informal or formal enforcement action," FDA interprets "informal enforcement actions" to include warning letters, recalls, and detentions. It interprets "formal enforcement actions" to include seizures, injunctions, and prosecutions. Informal actions include those that FDA can take administratively, while formal actions

are those that require the initiation of a judicial proceeding.

FDA believes that for purposes of section 307(b)(2)(B) of the act, a criminal action would be a "formal enforcement action pertaining to the food," even though the criminal action is against a corporation or individual and not the food itself (as a seizure action is), so long as the food in question provides the factual basis, or part of the factual basis, for the criminal charge (e.g., the charge is for introducing misbranded food into interstate commerce, and the allegedly misbranded food is the product that is to be the subject of the State action). FDA also believes that it is appropriate to regard a criminal action in this way, even though section 307(b)(1) only authorizes the state to bring proceedings for the civil enforcement, or to restrain violations, of the specified sections of the act because criminal proceedings may have the effect of eliminating the alleged misbranding, which would be the purpose of the State proceedings. FDA requests comments on these matters.

FDA is incorporating its interpretation of "informal enforcement action" and "formal enforcement action" in proposed § 100.2(j).

FDA is proposing to adopt in 21 CFR 100.2 a set of regulations that reflect the requirements of section 307 of the act. Proposed § 100.2(a) incorporates and reflects the provisions of section 307(b)(1) of the act. Similarly, proposed § 100.2(b) incorporates the provisions of section 307(b)(2)(A), (b)(2)(B), and (b)(2)(C) of the act, and proposed § 100.2(c) incorporates the provisions of the last sentence of section 307(b)(2).

FDA is also proposing to adopt procedures that a state should follow in notifying the agency of its intention to institute an enforcement action. First, in § 100.2(d), FDA is proposing a standard format for the letter of notification. The agency is also delineating the information that should be submitted in this letter. The letter should include the name and address of the State agency, the name and address of the firm against which enforcement action is proposed (if applicable), the specific products covered by the notification, the type and size of each product container, the manufacturing code (if applicable), and the reason for and type of anticipated State enforcement action, including the section of the act violated. For example, the notification would state that the product is in violation of section 403(b) of the act in that it is a product that is sold under the name of another food. It would go on to state that the product is sold as 100 percent pure blackberry juice, whereas it is actually a combination of grape and blackberry juice with grape juice being the predominant ingredient. Finally, it would state that the anticipated action is seizure. This information will enable FDA to quickly review the proposed State action and to determine whether the agency is contemplating, or has undertaken, action against the food in question, or would undertake action in light of the facts brought to its attention by the State.

Under proposed § 100.2(e), the letter of notification should be signed by a state official authorized to institute the proposed action. Such a signature will ensure that the state actually intends to institute the action in question. Under proposed § 100.2(f), the letter should be sent to the Food and Drug Administration, Division of Regulatory Guidance (HFF-310), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204. It is necessary that FDA headquarters be notified so that it can determine whether an action against the food in question has been brought or is contemplated anywhere in the country. Because Congress used the word "pertain" in section 307 of the act, FDA believes that an agency action anywhere in the United States against the food in question would, under section 307(b)(2), bar a State action against the food in Federal court. The agency does not interpret the act to require that FDA action be against the food in the state that has submitted a notice. This view is consistent with section 304(a)(1) of the act, which limits the number of actions against a particular misbranding to one, except in limited circumstances not applicable in this context.

FDA is proposing in § 100.2(g) and (h) to set out the procedures that it will follow in responding to a State's notification. Under proposed § 100.2(g), FDA will notify the state of the date on which it received the letter of notification within 2 working days after date of receipt of such letter. This notification is necessary so that the state is aware of the date on which the time periods set by section 307 of the act begin to run.

Under proposed § 100.2(h), the Director, Division of Regulatory Guidance, Office of Compliance, Center for Food Safety and Applied Nutrition will, within 30 days of the date of notification, respond to the notification by advising:

(1) Whether FDA has commenced an informal or formal enforcement action pertaining to the food that is the subject of the notification; or

(2) Whether FDA is prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled informal or formal enforcement action pertaining to such food.

The agency believes that the proposed regulations will be beneficial to the states and to FDA because having these procedures firmly in place will expedite the agency review process, will ensure an orderly and timely response to the state, and will facilitate coordinated Federal/State enforcement action against violative products in the marketplace.

State notifications to FDA pursuant to section 307 of the act will contain information compiled for law enforcement purposes and may contain trade secret or confidential commercial or financial information. Accordingly, FDA is proposing in § 100.2(i) that information contained in these required notifications will be exempt from public disclosure to the same extent to which such information would be so exempt pursuant to 21 CFR 20.61, 20.64, and 20.88 of this chapter.

FDA notes that it does not believe section 4 of the 1990 amendments on State enforcement precludes a state from taking enforcement action under its own statute or regulations in State court. It is the opinion of the agency that State regulations that are identical to Federal regulations are not preempted by section 6 of the 1990 amendments. Under section 6(c)(1) of the 1990 amendments, a provision of State law is not preempted unless such provision is expressly preempted under section 403A of the act (21 U.S.C. 343-1). Each clause of section 403A(a) of the act expressly preempts only those State regulations that are "not identical" to Federal requirements of section 403A(a) of the act (21 U.S.C. 343-1(a)(1)-(a)(5)). Accordingly, State regulations that are identical to Federal requirements are not preempted. Thus, a state may initiate enforcement proceedings under its own statute or regulations in State court. However, to facilitate uniformity in enforcement, FDA encourages states to discuss their State-court enforcement activities with the local FDA district office. Continued close cooperation between FDA and State regulatory agencies will ensure that the goals of uniformity and certainty underlying the act are met.

In implementing section 307 of the act, to avoid any suggestion of an unconstitutional delegation to states to enforce the (Federal) act, FDA retains full authority to advise states of what FDA believes is the proper interpretation of any of the sections of the act that they may seek to enforce. If FDA advises a state that its proposed

action is inconsistent with FDA's interpretation, FDA believes section 307 of the act requires that the state conform its interpretation to FDA's.

II. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the provisions of § 100.2 *State enforcement of Federal regulations* relating to submission of information to FDA will be submitted for approval to the Office of Management and Budget (OMB). These provisions will not be effective until FDA obtains OMB approval. FDA will give notice of OMB approval of these requirements in the **Federal Register** as part of any final rule that is based on this proposal.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore neither an environmental assessment nor an environmental impact statement is required.

IV. Economic Impact

FDA has examined the economic implications of the proposed rule pertaining to part 101 requirements as required by Executive Order 12291 and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking and the Regulatory Flexibility Act requires regulatory relief for small businesses where feasible.

This proposed regulation codifies conditions under which states can enforce certain sections of the act and provides a format for notification of FDA of a state's intent to enforce those provisions. FDA has no information as to the cost of the required submission by states, although the information requested is the minimum required for notification purposes. If, for example, the required paperwork costs $100 per state action to prepare, it would take over one million enforcement actions to cause this proposed requirement to become a major rule, an unlikely event.

Because very little paperwork is required to be submitted, FDA concludes that this proposed rule is not a major rule as defined by Executive Order 12291. In addition, FDA certifies that this action will not result in a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

V. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VI. Effective Date

The agency intends to issue final regulations pertaining to the state enforcement provisions of the 1990 amendments by November 8, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective November 8, 1992, in accordance with the requirements of the 1990 amendments.

List of Subjects in 21 CFR Part 100

Administrative practice and procedure, Food labeling, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 100 be amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR Part 100 is revised to read as follows:

Authority: Secs. 201, 301, 307, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 337, 342, 343, 348, 371).

2. Section 100.2 is added to Subpart A to read as follows:

§ 100.2 State enforcement of Federal regulations.

(a) Under section 307 of the Federal Food, Drug, and Cosmetic Act, a state may bring, in its own name and within its own jurisdiction, proceedings for the civil enforcement, or to restrain violations, of sections 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(k), 403(q), or 403(r) of the act if the food that is the subject of the proceedings is located in the state.

(b) No proceeding may be commenced by a state under paragraph (a) of this section:

(1) Before 30 days after the state has given notice to the Food and Drug Administration (FDA) that the state intends to bring such proceeding.

(2) Before 90 days after the state has given notice to FDA of such intent if FDA has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding.

(3) If FDA is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

(c) A state may intervene as a matter of right, in any court proceeding described in paragraph (b)(3) of this section.

(d) The notification that a state submits in accordance with paragraph (b) of this section should include the following information and be submitted in the following recommended format:

(Date)

Name of State agency _____

Post office address _____

Street address _____

City, State, and ZIP code _____

Name of products(s) covered by the notification

Reporting official, title, and telephone No.

FAX No. _____

Agency contact (if different from reporting official), title, and telephone No.

Director, Division of Regulatory Guidance (HFF-310), Center for Food Safety and Applied Nutrition, Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204.

Dear Sirs: The undersigned, _____, submits this letter of notification pursuant to section 307(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 337(b)(1)) with respect to

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(name of products covered by the notification and the enforcement action that is to be initiated)

Attached hereto, and constituting a part of this letter of notification are the following:

A. The name of the product.

B. The type and size of each product container.

C. Copy of the label and labeling of the product.

D. Manufacturing code (if applicable).

E. Name and address of firm responsible for violations.

F. Name and address of manufacturer or distributor responsible for violations.

G. Name and address of parent firm (if known).

H. Reason for the anticipated state enforcement action (list specific violations, including sections of the law violated).

I. Name of firm against which action is anticipated (if applicable).

Yours very truly,
Reporting Agency
By _____
(Indicate authority)

(e) The letter of notification should be signed by a State official authorized by

the State to institute the contemplated enforcement actions.

(f) The letter of notification should be sent to the Division of Regulatory Guidance (HFF-310), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, FAX number 202-472 1542.

(g) FDA will notify the state of the date on which its letter of notification was received by FDA, Center for Food Safety and Applied Nutrition, Division of Regulatory Guidance (HFF-310) (within 2 working days after date of receipt). This date will be the date of notification for the purposes of paragraph (b) of this section.

(h) The Director, Division of Regulatory Guidance, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, will respond to the State's notification within 30 days of the date of notification by advising:

(1) Whether FDA has commenced an informal or formal enforcement action pertaining to the food that is the subject of the notification; or

(2) Whether FDA is prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled informal or formal enforcement action pertaining to such food.

(i) Information contained in State notification letters required by this section shall be exempt from public disclosure to the same extent to which such information would be so exempt pursuant to §§ 20.61, 20.64, and 20.88 of this chapter.

(j) *Definitions.* (1) "Informal enforcement actions" include warning letters, recalls, detentions, or other administrative enforcement actions that pertain to the food in question.

(2) "Formal enforcement actions" include seizures, injunctions, prosecutions, or other judicial enforcement actions that pertain to the food in question.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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[Docket No. 85N-0061]

RIN 0905-AB67

Labeling; General Requirements for Health Claims for Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general requirements pertaining to: (1) The use of health claims that characterize the relationship of a food component to a disease or health-related condition on the labels and in labeling of both conventional foods and dietary supplements, and (2) the content of petitions regarding the use of such health claims pertaining to specific substances in food. This proposal is issued in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims. It supersedes in all respects FDA's reproposed rule concerning health messages (February 13, 1990, 55 FR 5176). Elsewhere in this issue of the **Federal Register**, FDA is issuing proposals that respond to the 1990 amendments directive that the agency consider 10 topics associating nutrients with diseases or health-related conditions. Those proposals have been developed in accordance with the general principles of the proposed requirements in this document.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following publication of a final regulation pertaining to health claims in food labeling in accordance with requirements of the 1990 amendments.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, 301-443-1751.

FOR FURTHER INFORMATION CONTACT: Victor P. Frattali, Center for Food Safety and Applied Nutrition (HFF-261), Food and Drig Administration, 200 C St., SW., Washington, DC 20204, 202-245-1064.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). This new law amends the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the most notable aspects of the 1990 amendments is that they confirm FDA's authority to regulate nutrient content claims and health claims on food labels and in labeling. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards contained in regulations established under section 403(r)(1)(B) of the act (21 U.S.C. 343 (r)(1)(B))

The enactment of the 1990 amendments reflects a determination by Congress that an orderly and accountable process is needed to control the dissemination of information concerning the relationship between diet and disease or other health-related conditions on the food label and in labeling. Congress characterized this need as "compelling" (Ref. 1). FDA is proposing general requirements to ensure that this information in food labeling will be valid, truthful, nonmisleading, and useful for consumers.

The agency fully recognizes the importance of conveying to American consumers information on the value of improved nutrition to help achieve or maintain good health. FDA is committed to facilitating the provision of such information wherever adequate scientific evidence confirms the validity of the information.

II. Regulatory History

For many years, FDA has permitted firms to label foods with truthful, nonmisleading information about the nutrient content of food. In the past, however, the agency did not permit firms to provide consumers with information on the label or in labeling concerning how the food may be used to affect a disease or health-related condition. FDA generally took a position that including disease-related information on food labeling resulted in the food being a drug within the meaning of the act. The act (section 201(g)(1)(B)) defines a drug, in part, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease in man * * *" (21 U.S.C. 321(g)(1)(B)). Thus, the agency has viewed mention of a disease on a food label as evidence that the product was intended to be used as a drug.

In addition, in the **Federal Register** of March 14, 1973 (38 FR 6950 at 6951), FDA promulgated regulations that provided, in part, that a food shall be deemed to be misbranded if its labeling represents, suggests, or implies that the food, because of the presence or absence of

certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom (currently, 21 CFR 101.9(i)(1)). This provision reinforced the agency's policy concerning disease-related information on food labels. In the **Federal Register** of August 4, 1987 (52 FR 28843) (the 1987 proposal), however, FDA proposed to change its policy to permit the use on food labeling of health messages (in this proposal, the term "health claim" is used in place of "health message" for consistency with terminology used in the 1990 amendments). The agency was responding to the developing scientific data on the relationship between the nutrient content of the diet and disease.

The 1987 proposal proposed to amend nutrition labeling regulations in § 101.9 to permit health claims when:

(1) They are truthful and not misleading;

(2) They are supported by valid, reliable, and publicly available scientific evidence derived from well-designed and well-conducted studies consistent with generally accepted scientific procedures and principles performed and evaluated by persons qualified by expertise and training in the appropriate disciplines;

(3) They are consistent with generally recognized medical and nutritional principles for a sound total dietary pattern; and

(4) The food bears nutrition information in accordance with the requirements of § 101.9.

The agency advised in the 1987 proposal (52 FR 28843) that firms could make health claims consistent with the proposed provisions without prior FDA approval. Thus, FDA created a "safe harbor" from agency enforcement action for such claims.

After publication of the 1987 proposal, health claims began appearing on foods with increasing frequency. In a number of situations, these claims conformed only partially with the proposed provisions. Some manufacturers took advantage of the broad manner in which the proposal was written by making drug claims on products and then, when challenged by FDA, asserting that these claims were consistent with how food could be labeled under the proposal.

Because of the wide divergence of opinion expressed in comments that responded to this proposal, the agency concluded that the issues raised by this proposal could not be resolved without additional and more specific comments from interested persons. In recognition of this need, FDA solicited additional comments on health claims in an advance notice of proposed rulemaking (ANPRM) published in the **Federal Register** of August 8, 1989 (54 FR 32610), that requested public comment on a wide range of food labeling issues. On December 7, 1989, FDA held a public hearing in Seattle at which the topic of health claims was a prime focus.

Based on the comments on the August 1987 proposal, on the August 1989 ANPRM, and at the public hearing, FDA withdrew the August 1987 proposal and published a reproposal in the **Federal Register** of February 13, 1990 (55 FR 5176) (the 1990 reproposal), stating that the former proposal was superseded in all respects. The agency stated that the 1987 proposal was too broadly written and allowed some manufacturers to take advantage of it by making drug claims on health fraud products. The 1990 reproposal proposed to more narrowly define appropriate health claims and offered criteria to be met to allow a claim. Further, the agency revoked the advisory opinion in the 1987 proposal that permitted firms to make health claims on food labeling where the claims were consistent with the proposal. The agency advised that, pending adoption of a final rule, there would be no "safe harbor" for any health claim in food labeling, and that any health claim may subject a food product to regulatory action.

However, the agency also set forth in the 1990 reproposal an interim enforcement policy that provided general guidance as to how the agency would likely exercise its enforcement discretion regarding health claims until a final rule was promulgated (55 FR 5176 at 5184). The agency stated that manufacturers could continue to include health claims on their products, but that FDA would scrutinize them on a case-by-case basis and exercise its enforcement discretion in deciding when it would bring a regulatory action.

FDA set out four basic principles that it said would guide its exercise of enforcement discretion. It also pointed to six topic areas about which significant evidence appeared to exist. The agency stated that claims regarding these topic areas were least likely to run the risk of regulatory action. In addition, FDA stated that a claim that used the phrases "may reduce the risk" or "may forestall the premature onset" would be less likely to be subject to regulatory action than one that more firmly asserted that a relationship exists between a food component and a disease.

After publication of the 1990 reproposal, FDA sent regulatory letters to a number of firms whose products bore labeling that contained false or misleading health claims. Most firms contacted made appropriate changes in their labels and labeling.

FDA received more than 200 comments on the 1990 reproposal from consumers, health professionals, industry, academia, government agencies, and organizations representing consumers, industry, and health professionals. Relevant comments are addressed throughout this document in locations appropriate for their content.

III. The 1990 Amendments

The 1990 amendments address health claims by amending the act to add section 403(r). This section specifies, in part, that a food is misbranded if it bears a claim that expressly or by implication characterizes the relationship of certain nutrients to a disease or health-related condition unless the claim meets the requirements of a regulation authorizing its use (section 403(r)(1)(B) of the act). Section 403(r) also directs FDA to issue regulations authorizing health claims for nutrients in conventional foods and in dietary supplements in appropriate circumstances. In addition, the 1990 amendments (section 3(b)(1)(A)(vi) and (b)(1)(A)(x)) require that FDA determine whether health claims respecting 10 specific nutrient disease topics are appropriate under the requirements of the act.

A. FDA Authority

Several comments on the February 13, 1990 reproposal questioned the agency's authority to regulate health claims. Congress specifically recognized these questions in the legislative history of the 1990 amendments (Ref. 1). Enactment of the 1990 amendments renders these comments moot. The agency now has clear authority to regulate all health claims on food.

B. Conversion to New Statutory Requirements

The passage of the 1990 amendments marks the beginning of a period in which FDA is endeavoring to convert the general requirements of the new law into specific, usable, and enforceable regulations. The issuance of this proposal, which supersedes the 1990 proposal in all respects, is an important step in this transition. During this period of transition, FDA is responsible for protecting the integrity of the food label.

The agency advises that it intends to evaluate any health claims that appear in labeling on a case-by-case basis. FDA is prepared to take action against products that bear false or misleading health claims or claims that evidence an intent that the product is to be used as a

drug but has not been approved for that use.

C. Statutory Provisions on Health Claims

Section 403(r)(1)(B) of the act identifies the substances that may be the subject of a health claim, that is, those nutrients of the type required by section 403 (q)(1) or (q)(2) of the act (new provisions concerning nutrition labeling added by the 1990 amendments) to appear on the label or labeling of a food and those present in dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances (section 403(r)(5)(D) of the act).

Section 403(q)(1) of the act provides that nutrition labeling shall include information on the total number of calories derived from any source; the number of calories derived from total fat; the amount of total fat, saturated fat (i.e., saturated fatty acids), cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein; and any vitamin, mineral, or other nutrient required to be placed on the label before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices. In the agency's supplementary proposal on the mandatory status of nutrition labeling published elsewhere in this issue of the **Federal Register**, FDA is proposing to require the listing of vitamin A, vitamin C, calcium, and iron under this provision. Section 403(q)(2) of the act provides that the agency may require information concerning additional nutrients in nutrition labeling when the Secretary concludes that the information will assist consumers in maintaining healthy dietary practices. Consequently, other vitamins and minerals may be required to be listed on the label in the future.

To assure the validity of health claims, Congress enacted a scientific standard in section 403(r)(3)(B)(i) of the act for conventional food that provides that the Secretary (and by delegation, FDA) shall promulgate regulations authorizing nutrient health claims only if the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) supports the claim, and there is significant scientific agreement among qualified experts that the claim is supported by such evidence. For health claims for dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances, Congress provided that the standard for the validity of such claims must be established by the Secretary (and by delegation, FDA) (section 403(r)(5)(D) of the act).

Where claims can be justified for conventional food, section 403(r)(3)(B)(ii) of the act requires that a regulation describe the relationship between the nutrient and the disease or health-related condition and describe the significance of the nutrient in affecting the disease or health-related condition. Section 403(r)(3)(B)(iii) of the act requires that the claim be "stated in a manner so that the claim is an accurate representation of the matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet."

Under section 403(r)(3)(A)(ii) of the act, health claims may only be made on foods that do not contain nutrients in an amount that increases "to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet * * *." However, this provision goes on to say that the Secretary may by regulation permit such a claim if he or she finds that such a claim would assist consumers in maintaining healthy dietary practices, and he or she provides for disclosure of the presence of the nutrient in conjunction with the claim.

In addition, the 1990 amendments revise the definition of "drug" in section 201(g)(1) (21 U.S.C. 321(g)(1)) of the act to provide that food for which a health claim is made in accordance with the requirements of section 403(r) of the act is not a drug solely because the label or labeling contains such a claim.

D. Same Scientific Standard for Dietary Supplements

FDA is proposing the same scientific standard for dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances as for all other foods. The agency recognizes that proposing the same standard for conventional food and dietary supplements is contrary to the view expressed by some members of Congress, and by some individuals in comments to the agency in response to a notice in the **Federal Register** of March 14, 1991 (56 FR 10906), on petition procedures, that a separate, more lenient standard should be established for supplements. However, FDA has reviewed the legislative history concerning section 403(r)(5)(D) and has tentatively concluded that Congress did not intend that the agency be forced to adopt a different standard for these products (Refs. 2 and 3). Instead, the exemption on its face gives the agency the discretion to adopt any appropriate scientific standard for supplements. The exemption gives the agency the same discretion with respect to establishing a procedure under which claims may be made.

The statement of House Floor Managers (Ref. 3), addresses section 403(r)(5)(D) of the act by stating, in part:

> The Senate version of the bill, which we are voting on today, retains this standard for all foods except vitamins, minerals, herbs, and other similar nutritional substances (referred to below as "vitamins"). The bill requires that vitamins that include claims defined under section 403(r)(1)(B) shall be subject to a "procedure and standard" defined by the Secretary in regulations that require an evaluation of the validity of the claim. The FDA is given the discretion to define both the procedure and the standard because the principals in the Senate could not agree on the appropriate procedure or the appropriate standard.
>
> It is obvious from the language that the agency could adopt the same procedure and standard that Congress has adopted for disease claims on food other than vitamins; it is also obvious that it could adopt a stronger standard for vitamins, minerals, herbs, and other similar nutritional substances.
> (Congressional Record, July 30, 1990).

In addition, the Metzenbaum-Hatch managers' statement in the Senate (Ref. 2) addresses section 403(r)(1)(B) of the act by stating, in part:

> The purpose for the different handling of conventional food products and dietary supplements is to provide the Secretary flexibility in the development of the procedure and standard for health claims for dietary supplements.
> (Congressional Record, October 24, 1990).

Thus, both the Senate and the House of Representatives agreed that FDA has the flexibility to adopt the standard and procedure for dietary supplements that appears appropriate to the agency.

Regarding the ability of the Secretary of Health and Human Services (and by delegation, FDA) to determine the appropriate procedure and standard for dietary supplements, the Metzenbaum-Hatch managers' statement further says that the following two factors should be taken into account:

> The rapid pace of scientific advance linking nutritional substances to the maintenance of long-term human health and prevention of long-term disease; and
>
> The ways in which dietary supplements are marketed and used by individuals differently from conventional food products.
> (Congressional Record, October 24, 1990).

Some consumers seek to ensure that the nutrient content of their diet is

adequate through conventional foods, others through dietary supplements. Ultimately, however, it is the nutrient content of the diet that is significant, not its source. For this reason, neither the pace of scientific advances with respect to nutritional substances nor the way individuals use supplements justifies different treatment for dietary supplements than for conventional foods.

From the Senate, there were mixed opinions as to what the agency should do with this flexibility. In the October 24, 1990 Congressional Record, on page S16611 (Ref. 2), Senator Hatch, one of the primary authors of the amendments made by the Senate, stated:

> By their very nature, the dietary supplements must be marketed so that the consumer is informed of the health or disease-prevention benefits that may be conferred. Greater flexibility is thus required to permit communication of these benefits. This increased regulatory flexibility is also mandated by the very rapid pace of scientific advances here and abroad linking the prevention of long-term disease to improved nutritional supplementation. For these reasons, a more lenient standard for dietary supplement[s] is envisioned. (Congressional Record, October 24, 1990).

However, in this same Congressional Record, (Ref. 2), Senator Metzenbaum, the other primary author of these amendments, stated:

> * * * It is my view that there is no reason to do anything other than utilize the same procedure and standard for dietary supplements.
>
> Whatever approach the Secretary takes, he must establish a system that evaluates the validity of health claims for dietary supplements. The system must be based on the same considerations that guide other agency decisions: Public health, sound scientific principles and consumer fraud.

The statement of House Floor Managers also addresses this issue (Ref. 3):

> * * * Whatever approach the agency takes, it must adopt a system that evaluates the validity of any disease claims made with respect to these substances. Its system must be based on considerations of public health and consumer fraud. As in every similar decision made by the agency today, we fully expect that the agency's evaluation of disease claims made with respect to vitamins will be based on sound scientific principles.
>
> There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims. The potential is just as great for vitamins as it is for other products. In our view, vitamins and other substances covered by this provision should be subject to at least as strong a standard as is applicable to other foods that contain claims that the food will treat a disease or health condition.

In the absence of clear Congressional direction about the way in which FDA should use the flexibility it has, the agency believes that it is appropriate to propose the same scientific standard and procedure for supplements as is mandated for conventional foods. If the agency were to adopt a more lenient standard and procedure for supplements, FDA believes that there would be a significant potential for consumer confusion when confronted with a situation in which there would be health claims for substances when they are present in supplements but not when they are present in conventional foods. Furthermore, FDA believes that a standard and procedure that is more lenient than that provided in section 403(r)(3)(B)(i) would not provide a basis on which to evaluate the validity of claims, which both the House Managers (Ref. 3) and at least one Senate author (Ref. 2) stated should be the goal of the approach that the agency adopts.

Nor does FDA consider a more stringent standard to be necessary. The standard that it is proposing for dietary supplements is the same as that which it proposed for all foods in 1990. FDA believes that this standard strikes an appropriate balance between the desire to make information available and the desire to ensure that that information is truthful, usable, and not misleading.

For FDA, a significant measure of whether a claim is valid is whether the evidence that supports that claim has stood the test of exposure to scientific scrutiny. Such scrutiny is a critical element in deciding whether any proposition is based on sound science. FDA cannot ignore such a critical element when deciding whether consumers should be advised that a particular diet-disease relationship exists. Such scrutiny is specifically provided for in the standard set forth in section 403(r)(3)(B)(i) of the act. Therefore, FDA believes that this standard should be applied in judging any health claim, whether for conventional foods or dietary supplements.

FDA does not believe that it could have a significant level of comfort, the standard for appraising claims suggested in the House Report (Ref. 1), about the validity of claims if it adopted any of the more lenient approaches suggested in comments to the March 14, 1991 notice. FDA has an obligation under the act to assure not only that claims comply with section 403(r) of the act but also that they are truthful and not misleading under section 403(a) of the act. Suggestions that the agency should delegate the primary responsibility for evaluating the validity of claims for herbs to industry committees are not consistent with this agency's responsibility. Of course, industry may, if desired, work through committees to prepare well-supported petitions for submission to FDA. However, FDA would still have the ultimate obligation of ensuring that there is compliance with the act.

FDA also does not agree with comments that suggested that it should adopt a regulatory framework for evaluating health claims for supplements that establishes three categories of claims, each of which would be subject to a different level of validity substantiation and different procedures. As suggested, Category I claims would be subject to the same validity requirements as established for conventional food. Category II claims would pertain to claims for which there is substantial scientific evidence but not yet significant scientific agreement. Category III claims would pertain to claims for which there is sound scientific evidence, which on balance supports the claim but is more preliminary in nature. Categories II and III claims would be subject to a certification and notification procedure and would not have to be affirmatively authorized by regulation.

FDA does not believe that the suggested certification and notification procedure for Categories II and III claims are adequate or appropriate under section 403(r)(5)(D) of the act. As discussed above, the legislative history from both the Senate and the House points to the fact that the procedure and standard that FDA is to establish under this section should evaluate the validity of health claims. Yet, the procedure suggested in the comment would not provide the agency with a full opportunity to do so. Under the procedure suggested in the comment, the greater the question about the validity of the claim, the less opportunity that FDA would have to review it. Such a system would not be fair to consumers, who would be exposed to claims whose validity had not been evaluated by FDA, or the manufacturers of conventional foods, who would be subject to the much higher congressionally mandated standard. For these reasons, under the discretion granted the agency by section 403(r)(5)(D), FDA is rejecting the comment.

E. FDA Requests For Data

In the **Federal Register** of March 28, 1991 (56 FR 12932), FDA published a notice requesting scientific data and information on the ten nutrient-disease topics that paragraphs (vi) and (x) of

section 3(b)(1)(A) of the 1990 amendments require FDA to consider. FDA established ten dockets for information relating to these topics, as follows: Calcium and osteoporosis, 91N-0094; sodium and hypertension, 91N-0095; lipids and cardiovascular disease, 91N-0096; lipids and cancer, 91N-0097; dietary fiber and cancer, 91N-0098; dietary fiber and cardiovascular disease, 91N-0099; folic acid and neural tube defects, 91N-0100; antioxidant vitamins and cancer, 91N-0101; zinc and immune function in the elderly, 91N-0102; and omega-3 fatty acids and heart disease, 91N-0103. The compiled scientific data and information were considered by FDA in its development of the proposed regulations pertaining to specific health claims that are published elsewhere in this issue of the **Federal Register**. FDA generally will address that data and information that it received in response to the March 1991 notice in the documents on those proposed regulations.

F. How Claims Are Made

When FDA determines on the basis of its review of the evidence on a nutrient-disease relationship, as it has with respect to some of the topics that are the subject of the specific documents published elsewhere in this issue of the **Federal Register**, that a health claim should be authorized, the agency will propose a specific regulation permitting a claim in subpart E of 21 CFR part 101. (FDA is proposing to create subpart E in this document.) The proposal will clearly identify the elements that must be included in the claim to assure its validity. In addition, the agency will illustrate the claim that is permitted through an example of an appropriate claim (referred to as a "model health claim"). If, after its review of comments, FDA decides to issue a final regulation based on that proposal, firms will be able to make claims that comply with that regulation on appropriate foods. Firms will not be required to use the language in the model claim but will be free to develop their own specific claims within the terms of the regulation.

In the authorizing regulation, FDA will set out requirements to ensure that any claim made under it will fully reflect the scientific facts justifying the claim. These requirements will not only describe the nutrient-disease relationship but will define other relevant factors, such as nondietary elements (e.g., the need for exercise) and relevant nutrient interactions (e.g., calcium and phosphorus levels in a food).

For conventional foods, many of the elements that will be included in the authorizing regulations will reflect the requirements of the 1990 amendments. As discussed previously, section 403(r)(3)(B)(ii)(I) of the act, which was added by the 1990 amendments, requires that regulations authorizing claims require that those claims describe the relationship between the nutrient and the disease or health-related condition. FDA is applying this requirement in the proposed regulations on health specific claims published elsewhere in this issue of the **Federal Register**. For example, the proposal authorizing a health claim on the relationship between calcium and osteoporosis requires, in part, that the claim explain that adequate calcium intake during adolescence and early adulthood appears to have a positive effect on bone health, and that optimizing peak bone mass during that period may reduce the risk of osteoporotic fracture in old age (see proposed § 101.72(d)(3)).

Section 403(r)(3)(B)(ii)(II) of the act requires that regulations authorizing health claims require that claims describe the significance of the nutrient in affecting the disease or health-related condition. Thus, the proposal concerning calcium and osteoporosis requires, in part, that a claim explain the various factors other than calcium intake that bear on the risk of developing osteoporosis, that is that being a white female or having a family history of fragile bones with aging, places an individual at risk for the development of osteoporosis in later life (see proposed § 101.72(d)(2)).

Further, section 403(r)(3)(B)(iii) of the act requires that the public be able to comprehend the information in the claim and to understand the significance of the information in the context of the total daily diet. Under this requirement, a wide variety of factors may need to be addressed in the claim. For example, the proposal concerning calcium and osteoporosis requires, in part, that claims point out that adequate calcium intake is not enough. The proposal provides that the claim must advise that adequate calcium intake should be accompanied with exercise and maintenance of a balanced diet.

As stated above, section 403(r)(5)(D) [1] of the act directs FDA to establish a procedure and standard to assure the validity of health claims for dietary supplements. In section III.D. of this document, FDA discussed why dietary supplements should be subject to the same scientific standard, and procedure for assessing conformity with the standard, that is used for conventional foods. The agency has tentatively determined that it is also appropriate to subject dietary supplements to the same procedures with respect to how claims are made and how they are petitioned for as those that apply to conventional foods. The agency has reached this tentative conclusion based on three factors:

1. FDA has an obligation to ensure that food labeling is truthful and not misleading. Under the act, a claim can be misleading, and thereby misbrand the food, based on the information that it does not include as well as the information that it does include. The agency believes that the procedures that it is proposing are necessary to ensure that claims that are made are fully informative to consumers. Because claims for dietary supplements must be as informative as claims for conventional foods, FDA believes that it is appropriate to subject the former claims to the same procedures as the latter.

2. As stated above, FDA has an obligation to treat all segments of the regulated food industry with fairness. If dietary supplements were subject to different rules, whether with respect to the procedure for assessment of conformity with the scientific standard or to the manner in which claims are made, there is a possibility that supplements could be made to appear somehow superior to conventional foods that contain the same nutrient. Such an appearance would not only be untrue, it would be unfair to firms producing conventional foods. FDA knows of no differences in the marketing or use of dietary supplements and conventional foods that would compel a different result.

3. As stated previously in the discussion of the scientific standard in section III.D. of this document, some consumers seek to ensure that the nutrient content of their diet is adequate through conventional foods, others through dietary supplements. Ultimately, however, it is the nutrient content of the diet that is significant, not its source. For this reason also, the pace of scientific advances with respect to nutritional

[1] FDA notes that section 403(r)(3)(A) of the act states "Except as provided in paragraph (5)," and that that provision relates to only "a procedure and standard." Thus, it is possible that various aspects of how health claims on dietary supplements are made are governed by section 403(r)(3) of the act. However, because FDA, in exercising its discretion, has tentatively decided under section 403(r)(5)(D) of the act that dietary supplements should be subject to the same requirements that conventional foods are subject to under section 403 (r)(3) and (r)(4), FDA finds that the question of the extent to which the latter sections apply to dietary supplements is moot.

substances does not justify different treatment for dietary supplements than for conventional foods.

In sum, it is the nutrient that is significant, not its source. To ensure that labeling is truthful and not misleading, the same substantive rules should thus be applied to conventional foods and to dietary supplements.

IV. Proposed Provisions

A. Definitions

FDA is proposing the following definitions in § 101.14(a) to clarify the meaning of specific terms used in this proposed rule.

1. Health Claim

FDA is proposing to define "health claim" as any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication characterizes the relationship of any substance to a disease or health-related condition. Such claims could include "third party" endorsements, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes. This definition is derived almost directly from section 403(r)(1)(B) of the act, although it has been modified slightly to incorporate that section's reference to section 403(r)(5)(D) of the act.

The definition includes examples of implied claims and expressly limits them to those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or would be likely to be understood, to assert a direct beneficial relationship between the presence or level of any substance in the food and a health or disease-related condition. The definition is intended to make clear that vignettes or other forms of communication that depict the general wholesomeness of a product or other attributes that do not involve more specifically the relationship between a substance in the food and a health or disease-related condition are not health claims for the purpose of this regulation.

FDA recognizes that there is often ambiguity in the message conveyed by a logo or symbol, such as the heart symbol that is often used on labels and restaurant menus. FDA specifically invites comment on the appropriate meaning or warnings to be attributed to the heart symbol and other currently used logos and symbols. Should they be regarded as nutrient content descriptors, health claims, or both? Should they be defined as such by FDA and, if so, how? FDA's goal in considering these questions will be to retain the use of logos and symbols where they are useful in communicating health-related information to consumers but to guard against their use in a manner that would be confusing or misleading to consumers.

While the act focuses on the substance-disease relationship, it is clear that the Congress was concerned about any disease claims that are made on food (Ref. 1). In reviewing the evidence on the 10 topic areas, however, FDA has become aware that there may be certain relationships between foods and diseases that are supported by the available evidence but that cannot be attributed to a particular nutrient. For example, the scientific evidence shows that diets high in whole grains, fruits, and vegetables, which are low in fat and rich sources of fiber and certain other nutrients, are associated with a reduced risk of some types of cancer. The available evidence does not, however, demonstrate that it is total fiber, or a specific fiber component, that is related to the reduction of risk of cancer. The question is thus whether, to fulfill Congress's intent in the 1990 amendments, FDA should regulate claims about apparent food-disease relationships and, if so, how it should do so. For example, the recent National Cancer Institute "Five-A-Day" program constitutes dietary guidance and not a health claim (Ref. 1). It could appear on the label of foods that appropriately fall within the terms of the dietary guidance. FDA requests comments on what regulatory approaches, if any, with respect to these types of claims would be most consistent with the act's and the agency's goals of assuring both that useful nutritional information is available to consumers, but that the information is scientifically valid and not misleading. The agency also requests comments on whether, if the agency should regulate such claims, it should do so under proposed § 101.14 or under the general regulatory regime of a label needing to be truthful and not misleading.

2. Substance

In proposed § 101.14(a)(2), FDA is proposing to define the term "substance" to facilitate identification, within the proposed regulation and in this document, of all food components that are candidates to be the subject of a health claim. Thus, FDA is proposing to define the term "substance" to include any component of a conventional food or of a dietary supplement of vitamins, minerals, herbs, or other nutritional substances. Reference in the definition to "a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances" incorporates the statutory language in section 403(r)(5)(D) of the act, which directs the agency to establish a procedure and standard for claims for dietary supplements.

3. Nutritive Value

FDA is proposing to define the term "nutritive value" to facilitate use of one of the criteria under which a substance is a food and thus appropriately the subject of a health claim. FDA proposes to define the term "nutritive value" as value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy. FDA developed this definition based on the common meaning of the words that make up this term.

"Nutrient" is defined in the *Random House Dictionary of the English Language* as "* * * [a substance capable of] providing nourishment or nutriment." This dictionary defines "nutriment" as "any substance or matter that, taken into a living organism, serves to sustain it in its existence, promoting growth, replacing loss, and providing energy." The dictionary defines "nourishment" as "something that nourishes; food, nutriment, or sustenance." Further, the dictionary defines "nourish" as "to sustain with food or nutriment; supply with what is necessary for life, health, and growth." The agency's proposed definition for "nutritive value" encompasses these common definitions except that the definition is specific for humans, for consistency with section 403(r)(1) of the act.

Use of the phrase "such processes as" in the proposed definition conveys a measure of flexibility that the agency believes is necessary for evaluating future petitions. Within the context of the daily diet, there may be a wide array of substances that could logically supply nutritive value. For example, if a substance as a component of a food is of value for cellular functions by providing catalytic support for protective reactions (e.g., inhibiting harmful processes), that substance could be viewed by FDA as providing nutritive value. FDA also advises that any substance that is identified as a nutrient in section 403(q)(1)(C), (q)(1)(D), or (q)(1)(E) of the act conforms to the proposed definition of "nutritive value."

4. Dietary Supplement

FDA is proposing to define "dietary supplement" as a food, other than a conventional food, that supplies a component with nutritive value to supplement the diet by increasing the

total dietary intake of that substance. A dietary supplement includes a food for special dietary use within the meaning of § 101.9(a)(2) that is in conventional food form.

This term, although used in section 403(r)(5)(D) of the act, is not defined in the 1990 amendments. In the past, FDA has taken a position that the term "dietary supplement" applied only to supplements composed of essential nutrients. However, FDA is not proposing to limit the definition in § 101.14(a) in this way because section 403(r)(5)(D) of the act includes dietary supplements of "herbs" which, as foods, are generally used for flavor or aroma rather than for nutritive value. Herbs contain few essential nutrients, and those essential nutrients that are present are seldom present in significant amounts on a per serving basis. In addition, the legislative history indicates that the term "other nutritional substances" could include a number of substances that have not been shown to be essential (Ref. 2).

5. Disqualifying Nutrient Levels

Section 403(r)(3)(A)(ii) of the act provides that a health claim may only be made for a food that does not contain, as determined by regulation, a nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition that is diet related, taking into account the significance of the food in the total daily diet. There is no indication in the legislative history of this provision as to what Congress considered to be an amount of a nutrient in a specific food that would increase the risk of a disease.

The statute provides the same standard in section 403(r)(2)(B)(ii) of the act for nutrient content claims, with the requirement that the label or labeling of any food that contains a nutrient at a level that increases the risk of a diet-related disease or health condition shall identify that nutrient in immediate proximity to the claim. A similar requirement for a cholesterol content claim is in section 403(r)(2)(A)(iii)(II) of the act. In referring to these levels for nutrient content claims, FDA uses the term "disclosure levels" (see companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**). The disclosure level for a nutrient for a content claim is the same as the disqualifying level for the nutrient for a health claim.

FDA is defining "disqualifying nutrient levels" (referred to in this document as "disqualifying levels") in proposed § 101.14(a)(5). FDA is proposing to define "disqualifying nutrient levels" as the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. The agency is proposing that the disqualifying levels are 11.5 grams (g) of fat, 4.0 g of saturated fat, 45 milligrams (mg) of cholesterol, or 360 mg of sodium per reference amount commonly consumed, per labeled serving size, and per 100 g. Any one of the levels, on a per reference amount commonly consumed, a per labeled serving size, or a per 100 g basis, will disqualify a food from making a health claim.

These disqualifying levels are intended to ensure that a food that bears a health claim does not at the same time contain a nutrient at a level that increases the risk of a disease. Because Congress did not identify any specific nutrients that were of concern, consistent with section 403(r) of the act, FDA considered the risk presented by nutrients of the type required by section 403(q)(1) and (q)(2) of the act to be in the label or labeling of food. Of these, nutrients, total fat, saturated fat, cholesterol, and sodium have been associated with increased risk of disease. For maintenance of good health, recommended limits for dietary intake levels have been identified for each of these nutrients (Refs. 5 through 7).

Excessive intake of sugars has been associated with increased risk of tooth decay. However, the specific dietary level at which this increased risk occurs is uncertain, and there is, therefore, no recommended level for dietary intake for sugars. In addition, excessive intake of calories is associated with obesity which is a positive risk factor for a number of diseases. "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7, hereinafter referred to as "Dietary Guidelines for Americans") recommends that all Americans maintain a healthy body weight. However, the level of calories needed to maintain a healthy weight can vary widely among individuals depending on age, sex, build, and physical activity, and there is no specific recommended level for calories in terms of an absolute number or as a function of the intake of other nutrients. Therefore, FDA cannot identify any single level of calories or sugar in a food that would increase the risk of disease.

Although there are recommended levels for dietary intake for total fat, saturated fat, cholesterol, and sodium, there are no generally recognized levels at which these nutrients in an individual food pose an increased risk of disease. Thus, FDA knows of no established or accepted approach for identifying disqualifying levels for these nutrients. FDA has, therefore, used an approach that is based upon the recommended levels for dietary intake of these nutrients in setting the proposed disqualifying levels because deviation from the recommended levels has been associated with an increased risk of disease.

As discussed in the supplementary proposal on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, FDA is proposing to codify the recommended dietary levels for fat, saturated fat, cholesterol, and sodium, as well as for several other nutrients, as Daily Reference Values (DRV). The DRVs reflect current and established scientific evidence related to overall nutrient intake and risk of diet-related disease. They are intended to reflect total dietary intake, not intakes from individual foods. Therefore, to derive disqualifying levels for health claims, FDA had to find a way of translating total dietary intake into nutrient levels in individual foods that could be considered to increase the risk of disease.

To determine the appropriate disqualifying levels based on the DRVs for total fat, saturated fat, cholesterol, and sodium, FDA used an approach based on the number of servings of food in a day and available information on food composition. An estimate for the number of servings of food in an average daily meal pattern is approximately 16 to 20 servings (Refs. 8 through 10). If the nutrients under consideration were evenly distributed, then each food serving in a recommended diet would contain 5 to 6.25 percent of each DRV. However, as expected, analyses of FDA's Regulatory Food Composition Data Base (Ref. 11) revealed that these nutrients are not evenly distributed within foods.

In this approach, FDA considered that a nutrient is found in a food category if over half of the foods in the category contained 2 percent or more of the proposed Reference Daily Intake (RDI) or DRV, as appropriate, for the nutrient. Two percent of the label reference value has been used by the agency in the past as a measurable level of a nutrient in a food. The agency further considered a nutrient to be: (1) ubiquitously distributed if it was found in more than 75 percent of the food categories; (2) moderately distributed if it was found in 51 to 70 percent of the food categories; and (3) not widely distributed if it was found in 50 percent or fewer of the food categories. Total fat, saturated fat, cholesterol, and sodium were found to be in 50 to 70 percent of the food

categories (Ref. 12). If the nutrient is available from approximately 50 to 75 percent of food categories, then it is reasonable to expect that it may be available from perhaps as few as half of the foods/beverages consumed. That is, assuming that as many as 20 foods/beverages are consumed in a day (Ref. 10), it is reasonable to expect that the nutrient may be available from perhaps as few as 10 of the foods/beverages. Consequently, if these nutrients are not available in up to half of the food in a balanced diet, then the remaining half of the foods can contain an average of twice the 5 to 6.25 percent, or 10 to 12.5 percent, of the DRV without causing the daily intake to exceed the DRV for any nutrient. The agency used this result as a starting point for determining the appropriateness of 10 percent of the DRV as the disqualifying level for nutrients in foods.

As an initial calculation, the agency determined that the consumption of 10 foods per day containing 10 percent of the DRV would result in a consumption of 100 percent of the DRV in a day. This level of intake is not considered to constitute a risk for diet-related diseases and suggests that the level of 10 percent is too low as a criterion. The agency then doubled the 10 percent value to 20 percent and determined that, assuming the consumption of 10 foods per day at the level of 20 percent of the DRV, the 20 percent criterion results in consumption of twice the DRV. This level of intake is more than sufficient to constitute risk. Thus, the agency tentatively concluded that the appropriate percent of DRV constituting a risk for individual foods was likely to be found between 10 and 20 percent of the DRV.

Accordingly, with the data base available to the agency, FDA evaluated 10, 15, and 20 percent using two criteria to determine whether the consequences of each as the disqualifying level would be reasonable (Ref. 13). The agency analyzed a list of foods to see which foods would be disqualified from bearing a health claim and which would not, and whether the results made sense from a nutritional standpoint. Foods that contain relatively high levels of one or more nutrients that should be consumed less frequently to maintain a diet that meets the guidelines, should be disqualified by an appropriate criterion. On the other hand, foods that would be helpful in a recommended diet should not be disqualified.

Using this analytic strategy, the agency found that the 10 percent level was too low. A number of foods thought to be useful in maintaining a balanced diet would be disqualified at this level, including many vegetable and cereal products. The 20 percent level was too high. Under it, some foods would be permitted to bear health claims that should not be consumed frequently in a healthy diet, including some shortenings and candies. The results of testing the three different levels demonstrated that a level of 15 percent of the DRV was the most reasonable.

Based on these analyses, FDA is proposing that 15 percent of the DRV per reference amount commonly consumed and per labeled serving size (as discussed in the proposal on serving sizes published elsewhere in this issue of the **Federal Register**) of a food be the disqualifying/disclosure level (i.e., 11.5 g of fat, 4.0 g of saturated fat, 45 mg of cholesterol, and 360 mg of sodium for the subject nutrients). These levels are those above which total fat, saturated fat, cholesterol, and sodium will be deemed to increase risk of a diet-related disease or health condition.

However, an analysis (Ref. 14) also showed that there were some foods that do not exceed the 15 percent DRV level on a per serving basis because of small serving sizes but that contain relatively high concentrations of one or more of the subject nutrients on a caloric basis. The agency believes that nutrient-dense foods like these should not be promoted for increased use in a diet because they do not conform to national guidelines, and that these foods should not bear health claims. Therefore, the agency is proposing to also disqualify a food from bearing a health claim (or require nutrient disclosure for content claims) if the food contains more than 15 percent of the DRV for fat, saturated fat, cholesterol, or sodium per 100 g. Based on analyses using FDA's Regulatory Food Composition Data Base (Ref. 14), foods that might be disqualified from bearing health claims because of this criterion include some dessert toppings, gravies, crackers, cookies, and chocolate candies.

The agency recognizes that the nutrients fat, saturated fat, cholesterol, and sodium are not found in the same number of foods nor are they present in foods at the same level. For instance, sodium is more ubiquitous than cholesterol among food categories, but cholesterol is generally found to be present in a food at higher levels of the DRV than is sodium. Therefore, the agency specifically requests comments on this approach for determining the disqualifying/disclosure levels particularly as it relates to the variations in nutrient distributions among foods and to the appropriateness of establishing different levels for different nutrients.

The agency stresses that disqualification of a food from bearing a health claim does not, and should not, imply that the food cannot be incorporated into a balanced diet. To illustrate this point, one of the dietary guidelines advises American consumers to choose a diet that is low in fat, saturated fat, and cholesterol to achieve the benefit of lowered risk for several diet-related diseases (Ref. 7). It is recognized, however, that some foods containing these dietary lipids, such as meats, milk, cheese, and eggs, are also good sources of high quality protein, certain vitamins, and essential minerals. Although such foods when modified to be low in fat may make it easier for consumers to comply with the dietary guidelines, the unmodified foods can still be part of a healthy diet with judicious selection.

FDA does not intend that the establishment of disqualifying levels, as required by the 1990 amendments, be perceived as the creation of a good-food/bad-food concept. It is not true that a food that qualifies for a health claim is good, while one that does not is bad. Rather, a health claim on a food label is a promise to consumers that including the food in a diet, along with other dietary modifications, will be helpful in attaining the claimed benefit and will not introduce a risk of another disease or health-related condition.

The agency also notes that under section 403(r)(3)(A)(ii) of the act, a claim that would otherwise be disallowed because of a disqualifying level of a nutrient may be permitted by regulation for a food based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the presence of the nutrient that would otherwise be disqualifying be prominently disclosed on the label or labeling in proximity to the health claim. The agency is not, however, aware of information to support such a regulation. FDA will address such situations on a case-by-case basis when evaluating potential health claim topics. If there is information to support permitting a claim on this basis, it should be submitted as part of a petition requesting a regulation authorizing a health claim.

The agency requests comments on how it should exercise its authority under section 403(r)(3)(A)(ii) of the act. For example, the agency notes that whole milk will be disqualified from making a claim about calcium and osteoporosis because it contains fat in

an amount that exceeds the disqualifying level. FDA is not proposing to make an exception for whole milk because low fat milk and skim milk could bear such a claim. Thus, the agency believes that there is no basis to make a finding that permitting such a claim on whole milk would assist consumers in maintaining health dietary practices. The agency requests comments on the appropriateness of its approach to this issue. It has been suggested that the agency should consider the net public health benefit in deciding whether to permit a claim on a food that contains a nutrient at a level that exceeds the disqualifying level (e.g., an osteoporosis claim on a food high in fat). This suggestion is that there are advantages in allowing such claims with full and prominent disclosure regarding other nutrients, similar to the requirements for nutrient claims, because the public health gain from consuming the nutrient that is the subject of the health claim would outweigh the risks from consuming the nutrient that would otherwise disqualify the food. A benefit would derive from consuming the nutrient that is the subject of the claim, and a person could balance his or her intake of the disqualifying nutrient by other food selections as part of a total diet. FDA requests comments on this and other approaches in implementing section 403(r)(3)(A)(ii) of the act.

FDA requests comments, including data or other information, on the proposed disqualification levels. If the agency is persuaded by comments that other disqualifying levels, or that modifications in the proposed disqualifying levels, would be more appropriate, FDA will consider making any appropriate changes in the final rule that is based on this proposal.

The agency recognizes that dietary supplements are not subject to the provisions of section 403(r)(3) of the act. However, as explained previously, FDA has tentatively determined that supplements are appropriately subject to the same rules as conventional foods. As a practical matter, however, FDA doubts that disqualifying levels will have any significant impact on supplements because supplements are formulated products that are being promoted as healthful. It would not be logical for such products to be formulated with significant levels of nutrients with known adverse effects.

B. Preliminary Requirements

Congress and FDA, in proposed § 101.14(a)(2), have broadly defined the substances that may be the subject of a health claim. Consequently, FDA anticipates receiving a wide range of petitions for health claims. However, based on the act as a whole, FDA believes that there are certain criteria that must be met before a substance would qualify as the subject of a health claim. The agency is proposing these criteria in § 101.14(b). They reflect not only the requirements of section 403(r) of the act but also the fact that FDA is charged with ensuring the safety of the food supply, and that the food label is not misleading. Given that agency evaluations of the validity of a health claim will be resource intensive, FDA is proposing not to make such an evaluation unless a petition for a health claim demonstrates that the preliminary requirements in proposed § 101.14(b) are met.

1. Effect on General U.S. Population

Section 403(r)(3)(b)(iii) of the act requires that a health claim be stated in a manner "* * * so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet." FDA believes that, for this requirement to be satisfied, the general U.S. population or some identified subgroup must be at risk with respect to the particular diet-related diease or condition, or, if that is not the case, the proponent of the health claim and any claim approved by FDA otherwise explains the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet. This would permit claims to be evaluated even if no showing was made that any particular population group is currently at risk, but it would require that such information be provided as part of any resulting health claim. In addition, the label or labeling would be required to include any potential risks posed by the nutrient for which the claim is made.

2. Components in Food Within Context of Daily Diet

As stated above, Congress and FDA have provided for a wide variety of food components as potential subjects of health claims. These components range from desirable components, such as essential nutrients, to components whose intake should be limited, such as saturated fat, and even to components that have traditionally served primarily as sources of flavor or aroma, such as herbs.

However, the agency does not believe that Congress intended that everything that can be formulated into a form in which it could be consumed enterally should qualify for health claims. To the contrary, a firm could not add a drug to a food to justify a health claim (e.g., addition of aspirin or an herb whose only known use is for medicinal effects such as belladonna, rauwolfia, or yellow dock). Such addition would make the food a drug within the meaning of section 201(g) of the act. Any substance that is to be the subject of a claim must meet the definition of a "food" under section 201(f) of the act. Consequently, the agency is proposing § 101.14(b)(2) and (b)(3) to assure that claims are made only for substances that are foods.

With respect to what constitutes food, FDA advises that section 201(f) of the act states that the term "food" means "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any other such article." This statutory definition has been interpreted by case law (*Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983)) to include "common sense foods," that is, articles used primarily for taste, aroma, or nutritive value, as well as components of food, both inherent and added.

Consistent with the statute and applicable case law, FDA is proposing in § 101.14(b)(3)(i) that a substance that is the subject of a suggested claim that explains the advantages of consuming the substance at other than decreased levels must contribute taste, aroma, or nutritional value to a food, or serve one or more of the technical effects listed in 21 CFR 170.3(o) (e.g., nutrient supplement). In addition, Congress explicitly directed in section 403(r)(3)(B)(iii) of the act that regulations permitting health claims allow the public to comprehend the significance of the health benefit within the context of the total daily diet so that consumers may modify their diets to achieve public health goals. Obviously a substance must be a food for it to have any significance in the diet.

For consumption of a substance to have significance within the context of the daily diet, FDA is also proposing in § 101.14(b)(3)(i) that the substance must retain its food attributes at the levels that are necessary to justify the claim. For example, if the substance is a vitamin that must be present at a therapeutic level for a health benefit to occur, the supplement would not qualify for a health claim under this proposal. A therapeutic level of a vitamin would be far above that level that is normally characteristic of food, and, consequently, the vitamin would not retain its food attributes. However, FDA is not proposing a specific definition in the general provisions of this proposal

for an upper limit of any substance based on the context of the daily diet. Instead, the agency intends to leave it to the petitions that are submitted to demonstrate on a case-by-case basis that the substance is a food component and is appropriately the subject of a health claim regulation.

FDA is proposing that this provision apply to dietary supplements as well as conventional foods. Section 403 of the act applies to foods, and thus FDA considers it appropriate to require that the substances that are to be the subject of a health claim under the authority of section 403(r)(5)(D) of the act, as well as section 403(r)(3) of the act, satisfy the definition in section 201(f) of the act. This provision is fully consistent with section 411 of the act. The proposed provision places no limits on the potency of safe vitamins and minerals. However, if a claimed effect can only be achieved at a level of a vitamin, mineral, or other substance that scientifically cannot be characterized as nutritional, but rather as therapeutic, then that fact will be considered by the agency in deciding whether the claim is appropriate for a food, or whether it is in fact a claim that would make the product a drug under section 201(g)(1)(B) of the act.

Under proposed § 101.14(b)(3)(i), food components that are modified to such an extent that they no longer retain their food attributes will also not be eligible to be the subject of a health claim. If claims are made for such components, the agency may well regard the components as drugs.

In view of the necessity for a substance to be a food to qualify for a health claim, FDA disagrees with the comments that it has received that asserted that health claims should be permitted for over-the-counter (OTC) drugs. For example, a comment asserted that a manufacturer of a bulk-fiber laxative product that makes the drug claim "relief from constipation" should not be prohibited from making a cholesterol-lowering health claim on the label of that product.

FDA believes that a food claim on a drug product would be misleading to consumers. On a drug label, the thrust of all the information is toward what the product itself will do. For example, the label states that the product will relieve constipation. Moreover, it lists *active* ingredients. Thus, there is reason to believe that in the example cited in the comment, consumers will read the cholesterol-lowering claim as saying that the product itself will lower cholesterol levels, and not that a properly structured diet would have the effect. This interpretation would be wrong, and it is FDA's obligation to try to structure the rules for health claims to minimize the possibility that such misunderstandings will occur. Therefore, FDA believes that it would be inappropriate to put a health claim on a drug product.

Moreover, in a 1934 Senate report for a predecessor bill of the act, there was a discussion on the need for a provision to the effect that the definitions of food, drug, and cosmetic should not be construed to be mutually exclusive (Ref. 15). It was concluded that such language would be superfluous:

> The use of which the product is to be put will determine the category into which it will fall * * *. If it is sold to be used both as a food and for the prevention or treatment of disease it would satisfy both definitions and be subject to the substantive requirements for both. The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put. For example, the manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product. (Ref. 15).

A product that is labeled for relief from constipation has been fairly and unequivocally represented by its manufacturer as a drug. Thus, under this legislative history, the product is subject to regulation only as a drug. As such it would not be eligible to bear a health claim. This is not to suggest, however, that a fiber supplement would not in appropriate circumstances be a food and an appropriate candidate for a health claim. A determination as to whether a claim would be appropriate must be based on the factors proposed in this document and on any specific factors in the regulations in part 101, subpart E.

Further, the comment stated that "dual labeling" of OTC drug products (i.e., drug claims and food health claims in the same labeling) should be permitted to avoid excess proliferation of similar products with different labeling in the marketplace and to be consistent with well-established precedents for dual labeling for drug and cosmetic claims on drug products (e.g., a cosmetic claim, such as "promoting white teeth," and a caries prevention claim for toothpaste).

FDA also rejects this aspect of the comment. The agency believes that the potential for consumer confusion outweighs any concerns about a proliferation of products with health claims. That part of the comment on precedents for drug and cosmetic claims in labeling of the same article is not pertinent to this proposal because of the differences in the substantive requirements for a food health claim compared to those for a cosmetic claim.

3. Safety

As discussed in section IV.A.5 of this document, section 403(r)(3)(A)(ii) of the act states that a health claim may only be made for a food that does not contain any nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition that is diet related, taking into account the significance of the food in the total daily diet. FDA believes that, in addition to requiring establishment of disqualifying levels, this provision evidences a concern by Congress that a substance that is the subject of a health claim be used in a manner that is safe. This concern was reflected in the statements of the sponsors in both the House and the Senate (Refs. 2 and 3). Further, section 9 of the 1990 amendments states that the amendments "shall not be construed to alter the authority of the Secretary of Health and Human Services * * * under the Federal Food, Drug, and Cosmetic Act * * *." Thus, FDA's responsibility for ensuring the safety of foods has in no way been diminished by the passage of the 1990 amendments.

This fact is particularly significant because the agency will be specifically providing for the health claims that will be made. The agency believes, given its responsibilities under the act, that it would be inappropriate for it to provide for a claim for a substance without assurance that the levels at which the substance will be consumed, or will likely be consumed, in response to the health claim will be safe and in compliance with the food safety provisions of the act.

Accordingly, FDA is proposing in § 101.14(b)(3)(ii) that the substance must be a food ingredient, or a component of a food ingredient, that the proponent of the claim can demonstrate to FDA's satisfaction to be safe and lawful when used at the level that is likely under the claim. This showing can be based on: (1) A demonstration that the substance is generally recognized as safe (GRAS) within the meaning of 21 CFR 170.30; (2) a listing of the substance as GRAS in 21 CFR part 182 or as affirmed as GRAS in 21 CFR part 184; (3) a food additive regulation; or (4) a sanction or approval granted by FDA or the United States Department of Agriculture prior to September 6, 1958. If the safety and lawfulness of the substance is not expressly recognized in an FDA regulation, the burden will rest on the

claims proponent, as a prerequisite to FDA's evaluation of the health claim, to submit all the scientific data and other relevant information required to demonstrate safety and lawfulness in accordance with applicable petition requirements. FDA will withhold review of the health claim until it is satisfied on these points. Given the timeframes that FDA is proposing in response to the act for action on petitions for health claims, the agency anticipates that it may be necessary in many cases to deny the health claim petition without prejudice until the agency has completed its review of the petition for safety of the use of the food ingredient.

By way of explanation, FDA has recognized that it is impracticable to list all substances that are GRAS for their intended use based on their common use in food prior to 1958. For example, FDA regards food ingredients such as salt, pepper, vinegar, and baking powder that were in common use before January 1, 1958, as safe for their intended use. Similarly, § 170.30(d) pertains to food ingredients of natural biological origin that have not been listed by the agency as GRAS and states that such an ingredient will ordinarily be considered to be GRAS if it has been widely consumed for its nutrient properties prior to January 1, 1958, without known detrimental effects, is subject only to conventional processing as practiced prior to January 1, 1958, and no known safety hazard exists. The GRAS ingredients listed in part 182 include manmade ingredients and ingredients of natural origin that were listed in most cases during 1958 through 1962 without a detailed scientific review of all available data and information relating to their safety, and thus their GRAS status is likewise based primarily upon common use in food before January 1, 1958.

In the case of ingredients used in accordance with a food additive regulation, a GRAS affirmation regulation under part 184, or a prior sanction, use of the claim within the provisions of the regulation or sanction will ensure that the ingredient is used under conditions found by the agency to be safe, particularly in the case of food additives and substances affirmed as GRAS because these two classes of ingredients have been subjected to extensive safety review by the agency.

The agency recognizes that health claims are likely to have a significant impact on the level of total consumption of food substances within the U.S. population (e.g., where the total number of foods consumed containing the substance increases without the level of use of the substance within those foods increasing). FDA intends to monitor such consequences closely. To assure that safety is not compromised by changes in consumption patterns, FDA intends to consider whether existing GRAS and food additive regulations need to be revised to adequately ensure the safety of the food supply.

For example, the agency is concerned about the changing consumption patterns associated with the development and introduction into the marketplace of new sources of dietary fiber, along with the increased use of fiber sources as food ingredients or as supplements of fiber, that has occurred in recent years and that could be exacerbated if a claim is ultimately authorized for fiber. FDA intends to update its GRAS regulations for sources of fiber in the near future. To deal with this issue, the agency intends to initiate a review of the existing types of isolated dietary fibers and their use as a broad class of foods to identify and assess scientific information on the safety of this use. This review will include consideration of the biological effects of different fibers, the extent to which such effects are significantly different for subclasses of dietary fiber, and whether biological effects are significantly altered by chemical or physical changes and by processing. FDA may use the results of this or other reviews to develop a new strategy for assessing food safety.

Because sections 201(s) and 409 of the act apply to substances that become components of food by virtue of their intended use, and not to naturally occurring components of food such as cholesterol, these statutory provisions do not apply in instances in which the substance for which a claim is made is a nutrient identified in section 403(q)(1)(C) or (D) of the act that is a component of a whole food (not a food ingredient). However, the previously discussed disqualifying levels proposed under authority of section 403(r)(3)(A)(ii) of the act should provide an appropriate measure of safety for these substances.

C. Validity Requirements

1. The Scientific Standard

FDA is proposing in § 101.14(c) that health claims for all substances, including vitamins, minerals, herbs, and other similar nutritional substances in dietary supplements, be required to meet the following scientific standard:

> FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

This standard embodies the language in the statutory requirements for conventional food in section 403(r)(3)(B)(i) of the act that there be significant scientific agreement about the support for the claim and the mandate provided in the legislative history of the 1990 amendments that FDA have "a high level of comfort that the claim is valid" (Ref. 1).

As Congress recognized (Ref. 1), this standard has essentially the same content as the standard proposed by the agency in the 1990 reproposal. Some of the comments about the appropriate content of the standard favored it as proposed. However, other comments objected to the standard or suggested modifications. Some of these comments expressed concern about the provision of the standard concerning "the *totality* of publicly available scientific evidence." A few comments asserted that this provision should be deleted because new, unreproduced, or controversial findings might not be considered. Other comments asserted that unpublished research findings, including proprietary data, should be considered in assessing conformity with the standard. Many comments objected to the provision requiring "significant scientific agreement" because of a belief that this provision means "consensus" or "unanimity." Several comments maintained that, instead of "significant scientific agreement," FDA should use a scientific standard encompassing different degrees of certainty for different types of health claims.

There is now no basis under the act for the agency to modify any provisions of the proposed standard. The statute ratifies and adopts this proposed standard (section 403(r)(3)(B)(i) of the act). FDA advises, however, that it will consider under this standard the *totality* of publicly available scientific evidence concerning potential health benefits, including new, unreproduced, or controversial findings. Consistent with the intent of Congress in enacting the 1990 amendments (Ref. 1), FDA will use its discretion to give greater weight to those studies that are more persuasive, regardless of the nature or age of the studies.

The agency cannot delete the provision in the standard for the evaluation of validity to be based upon publicly available scientific evidence

because this provision is a requirement of the act (section 403(r)(3)(B)(i)). Any interested party may submit information that is not publicly available in support of a proposed health claim. However, the agency will make all information that is submitted to support a health claim publicly available through its Dockets Management Branch (address above).

In addition, Congress stated that while the studies relied on to support a claim need not necessarily be published in peer reviewed journals, the agency may look to publication as a factor in evaluating the weight to be given the study (Ref. 1). The agency also cannot revise the requirement for "significant scientific agreement" because this requirement is also now a provision of the act. However this provision does not require a "consensus" or "unanimity" of scientific opinion. The requirements of this provision are explained in the legislative history of the 1990 amendments. The House Report (Ref. 1) states:

> The standard is intended to be a strong one. The bill requires that the Secretary have a high level of confidence that the claim is valid. However, the standard does not require a unanimous agreement among experts. Instead, the standard requires that there must be a significant agreement among experts, but it does not require that every expert in the field approve or agree with the claim.
> (H. Rept. 301-538, 101st Cong., 2d sess., 19).

For dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances, the agency has the discretion to propose different requirements for a scientific standard. However, for reasons explained above in section III.D. of this document, FDA is proposing the same standard.

FDA has applied the standard in proposed § 101.14(c) in reading its tentative determinations on the 10 substance-disease topics that are addressed elsewhere in this issue of the **Federal Register.**

2. Assessment of Conformity With the Standard

FDA is proposing no specific provisions pertaining to the agency's assessment of conformity with the standard. However, FDA envisions that to satisfy the scientific standard, a health claim must be supported by a sound body of scientific evidence that establishes the relationship between a substance and a particular disease or health related condition. The data must persuade FDA that the proposed claim is valid, and that the benefits featured in the claim pertain to the general U.S. population or to a significant segment of the U.S. population. Thus, the body of scientific data must be strong. A few unconfirmed studies, incompletely documented data, or significantly contradictory findings do not constitute a sound body of evidence.

Further, the standard also requires that significant agreement exist among qualified experts that the claim is valid. "Qualified experts" include individuals whose training and experience have produced a general or specific scientific expertise in the diet/health topic being considered for a specific claim. FDA is not proposing to define "significant agreement" among these experts because each situation may differ with the nature of the claimed health benefit. The agency believes that any specific definition of such agreement might prove arbitrary when viewed in light of the multiplicity of potential health benefits and the widely variable nature of expertise required to evaluate the significance of these benefits. Instead, FDA intends to use the discretion granted it by the 1990 amendments to assess the degree of agreement on a case-by-case basis. Nevertheless, FDA will take into account the full range of opinions among qualified scientific experts on a specific claim in determining whether significant agreement exists.

FDA is not prescribing a specific set, type, or number of studies as being sufficient to support a health claim. The agency will consider all relevant data on a topic, including clinical studies (human studies conducted in a controlled clinical setting), epidemiological data (data from uncontrolled human populations), and animal studies. However, the type, quality, and relevance of a study from which data are derived have an important bearing on how much weight is placed upon the data. A full discussion of how to evaluate all types of studies on the impact of intake of a dietary substance on health is contained in chapter two of "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 6). Important aspects from that reference provide part of the basis for the following discussion of how the agency intends to evaluate the quality of a study supporting a health claim. FDA requests comments on this approach.

FDA believes that, for human studies, data relied upon must be generalizable to, and preferably obtained from, the U.S. population. FDA intends to give the greatest weight in its evaluation to well designed studies conducted with human subjects and in conformity with the agency's requirements regarding institutional review (21 CFR part 56) and informed consent (21 CFR part 50). Data from laboratory studies using animals, in vitro tests, and chemical analyses of the food substance will also frequently be required to understand the nature of the relationship between the substance and the disease or health related condition. If nonclinical studies (animal or in vitro laboratory studies) are to be considered, those conducted in conformity with the good laboratory practice provisions in 21 CFR part 58 will be given greater weight.

Among human studies, certain types of designs may carry greater weight in demonstrating the purported substance-to-disease relationship. Ecological studies (correlational studies using grouped population data) of diet-disease relationships relate dietary patterns of whole populations to disease incidence or mortality rates for whole populations. Because these studies do not examine the relationship between diet and disease among individuals, the studies have been traditionally regarded as useful for generating, rather than definitively testing, a scientific hypothesis (i .e., an unproved theory). Such studies are descriptive in nature rather than analytical. Thus, the results of ecological studies would be insufficient to demonstrate a relationship without other types of data to support them.

Analytical epidemiology studies (controlled studies on human populations) include case-control studies and cohort studies. In case-control studies, the relationship of a substance to a disease would be examined retrospectively by comparing persons with the disease to persons without the disease as to their exposure to the substance. Cohort studies, on the other hand, observe prospectively individuals who have been exposed to the substance, and those who have not, to determine if disease develops over time. Case-control studies provide less reliable estimates of the strength of associations than cohort studies because they are subject to bias in the detection and selection of cases and to bias in assessing exposure. Also, case-control studies require careful consideration of the validity of dietary data and of the appropriateness of control groups.

An intervention study is a type of cohort study in which the "exposure," or substance under study, is administered, or controlled, by the study investigators and the subjects for disease occurrence. For example, the study investigators may select a group of people to undergo a life-style modification, such as cessation of smoking, whereas an

additional group would make no changes. Both groups would then be followed over time, and their incidence of disease compared. The study investigators would have more control over an intervention study than a routine prospective cohort study because they can randomly select individuals for each group, thereby controlling for attributes other than the one under study that may affect disease occurrence.

Although intervention studies are the most reliable of epidemiology studies for determining cause-and-effect relationships, FDA recognizes that generalizing from selected populations often presents serious problems in the interpretation of such studies. Furthermore, in some cases, such as with cancers of different sites, intervention dietary studies are not feasible because diseases with lower frequency of occurrence, such as rare forms of cancer, require very large study samples to detect an effect. Moreover, there frequently are long latency periods from dietary exposure to onset of disease, often 20 to 30 years.

In evaluating proposed claims, FDA will take into account the feasibility of obtaining what might be considered to be the best evidence and will weigh issues of feasibility against the scientific merits of available studies. In some situations, scientific or ethical conditions may exist that would preclude the acquisition of data from human studies. Such scientific conditions associated with human research include the length of time needed to show an effect (e.g., years versus months), the ability to measure specific indicators (e.g., tissue samples), and the numbers of subjects required to show an effect. Ethical conditions would include potential risks associated with human studies in situations in which the study design would require removal of an individual from known beneficial treatment for the disease or would have an unreasonable, potentially detrimental impact on control subjects. Consequently, the agency would give data from uncontrolled studies greater consideration when either scientific or ethical conditions prevent more controlled studies.

A combination of various types of studies can frequently compensate for deficiencies in individual studies and thus provide a stronger case to prove or disprove a hypothesis. Where FDA evaluates a meta-analysis (i.e., a reanalysis of pooled data from several distinct human studies), the agency considers such an analysis primarily as supporting evidence, rather than as primary evidence, that can confirm the validity of data concerning a health claim. The agency must carefully scrutinize each meta-analysis to assess the soundness of its design and the quality of the data from individual studies to determine the significance of the data. Such scrutiny requires review of copies of all the original studies used for the meta-analysis.

Data from animal laboratory studies, in vitro tests (tests in an artificial environment outside the living organism), and chemical analyses of the substance are particularly valuable in providing information on mechanism of action and pathogenesis (the development of a diseased or morbid condition) to help in understanding the nature of the relationship between the substance and disease or health-related condition. Experiments in different animal species can examine genetic variability and can permit more intensive observation under controlled conditions than can human studies. However, extrapolation of data from animal studies to humans is limited by the comparability of physiologic and metabolic parameters between animals and humans.

The consistency of the demonstrated association between a substance and the disease or health-related condition is important when considering whether evidence from animal studies supports a health claim. Thus, the strongest animal evidence would be based on data derived from studies on more than one animal species or test system, on data that have been reproduced in different laboratories, and on data that give a statistically significant dose-response relationship.

In assessing the overall data in each topic area, FDA will apply these general considerations but will seek to avoid the pitfalls of inflexible adherence to rigidly defined criteria. The overriding principle will be to determine whether there are consistent results from different types of well-conducted human studies by different investigators in different populations. The strengths and weaknesses of each individual study will be evaluated. When experiments with animal models are appropriate, consistency of results between human and animal studies will also be considered. Such results will be interpreted in the light of any available evidence on the biological mechanism of the substance-disease relationship, evidence of a dose-response relationship, and similarity of the test substance with the nutrient or food component of interest. The significance of the disease from a U.S. public health standpoint will also be evaluated. In sum, FDA intends that its judgments concerning the overall quality of available data, the appropriateness of the study design, the consistency across different types of studies and laboratories, and the conclusions derived from the total body of evidence will be based on those generally recognized scientific procedures and principles that are most appropriate to the issues being addressed.

3. Use of Scientific Summaries

A number of comments on the 1990 reproposal addressed the concept of development of a scientific summary as part of the procedure for regulating health claims. However, FDA no longer intends to use a separate document called a "Scientific Summary." The 1990 amendments require that health claim decisions be made by regulation. The agency will discuss the scientific information substantiating the substance/disease relationship in the **Federal Register** document that proposes a regulation for the health claim. The regulation itself will include a summary of the scientific information and the conclusions supported by the science. Therefore, there is no longer a need for the Scientific Summary document.

The 1990 amendments resolve many other issues raised in the comments. The request that scientific summaries be developed in an open process is met by the rulemaking process for establishing regulations. There is opportunity for public comment on the agency's proposed analysis of the scientific information and conclusions. The petitions process that FDA is proposing in response to the 1990 amendments provides the opportunity requested by some comments for manufacturers to develop a scientific summary for the agency's evaluation.

One comment questioned the agency's ability to keep a health claim scientific summary current with the evolution of new data and information on the subject of the summary.

This point is well taken and indicates a need for the agency and the food industry to be mindful of new scientific information on the association between a substance and disease or health-related condition for which a claim is permitted by regulation. The likelihood of a need for frequent revision of any health claim regulation is greatly diminished, however, by the requirements of the statutory standard. The statute requires that, for each health claim, there be significant agreement among experts qualified by training and

experience that the claim is supported by a sound body of substantive scientific evidence. Accordingly, the likelihood of a regulation for a claim rapidly becoming obsolete is small, although not nonexistent. While resource limitations make it impossible for FDA to commit that it will ensure that its health claim regulations will reflect significant developments, any person who concludes that a revision is appropriate can request the revision in a petition using the procedures established by this rulemaking.

4. PHS Committee

In the reproposal (55 FR 5176), FDA proposed to establish a Public Health Service (PHS) Committee on Health Messages to serve as an advisory body to FDA on issues relating to the use of food labels to communicate information on the relationship between diet and health. This committee would have played a key role in assessing conformity with the scientific standard.

Although FDA still sees merit in the proposed role of this committee, section 403(r)(4)(A)(i) of the act provides short timeframes for an FDA decision on whether to file a petition for a health claim and on whether to issue a proposed regulation in response to the petition. With such short timeframes, it would be difficult to incorporate the committee into the regular procedures for assessing requested claims. The agency would find it difficult to assess the petition; forward that assessment to the committee; provide a reasonable time for the committee to consider FDA's assessment; reevaluate the agency's assessment, if necessary, in light of the committee's conclusions; and publish a proposed rule in the **Federal Register** within the statutorily required 90 days from the filing of the petition. However, the agency reserves the right to convene a panel of experts from within the Public Health Service of the Department of Health and Human Services (DHHS) to consider particular petitions. When such a panel is convened, selected DHHS Nutrition Policy Board representatives and key FDA and PHS scientists, with expertise in the subject under consideration, will review the suggested claim. These reviews will provide comments to FDA on the science relating to the claim.

Because the committee is not being formally established, the agency is not addressing specific comments concerning the committee. (Comments concerning the committee were mixed. Some comments endorsed the establishment of a committee, while other comments opposed it or suggested modifications in its proposed role or its composition.)

D. General Labeling Requirements

As explained previously in this document, FDA will propose a regulation in part 101, subpart E when the agency determines that a health claim is valid. The first proposed provision of § 101.14(d)(1) sets forth this agency commitment. This provision also advises that FDA will propose to provide for the listing in the nutrition label of a substance about which FDA is authorizing a health claim if no provision for listing the substance exists. FDA believes that such a provision is necessary to ensure that consumers can readily obtain specific information concerning how much of the substance is present in at least those foods on which a claim about the substance appears.

The other provisions of proposed § 101.14(d) contain general labeling requirements for the health claims that the agency provides for by regulation to ensure that consumers are provided with valid and reliable information about the value that ingestion (or reduced ingestion) of the particular substance, as part of a total dietary pattern, may have in affecting certain diet-related diseases or conditions. (Proposals concerning specific health claims in part 101, subpart E that appear elsewhere in this issue of the **Federal Register** list additional requirements for specific health claims on food labels.) The following is a description of the general requirements for health claims and FDA's rationale for them:

1. The Claim Must Be Consistent With the Authorizing Regulation

Proposed § 101.14(d)(2)(i) states that all label or labeling statements about the health benefit that is the subject of the health claim shall be based on, and consistent with, the conclusions set forth in the summary of scientific information and model health claims provided in regulations in part 101, subpart E.

This provision reflects the requirement under section 403(r)(3)(A)(i), that a health claim may only be made if it complies with the regulations issued by the Secretary (and by delegation, FDA). The act establishes fairly detailed requirements for such regulations. Section 403(r)(3)(B)(iii) of the act states that a regulation authorizing a health claim shall require that the claim accurately represent the relationship between a nutrient and a disease or health-related condition and the significance of each such nutrient in affecting such disease or health-related condition. Further, under this section of the act, the claim is to be stated in a manner that enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

To facilitate compliance with these requirements, FDA intends to provide in each regulation authorizing a claim a summary of the scientific information on the substance-disease relationship and a model health claim that includes all the required information.

FDA proposed to establish model health claims for each acceptable health claim in the February 1990 reproposal. The model health claims were to serve as examples for acceptable label statements and to provide guidance for manufacturers who chose to use different phrasing in a health claim. The 1990 reproposal stated that the model health claim would include:

(1) A brief capsulized statement (e.g., about 50 words in length) of the relevant conclusions of the appropriate scientific summary;

(2) A statement of the extent to which the food product contains or does not contain the key food component, and how this food product helps the consumer to attain a total dietary pattern or goal associated with reduction in the risk of the relevant chronic disease;

(3) A reference indicating that more complete nutrition/chronic disease information is available from the appropriate consumer health claim summary, and how that summary may be obtained; and

(4) A statement directing the consumer's attention to the nutrition label for further nutrition information.

The above elements for the model health claim are not as comprehensive as the 1990 statutory requirements for a health claim. Much of the information that would provide an understanding of the significance of the claim within the context of the daily diet would have been included in a consumer health claim summary which, under the 1990 reproposal, was not required to be readily available at the point of purchase. However, under the 1990 amendments, the health claim must include all relevant information (see section 403(r)(3)(B)(iii) of the act). The agency will ensure that all model health claims that it prepares, including those on the specific substance disease topics published elsewhere in this issue of the **Federal Register**, will comply with this requirement.

A summary of the comments pertaining to the reproposal's elements for the model health claim follows.

a. Most of the comments on this subject accepted the concept of a model health claim. Many comments, however, focused on the extent to which a claim on a product label or in labeling would be allowed to depart from the model claim. One consumer organization urged that only claims developed by FDA be allowed as health claims on food products. Recommending that deviation from model health claims not be permitted, the comment suggested that allowance could be made for manufacturers to devise their own health claims provided that they are precleared by FDA. Other comments requested that a model health claim serve as an example for a health claim and that it not be prescriptive. Some urged that manufacturers be allowed the flexibility to make changes in a model health claim so as to vary the content of the claim. They contended that after a time, unvarying messages are likely to become unnoticed and, hence, ineffective.

Section 3(b)(1)(A)(vii) of the 1990 amendments, in describing the regulations on health claims to be established by FDA, states that the regulations shall not require a person who proposes to make a claim described in section 403 (r) (1) (B) of the act (health claims) which is in compliance with such regulations to secure the approval of (the agency) before making such claim. This provision prohibits the agency from requiring preclearance of the phrasing of a claim provided the claim meets the criteria established in the regulation.

The principal reason for developing model health claims is to provide examples of health claims that are clear, accurate, and contain all elements that are necessary for consumers to use and understand the claim. Manufacturers may use a model health claim with the assurance that it is consistent with the permissive regulation authorizing the claim. Manufacturers who choose to craft their own version of a claim from a model claim are free to do so under section 3(b)(1)(A)(vii) of the 1990 amendments. However, the claim they use must be fully consistent with all the regulatory requirements for that health claim. If the labeling does not conform to the regulation, the product is subject to regulatory action as a misbranded food and, possibly, as a drug.

b. Several comments stated that the minimum material facts for a health claim, as generally described for the proposed content of a model health claim in the 1990 reproposal, would be too "wordy" to be effective and too extensive to be accommodated on a product label.

FDA recognizes that some model health claims may be "wordy," but the 1990 amendments have imposed new statutory requirements for health claims to ensure that consumers have sufficient information on the label or labeling to permit a fully informed purchasing decision. As explained previously, section 403(r)(3)(B)(iii) of the act requires that the claim for conventional foods be stated in a manner that enables consumers to understand the relationship of the substance to the disease, the significance of the substance in affecting the disease, and the relative significance of the information in the context of the total daily diet. These statutory requirements cannot be ignored even though, in some instances, the requirements may result in "wordy" claims.

Nevertheless, FDA will attempt to craft specific model health claims that are brief but yet include all essential information to meet the requirements of the act. With specific, rather than generalized, model health claims in the documents on the substance-disease topics elsewhere in this issue of the **Federal Register**, the agency will be able to more easily respond to comments on the content of the proposed claims to determine if they can be made less "wordy" while retaining essential information.

c. One comment said that it would be unnecessary to require a statement directing a consumer's attention to the nutrition label because most consumers interested in the nutritional value of a food would be aware of the nutrition label.

The agency agrees that a health claim need not require a statement directing the consumer's attention to the nutrition label for further nutrition information. With the significant changes in the 1990 amendments to expand the use of nutrition information on a food label, and with education activities addressed to consumers about the importance of that information in maintaining healthy dietary practices, an explicit reference in conjunction with a health claim to nutrition information should not be necessary. This position is consistent with the 1990 amendments which do not require a referral statement in conjunction with health claims as they do in section 403(r)(2)(B) of the act for nutrient content claims (but see section 403(r)(3)(A)(ii)).

d. One comment maintained that a model health claim may be inadequate to convey to consumers all that is necessary to understand the claim. The comment suggested that a manufacturer should have the option for providing information related to a health claim in a product or package insert.

As explained previously in this section, the 1990 amendments impose more comprehensive labeling requirements for health claims than FDA proposed for model health claims in the 1990 reproposal. Thus, Congress has ensured that health claims will be adequately informative for consumers to understand the claim. However, the 1990 amendments refer to health claims made in the labeling of a food as well as on the label (21 U.S.C. 343(r)(1)). Consequently, labeling such as a package insert may serve as the means of providing the required information when the label does not contain sufficient space for the complete health claim, so long as the claim is presented in a manner that complies with proposed § 101.14(d)(2)(iv).

Firms may provide information on labeling in addition to that required by FDA that may be helpful to the consumer in obtaining a deeper understanding of the claim. However, any such additional information would need to be truthful and not misleading. Such information would also have to be consistent with the agency's assessment of the scientific information justifying the health claim, as published in **Federal Register** rulemaking proceedings.

2. Claim Shall Describe Only Those Effects Found To Be Substantiated by Evidence

Proposed § 101.14(d)(2)(ii) states that the claim shall be limited to describing the value that ingestion (or reduced ingestion) of a substance, as part of a total dietary pattern, may have on a particular disease or health-related condition.

FDA will evaluate all relevant data when determining whether to authorize a claim on a substance-disease relationship. On finding that a claim is supported by the available evidence, the agency will describe all the effects of ingestion (or reduced ingestion) of a substance on the disease or health-related condition in the regulation authorizing the claim, which will be codified in part 101, subpart E. Proposed § 101.14(d)(2)(ii) limits the effects described in a claim to those that the agency finds are substantiated by the evidence. Any other effect would not have been substantiated, and including such an effect in a claim would be misleading. FDA is proposing this provision under section 403(r)(3)(B)(iii) of the act, which requires that the claim accurately represent the significance of

each substance in affecting the disease or health-related conditions.

3. Claim Shall be Complete, Truthful, and not Misleading

Proposed § 101.14(d)(2)(iii) states that the claim shall be complete, truthful, and not misleading. Where factors other than consumption of the substance affect the health benefit, such factors shall be addressed in the claim.

This criterion is central to the successful implementation of the proposed health claims policy. "Truthful and not misleading" claims are already mandated by section 403(a)(1) of the act, which deems a food misbranded if its labeling is false or misleading in any particular. Labeling claims are also already subject to statutory requirements concerning adequate disclosure of significant information. Under section 201(n) of the act, labeling can be misleading based on what is omitted from, as well as on what appears on, the label. For example, it would be misleading if a claim omitted significant information that is needed to properly interpret the claim. Even though this proposed provision reflects these statutory requirements, FDA believes that it is important to include the provision in the regulations to ensure that manufacturers understand that the claims that they formulate under FDA's regulations must be complete, truthful, and not misleading.

It has been suggested that FDA should allow claims that reflect more preliminary or controversial scientific findings so long as such claims are qualified in a way that appropriately reflects the state of the scientific evidence. For example, under this suggestion, FDA would allow a claim such as "Preliminary data show that diets rich in fiber reduce the risk of heart disease," so long as there is significant scientific agreement that this is in fact what the evidence shows. FDA has significant reservations about these types of claims, however, because of their potential to be misunderstood by consumers and therefore to be misleading. The agency is also concerned that such claims will undercut the credibility of the food label. This concern exists despite the fact that because such claims arguably do not assert a casual relation between diet and diseases they can never by disproved. FDA requests comments on whether it should authorize these types of claims in implementing the health claim provisions of the act.

Related to proposed § 101.14(d)(2)(iii), FDA is proposing to retain § 101.9(i)(1) (redesignated as § 101.9(k)(1)). This regulation states that any claim on a food product that implies that a substance is effective in the cure, mitigation, treatment, or prevention of a disease that is diet related not only makes the product a drug, but is misleading and will render the product a misbranded food. Such claims imply a degree of association between the substance and the disease that is not supportable for any food within the context of a daily diet. The Surgeon General's Report on Nutrition and Health (Ref. 5) points out that, apart from classic disorders resulting from dietary deficiencies of essential nutrients (e.g., pellagra and niacin), it has proved difficult to demonstrate causal associations between specific dietary factors and chronic or other diseases (e.g., dietary fiber and cancer). The report states:

> Development of the major chronic disease conditions—coronary heart disease, stroke, diabetes, or cancer—is affected by multiple genetic, environmental, and behavioral factors among which diet is only one—albeit an important—component. These other factors interact with diet in ways that are not completely understood. In addition, foods themselves are complex; they may contain some factors that promote disease as well as others that are protective. The relationship of dietary fat intake to causation of atherosclerotic heart disease is a prominent example. An excess intake of total fat, if characterized by high saturated fat, is associated with high blood cholesterol levels and therefore an increased risk for coronary heart disease in many populations. A higher proportion of mono- and polyunsaturated fats in relation to saturated fats is associated with lower blood cholesterol levels and, therefore, with a reduced risk for coronary heart disease.
>
> Because of these complexities, definitive scientific proof that specific dietary factors are responsible for specific chronic disease conditions is difficult—and may not be possible—to obtain, given available technology * * *
> (Ref. 5).

4. Claim Shall be Presented in One Place

Proposed § 101.14(d)(2)(iv) requires that all information that is required by the authorizing regulation appear in one place without other intervening material. The entire claim must appear on the label or other labeling. However, this provision contains an exception so that when the entire claim appears on other labeling than the label, the label may bear the statement, "See ____ for information about the relationship between ____ and ____," with the blanks filled in with references to the location of the labeling containing the health claim, the name of the substances, and the disease or health-related condition. This statement may be coupled with the use of the relevant nutrient content claim. Thus, the food label could state: "High in calcium. See side panel for nutrition information. See attached pamphlet for information about the relationship between calcium and osteoporosis."

This provision is proposed under sections 201(n), 403(a), and 403(r)(3)(B)(iii) of the act to ensure that consumers are not misled by the omission of any essential elements of the health claim but at the same time to permit manufacturers to make consumers aware of the claim. Because labels may be too small to accommodate the entire claim in some circumstances, FDA is proposing an exception to the requirement for complete listing. However, the exception is not limited to situations where the label is too small because the agency sees no potential for consumer deception under the proposed provisions.

5. Claim Shall Enable Public To Understand Information Presented

Proposed § 101.14(d)(2)(v) requires that claims enable the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

This provision is a reiteration of the statutory language in part of section 403(r) (3) (B) (iii) of the act. FDA has considered this requirement in developing the content of the proposed model health claims in the proposals to authorize health claims that appear elsewhere in this issue of the **Federal Register**. The model health claims have been written to provide the basis for a consumer to decide whether (and how) the labeled food best fits into his or her diet. Thus, for example, when a substance-disease relationship has more significance for a particular segment of the population than for the general population (e.g., a segment defined by age, sex, race, or other determinant), the agency has tried to reflect that fact in the model claim.

Further, the proposed provision requires that the claim permit the consumer to understand the significance of the information that it provides within the context of the total daily diet. For example, where the level of an increasable nutrient in a food is at the upper range of normal dietary levels, there may be no known benefit from further intake of that nutrient. In such circumstances, consumers should be advised of this fact as part of the claim. The proposed regulation on calcium and osteoporosis that appears elsewhere in this issue of the **Federal Register**, for example, requires that foods that make

a claim on this topic bear a label statement indicating that there is no known benefit from intake of more than 200 percent of the RDI for calcium.

6. Claim Shall Be Made on Foods With Appropriate Levels of the Substance

Unless the authorizing regulation provides otherwise, FDA is proposing in § 101.14(d) (2) (vi) that a claim about the effects of a decreased dietary intake of a substance can be made on any food in which the substance is present at a level that meets the definition for the use of a "low" nutrient content claim for that substance, if such a definition has been established under Part 101, or is present in an amount that is consistent with that specified in the regulation. Such levels are appropriate for this purpose because FDA has sought to define "low" as a level of a substance (nutrient) that will be helpful to individuals in attempting to comply with dietary recommendations. FDA is proposing in separate documents published elsewhere in this issue of the **Federal Register** definitions in part 101, subpart D for the terms "low fat," "low saturated fat," "low cholesterol," and "low sodium."

If a definition for a "low" nutrient content claim does not exist for the substance, in authorizing a claim, the agency will determine the level of the substance that would qualify a food for a health claim. This determination will be based on any relevant dietary recommendations and on the available scientific information on the specific substance/disease relationship. This level will be included in the regulation in part 101, subpart E that authorizes a claim.

To bear a claim that is based on increased dietary intake of a substance, a food must contain that substance in an appropriate form and at a sufficiently high level. FDA is proposing in § 101.14(d) (2) (vii) that to meet this requirement, the food must contain the substance at a level that would meet the definition for a "high" nutrient content claim if such a definition has been established for that substance in part 101, subpart D. If no definition for a "high" nutrient content claim has been established for the substance, then the agency will propose to establish a specific level in the authorizing regulation.

FDA is proposing that a "high" nutrient content claim be defined as 20 percent or more of the RDI or DRV (§ 101.54(b)). Given the fact that nutrients are not ubiquitously distributed in the food supply, the agency believes it is necessary to meet this proposed requirement to ensure that the food carrying a health claim makes a significant contribution to daily intake. For example, since calcium is not ubiquitously distributed in foods, to achieve 100 percent of the RDI, at least five foods containing 20 percent of the RDI would need to be consumed daily. Based on food consumption patterns, this is a reasonable number of servings and could result in a diet that will achieve the level of the nutrient necessary for the claimed benefit.

FDA believes that a claim based on a increased level of a substance in the diet implies that the food contains a level of the food that makes a significant contribution to the daily diet. Thus, if the food fails to comply with proposed § 101.14(d)(2)(vii), its labeling would be misleading and would misbrand the food.

The agency considered alternatives to the criterion that for health claims dealing with decreased or increased dietary intake of a substance, the level of the substance in a food must meet the definition for a "low" or "high" nutrient content claim. It considered whether a food meeting the definition for a "reduced" or "more" nutrient content claim should also be deemed to qualify for a health claim for that nutrient. On the one hand, some have argued that because the claimedbenefits derive from either decreased or increased dietary levels of the substance, any food that would be helpful in achieving those levels should be permitted to bear a claim. For example, the guideline for lowering salt and sodium dietary intake advises consumers to choose foods that are lower in sodium most of the time. On the other hand, others assert that any health claim should be permitted only for those foods that, when incorporated in a daily diet, are fully compatible with public health recommendations for improving dietary practices within the general U.S. population. "Dietary Guidelines for Americans" (Ref. 7), for example, states that diets low in fat, saturated fat, and cholesterol can be attained through appropriate food selection that includes choosing dairy products that are either lowfat or fat-free. Moreover, if a food starts with a high level of a nutrient, it could meet the definition of "reduced" but still contain a large amount of the nutrient (e.g., a reduced-sodium pickle).

The agency has taken these and other factors into account. Because it believes that compliance with dietary recommendations will be facilitated if only foods that conform to the "low" and "high" nutrient content claim definitions, FDA is proposing to require conformity with those definitions in § 101.14(d) (2) (vi) or (d) (2) (vii).

The agency, however, specifically solicits comment on this issue. Its desire is to establish a sound, equitable requirement that will promote public health. The agency requests comment on whether use of claims on foods that meet the definitions of "reduced," "more," or even other comparative claims will be useful to consumers in achieving the efforts that are highlightedby the claim, or whether allowing the claims on such foods will be misleading because the nutrient levels are not low enough, or not high enough, to really contribute to the claimed effect.

7. Nutrition Labeling for Restaurants

Proposed § 101.14(d) (3) requires that a food that bears a health claim be the subject of nutrition labeling in accordance with §§ 101.9 and 101.36.

Under current § 101.9(a), nutrition labeling is required on all products that contain an added vitamin, mineral, or protein or whose label, labeling, or advertising includes any nutrition claim or information. The agency adopted this requirement under sections 403(a) (1), 201(n), and 701(a) of the act (21 U.S.C. 303(a), 321(n), and 371(a)). Under section 403 (a) (1) of the act, a food is misbranded if its label or labeling is false or misleading in any particular. Under section 201(n) of the act, the label or labeling of a food is misleading if it fails to reveal facts that are material in light of representations actually made in the label or labeling. Finally, under section 701(a) of the act, the agency has authority to issue regulations for the efficient enforcement of the act.

The applicability of current regulations to restaurant foods was discussed in rulemaking promulgating § 101.10 *Nutrition labeling of restaurant foods* (21 CFR 101.10) (39 FR 42375, December 5, 1974 and 41 FR 51002, November 19, 1976). In the preamble to the proposed rule, the agency discussed its belief that nutrition education is of prime importance and stated that it will take every opportunity to foster the dissemination of such information to the consumer, including the use of nutrition labeling in restaurants. However, the agency acknowledged that if nutrition information provided in restaurants necessitates the expense of nutrition labeling, the restaurant "may choose not to provide any nutrition information in advertising or labeling, on the basis that the added cost of providing detailed information might cause the project of providing nutrition information not to be worth the expense" (39 FR 42375). Therefore, to encourage the dissemination of nutrition information in

the food service industry, FDA proposed to exempt ready-to-eat foods from the requirement of bearing nutrition labeling on food labels if the required nutrition labeling was displayed prominently on the premises by other means, e.g., counter cards or wall posters, where the information would be readily available to the consumer when he is making a menu selection.

Subsequent action on this proposal led to the issuance of a statement of policy in § 3.207 (recodified as 21 CFR 101.10 in the **Federal Register** of March 15, 1977 (42 FR 14302)) that if any advertising or labeling (other than labels) includes a claim or information about the total nutritional value of a combination of two or more foods (e.g., a combination consisting of a hamburger, french fries, and milkshake), then, as an alternative to providing nutrition information about each separate food on the food label, the restaurant may instead provide information about the total nutritional value of the combination of foods, provided that the statement of total nutritional value follows the nutrition labeling format and provided that the nutrition information is effectively displayed to the consumer both when he/she orders the food, and when he/she consumes the food.

As discussed in the supplementary nutrition labeling proposal published elsewhere in this issue of the **Federal Register**, the 1990 amendments specifically exclude restaurant foods from the requirement for nutrition labeling. However, as stated above, the agency believes that it has the authority to issue regulations requiring restaurants that choose to make health claims to adhere to the requirements for such claims, including nutrition labeling.

FDA is not, at this time, making any specific provisions for the nutrition labeling of restaurant foods. FDA specifically seeks comment on how it should handle this issue. On one hand, many believe that it is important that consumers be given useful and meaningful nutrition information. On the other hand, many continue to be concerned, as FDA was in 1974, that the cost of compliance not be so high that restaurants will not be willing to offer and identify through health claims those foods that will assist consumers in selecting diets that provide health benefits. Therefore, the agency is requesting comments on whether and to what extent it has a basis for nutrition labeling when health claims are made on restaurant foods, or whether a requirement for such labeling would discourage restaurants from making health claims because of the cost associated with nutrition labeling.

If, based on comments received, FDA were to require nutrition labeling of restaurant foods, should the requirement apply only to large restaurant chains with fixed menu items? Additionally, should the content or format of nutrition labeling be different for the food service industry than for packaged foods? If so, how and why?

FDA recognized in its July 19, 1990 (55 FR 29487 at 29504), reproposal on mandatory nutrition labeling that certain restaurant-type food service facilities cannot reasonably be expected to provide information concerning nutrient profiles, and that exemptive provisions should be established for such situations. The proposal advised that comments pointed out that nutrition labeling for foods served in restaurant-type facilities present significant feasibility problems in a number of situations. The comments made the following points: These facilities may not be able to develop consistent nutrient information on the foods that they sell because of frequent menu changes and variations in how the consumer wants the food prepared and served. Without nutrient consistency, frequent nutrient analyses would have to be performed to provide consumers with accurate nutrition labeling information. These analyses could become very burdensome. The cumulative costs of these analyses could place undue restrictions on some establishments. Firms could be inhibited from making frequent menu changes or forced to I imit the options that consumers have in ordering a food.

Because of these problems, FDA proposed an exemption under section 201(n), 403(a), and 701(a) of the act for restaurant-type foods in the mandatory nutrition labeling proposal (see proposed § 101.9(h) (2), SSFR 29516). Although the agency wanted to limit the exemptions to only those situations in which it is needed, FDA did not, and still does not, have sufficient indepth knowledge of the food service industry to develop adequate criteria to fairly impose such limitation. The agency therefore requests comments on this issue.

A related question is what to be done with § 101.10. Because § 101.10 was adopted under section 403(a) of the act, it is not subject to state enforcement under section 307. For this reason, and because § 101.10 has not been enforced by FDA, the agency believes that it is appropriate to make an affirmative statement about the cont.inuing need for this provision. Thus, if FDA elects not to make restaurant labeling part of the NLEA implementation, the agency will, in the final rule, delete § 101.10.

8. Dietary Supplements

Because the provisions in § 101.14(d) derive in large part from section 403(r)(3) of the act, an argument can be made that they should not apply to dietary supplements. However, FDA believes that these provisions are necessary to ensure that claims are not misleading, are valid, and are useful to consumers. Therefore, FDA is proposing to adopt these provisions for dietary supplements based on its authority under section 403(r)(5)(D) of the act to ensure the validity of claims on these foods.

E. Prohibited Claims

1. Claims not Authorized by FDA

Proposed § 101.14(e)(1) and (e)(2) prohibit on a food label or in labeling any claim that expressly or by implication characterizes the relationship of any substance to a disease or health-related condition unless: (1) The claim is a health claim specifically provided for in part 101, subpart E; and (2) the claim conforms to all general provisions of this section as well as to all specific provisions in the appropriate section of part 101, subpart E.

Although the nature of the proposed prohibition may be obvious for explicit claims (e.g., products bearing statements about cholesterol-lowering effects are explicit claims about a health-related condition) because of their forthright nature, the nature of the prohibition is not as obvious for implied claims. Proposed § 101.14 (a)(1) points out that implied claims include a wide variety of forms of expression, including "third party" endorsements, written statements (e.g., a brand name including a term such as "heart"), -symbols (e.g., a heart symbol), and vignettes.

With respect to "third party" endorsements of food, FDA considers this term to refer generally to any type of approval or implied support for the food pertaining to disease or health-related matters, with or without product specific information, by a person or organization that is independent of the product's manufacturer or distributor. When the endorsement is from a professional society or association that has been identified with treatment of a specific disease, consumers may be led to believe that the food may be useful with respect to the disease. Even when the endorsement is not product specific, there is a potential for consumer deception where consumers may be

given a false sense of security that consumption of products that bear labeling references to the organization or the organization's logo or seal will protect them from the disease.

Examples of some of the types of labeling endorsement programs that FDA has considered to be implied health claims include programs that have been sponsored by the American College of Nutrition, the American Heart Association, The American Medical Association ("Campaign Against Cholesterol"), and the American Medical Women's Association. The agency recognizes, however, that professional societies and associations provide a unique service in establishing criteria for assessing diets of both healthy population groups as well as those who require modifications or restrictions in their diets. FDA encourages such organizations to collaborate with the agency in the development of its regulations pertaining to health claims through submission of specific comments on this proposal as well as on the specific proposals on the 10 substance-disease topics that are published elsewhere in this issue of the **Federal Register.** The agency requests comments on whether it should consider all third-party endorsements that imply that a nutrient in a food has an effect on a disease or health-related condition to be health claims, or whether there are some limits on FDA's coverage of third party endorsements that should appropriately be drawn?

Where other Federal agencies have established programs to change dietary patterns to reduce the risk of diet-related diseases (e.g., the National Cholesterol Education Program), FDA recognizes that references to such programs on food labeling may also be perceived by consumers as "third party" endorsements. Although FDA is proposing to regulate labeling references to such Federal programs as implied health claims, the agency believes that the benefits of these programs to consumers may be significant if the labeling messages that are conveyed to consumers about the other Federal programs are properly merged with the specific health claims that are provided for under part 101, subpart E. Without appropriate merging of information about health benefits, consumers could, however, be confused about the significance of the benefits.

FDA believes that the most efficient way to ensure that consumers will not be confused about this significance is to establish, by regulation, the specific types of statements that may be made on food labeling concerning the Federal programs. The agency is requesting that comments concerning what statements about Federal programs would be appropriate on food labeling be submitted for the appropriate specific regulations in part 101, subpart E. Based on these comments, FDA intends to include a listing of the statements that may be used in the final rules on these regulations. FDA advises interested parties that, at this time, the agency believes that labeling references to the programs should not be made through logos because such visual representations may have too wide a variety of meanings to consumers.

A second, related question with respect to implied health claims is how to regulate the use of symbols such as a heart or electrocardiogram. The agency is aware that symbols are particularly useful in conveying information in a simple and efficient manner. Research has demonstrated that heart symbols, for example, on food labeling are perceived by consumers as meaning that the food has special usefulness relative to health and especially with regard to coronary heart or cardiovascular disease (Refs. 22 and 23). FDA has also heard from consumers, however, that symbols have been used in misleading ways.

The threshold problem with symbols is how to regulate them under the scheme established by the 1990 amendments. On the one hand, properly qualified by other statements on the food label, a heart symbol, for example, can be used as an implied nutrient content claim to denote a food that is low in fat, saturated fat, sodium, and cholesterol. On the other hand, as stated above, a heart that is not qualified by other statements on the label would arguably represent a health claim that a nutrient in the food has some special role in promoting coronary or cardiovascular health.

FDA invites comments on the regulatory approach that it should take to symbols for use on the food label.

FDA does not agree with comments that have suggested that statements identifying certain dietary components (e.g., fiber, calcium) constitute implied health claims, even when the label avoids directly mentioning a disease. Such claims are specifically regulated as nutrient content claims under section 403(r)(1)(A) of the act and are addressed in the agency's proposal on nutrient content claims published elsewhere in this issue of the **Federal Register.** After the effective date of the 1990 amendments, such claims are prohibited unless FDA has issued a regulation defining the particular claim.

2. Disqualifying Levels Exceeded

Proposed § 101.14(e) (3) requires that none of the disqualifying levels identified in paragraph (a) (5) of this section be exceeded in a food that bears a health claim, unless specific alternative levels have been established for the substance in part 101, subpart E, or unless FDA has by regulation permitted such a claim based on a finding that such a claim will assist consumers in maintaining healthy dietary practices. If FDA makes such an exception, the label of the food would have to bear a statement in immediate proximity to the claim that refers the consumer to the nutrition label for information about the nutrient that exceeds the disqualifying level. This statement must be made in a manner that complies with proposed § 101.13 (h). FDA is proposing this provision under the authority of section 403(r)(3)(A)(ii) of the act.

A complete discussion of the disqualifying levels was presented previously in section IV.A.5 of this document.

3. Inappropriate Levels of Other Substances

Proposed § 101.14(e)(4) prohibits claims for any food where a substance, other than one for which a "disqualifying level" is established, is present at an inappropriate level as determined in specific provisions of part 101, subpart E.

This provision implements a number of different provisions of the 1990 amendments. As was stated previously in this document, section 403(r)(3)(A)(ii) of the act prohibits a claim where any nutrient is present in an amount that increases the risk of a disease or health-related condition that is diet related to persons in the general population, taking into account the significance of the food in the total daily diet. In section IV.A.5 of this document, the agency advised that two approaches for implementing this provision include the preliminary requirement that use of the substance at relevant levels have been found to be safe under agency regulations, and that the "disqualifying levels" not be exceeded. A third approach, which the agency is also proposing to adopt, is to prohibit claims for foods containing any level of a substance, other than one for which a disqualifying level is established, where that substance increases such risk. This provision proposed in § 101.14(e)(4), is intended, in part, to provide for a situation in which

such a substance, or a level of a substance, is identified in one of the specific regulations in part 101, subpart E. However, at this time the agency is not aware of any such situations.

In addition, this provision is intended to implement other aspects of the 1990 amendments. Proposed §§ 101.14 (d)(2)(vi) and (d)(2)(vii) require that substances be present at a level sufficient and in an appropriate form to justify the claim. Proposed § 101.14(e)(4) supplements paragraphs (d)(2)(vi) and (d)(2)(vii) by providing the basis by which FDA can assure through provisions in specific regulations in part 101, subpart E that the appropriate form of the substance is used in light of levels of other nutrients or food components that may counter the effect of the substance for which the health claim is made. Counter effects may include interference with the substance to reduce its absorption, metabolism, or utilization by the body, thereby reducing or negating the substance's value.

For example, the proposed health claim concerning calcium and osteoporosis, published elsewhere in this issue of the **Federal Register**, contains a provision (proposed § 101.72(c)(5)) providing that a serving or recommended total daily intake of a food shall not contain more phosphorus than calcium on a weight per weight basis. As explained in that proposal, this provision is based primarily on scientific evidence demonstrating that diets high in phosphorus and relatively low in calcium result in osteoporosis in experimental animals.

Similarly, if a health claim were permitted in part 101, subpart E associating increased dietary copper intake with a reduced risk of a disease (although note that no such claim is contemplated at this time), it is conceivable that the interactive effect of dietary zinc intake on copper status would have to be considered to assure that an adequate dietary copper intake is attained for the claimed benefit. The antagonistic effect of high levels of dietary zinc on copper absorption and status has been demonstrated in humans and in a variety of animal species (Ref. 16). Some studies, but not all, have reported subtle negative effects of increased intake of zinc, not much in excess of the Recommended Dietary Allowance (RDA) for zinc, on biological indicators of copper status. For example, a study in men of the effect of zinc intake at 3⅓ times the RDA level reported a decrease in zinc, copper-superoxide dismutase, a red blood cell enzyme that is dependent on copper but not zinc status and that thus serves as an index of tissue copper status (Ref. 17). Accordingly, FDA would prohibit a health claim for copper on a food whose zinc level is above the RDA or RDI level.

4. Representing Food for Infants or Toddlers

Proposed § 101.14(e)(5) provides that no food may bear a health claim if it is represented or purports to be for infants and toddlers less than 2 years of age.

The American Academy of Pediatrics, in their comment to the 1990 reproposal, expressed concern that a health claim directed toward adults may be inappropriate or harmful to infants and young children. One example cited was that the link between lipids and cardiovascular disease is not established in young children as it is in adults. Consequently, though diets high in fats may be undesirable for adults, the comment stated that infants and toddlers must ingest a certain amount of fat for their growth and development. Accordingly, the comment recommended that a health claim for adults should indicate that it is not intended to apply to infants and young children.

Furthermore, both "The Surgeon General's Report on Nutrition and Health" (Ref. 5) and "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 6) state that, because of the increased nutrient demands of children during the early periods of rapid growth and development, the dietary recommendations are not applicable to persons under 2 years of age. The criteria for health claims being proposed in this and the companion documents are based on dietary recommendations for the U.S. population, excluding very young children. Therefore, the agency has tentatively concluded that health claims are inherently misleading if used on the labels of foods represented or purported to be for infants and for toddlers under 2 years of age. Therefore, under sections 201(n), 403(a), and 403(r) of the act, FDA is proposing in § 101.14(e)(5) to prohibit the use of health claims on foods for these young children.

F. Need for Additional Prohibited Claims

FDA is concerned that under these proposed regulations some foods that are inconsistent with generally recognized medical and nutrition principles for a sound total dietary pattern will be permitted to bear health claims. For example, some diet confections, which have no nutritional value, would be permitted to bear health claims for lipids and cardiovascular disease, lipids and cancer, and sodium and hypertension, if the regulations on these substance-disease relationships are finalized as proposed.

Such a situation seems contrary to one of the stated purposes of the health claims provisions of the 1990 amendments—to reinforce Federal dietary recommendations and help Americans maintain a balanced and healthful diet (Ref. 1). This purpose was reinforced through statutory provisions in section 403(r)(3)(A)(ii) of the act requiring FDA to consider the significance of the food in the total daily diet when determining whether a nutrient that increases the risk of a disease or health-related condition should disqualify a food from bearing a health claim. Congress explained (Ref. 1) that this provision "permits the Secretary to differentiate between different foods which have the same level of a nutrient. For example, a particular level of fat in a frozen dinner might not trigger the provision, whereas that same amount of fat in a snack food product might trigger it." Thus, FDA believes that provisions permitting health claims on only foods recognized as within a sound dietary pattern would be consistent with the intent of Congress.

However, FDA is not aware of any way to limit health claims to only those foods within a sound dietary pattern at this time. The agency considered, and decided against, proposing a provision prohibiting claims unless there is consistency with generally recognized medical and nutrition principles for a sound total dietary pattern (e.g., consumption of the food is consistent with the current edition of "Nutrition and Your Health: Dietary Guidelines for Americans," Third Edition, 1990 (Ref. 7), and the food is not a snack food such as candies or those low in essential nutrients.

For the general U.S. population, "Dietary Guidelines for Americans" provides guidelines on the relationship between diet and various diseases and conditions such as obesity, hypertension, cancer, and deficiency diseases. The guidelines reflect the dietary recommendations contained in the "The Surgeon General's Report on Nutrition and Health" (Ref. 5) and "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 6). The guidelines embody dietary principles for consumption of foods with significant nutritional value and for reduction or control of certain food components associated with diet-related diseases or conditions. Throughout FDA's development of both the specific health

claims proposals for part 101, subpart E, as well as the general provisions of this proposal, FDA has considered these guidelines.

At the present time, the guidelines are: Eat a variety of foods; maintain healthy weight; choose a diet low in fat, saturated fat, and cholesterol; choose a diet with plenty of vegetables, fruits, and grain products; use sugars only in moderation; use salt and sodium only in moderation; and if you drink alcoholic beverages, do so in moderation.

However, FDA believes that the guidelines are too general in nature to serve as binding rules upon which the agency can readily take regulatory action. For example, what foods would clearly fit into an appropriate variety of foods? What portion of foods would constitute a moderate amount of sugars? How would the agency define "snack foods?" The agency requests comments from all affected parties concerning what provisions might effectively permit health claims only on foods that can make a significant contribution to a healthful diet. If the comments suggest appropriate provisions, FDA will include them in any final regulation based on this proposal.

G. Exempted Foods

Medical foods, as defined in section 5(b) of the Orphan Drug Act, and infant formulas subject to section 412(h) (21 U.S.C. 350a) of the act are specifically exempted from requirements for health claims and nutrient content claims by section 403(r)(5)(A) of the ac' FDA is proposing to codify these statutory provisions in § 101.14(f).

In addition, section 403(q)(5)(A)(iv) exempts medical foods from nutrition labeling requirements. To deal with this latter exemption, the agency has incorporated the definition of "medical food" in the supplementary proposal on mandatory nutrition labeling, published elsewhere in this issue of the **Federal Register**, to clarify this definition by providing criteria in proposed § 101.9(j)(7) for use in identifying a medical food. As explained in that proposal, minimum criteria to distinguish a medical food from other foods include: The product must be a food for oral or tube feeding; the product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be intended for use under medical supervision (Ref. 18).

The supplementary proposal on mandatory nutrition labeling states that medical foods are not foods that are simply recommended by a physician or health care professional as part of an overall diet to reduce the risk of a disease or medical condition or promoted as weight loss products. Nor do medical foods include dietary supplements for the general population that can be openly purchased from retail outlets or by mail order, even though dietary supplements may be recommended by a physician for a specific condition or disease. The intended use and degree of medical oversight for dietary supplements are not regarded to be sufficient to qualify them as medical foods.

FDA is reevaluating its traditional policy to regulate medical foods as foods for special dietary use in light of the existing definition of foods for special dietary use and the definition of medical food enacted by Congress (21 U.S.C. 350(c) and 360ee(b)(3)). FDA intends to address the issue of medical foods in a future **Federal Register** document.

Infant formulas that are subject to section 412(h) of the act are known as "exempt infant formulas" because they are exempt from the requirements of sections 412(a), (b), and (c) of the act, which pertain to other infant formulas. Instead, exempt infant formulas are subject to regulations established by the Secretary under the authority of section 412(h)(2) of the act. Exempt infant formulas are defined in section 412 (h)(1) of the act as any infant formula which is represented and labeled for use by an infant: (1) who has an inborn error of metabolism or a low birth weight, or (2) who otherwise has an unusual medical or dietary problem. Regulatory requirements for exempt infant formulas, including claims, are contained in 21 CFR part 107.

H. Applicability of the Regulation

FDA is reflecting the applicability provisions of section 403(r)(1) of the act in proposed § 101.13(g). This provision states that the requirements of proposed § 101.13 apply to foods for human consumption that are offered for sale. Thus, the proposed health claim regulations apply to foods for human consumption sold in grocery stores and other settings.

I. Other Issues

1. Consumer Summaries

The 1990 reproposal would have required preparation of a consumer summary concerning a health claim on a food label. The summary would have been an extension of the health claim on the label to provide full information about the relationship between the food and the disease about which the claim pertained. The summary was intended to facilitate the consumer's assessment of whether the health claim applied to him or her and, in certain instances, to what extent it applied. The summary was also intended to help alleviate the potential problem of information overload on the label. A summary was to be developed for each diet and chronic disease relationship for which a health claim would be appropriate. The food label bearing the health claim would have been required to reference the summary.

The comments generally focused on the concept of developing the summaries through a process that is open and allows for public comment. Some of the comments expressed interest in the development and testing of the summaries. Other comments expressed concern about the accessibility of consumer information at the point of retail sale.

In view of new statutory requirements for the label or labeling of a food bearing a health claim, FDA believes that consumer summaries may no longer be necessary. Section 403(r)(3)(B)(iii) of the act states that the regulation authorizing a claim shall require that the claim be stated in a manner: (1) That accurately reflects the relationship between the substance and the disease or health-related condition, and the significance of the substance in affecting the disease or health-relate condition, and (2) that enables the public to comprehend the information provided in the claim and understand the relative significance of such information in the context of a total daily diet. This provision requires that the claim present the most significant aspects of the information that the agency was considering to require in the consumer summaries. Therefore, FDA fails to see what purpose a consumer summary would serve and is not proposing to require these summaries at this time.

However, FDA solicits comments on whether consumer health claim summaries can still serve a useful purpose. The agency asks that interested persons examine the specific model health claims proposed elsewhere in this issue of the **Federal Register** and the consumer summaries that FDA has prepared and consider whether these summaries, which present in lay language, information about the association between the substance and the disease or health-related condition, are needed. If comments persuade the agency that these summaries should in fact still be required, FDA may include a requirement for the summaries in any final rule that is based on this proposal.

The purpose of a consumer summary would be to provide supplementary information to that on the label about substance-disease relationships for consumers who are interested. Such information may include, among other things, a discussion about the disease or health-related condition, its prevalence in the U.S. population, and the relative degree of risk for specific subpopulation groups. In addition, dietary information on other food sources of the claimed nutrient or substance, information on nondietary risk factors for the disease, and other similar information may be provided.

2. Consumer Guide to Food Labeling

The 1990 reproposal would have required the agency to prepare a consumer guide to food labeling (consumer guide) as an adjunct to the procedure for health claims. The consumer guide would have discussed in general terms how the various types of consumer-oriented information found on the food label are to be used. The consumer guide was intended to address questions such as:

(1) What is a consumer health claim summary, and who is it for?

(2) What is nutrition labeling, and how is it used in dietary planning?

(3) What is the importance of the total diet in maintaining good health?

(4) How do dietary supplements best fit into a total daily diet?

(5) What is the process used to develop label statements and consumer health claim summaries?

(6) Are label statements and consumer health claim summaries applicable to specific groups (e.g., certain statements or claims may not be appropriate for children)?

(7) How can consumers use ingredient statements, common or usual names of foods, and nutrient content claims (e.g., low sodium) to assist them in achieving sound dietary practices? FDA conceived of developing one "umbrella" consumer guide that would be broadly applicable to all health claim subject areas.

All comments on the 1990 reproposal endorsed development of the guide. Most of the comments addressed the availability of the consumer guide, stating that it should be widely distributed, accessible, or available. One comment said that information on availability of the consumer guide should be given on the product label. One comment suggested that the consumer guide should be published in the **Federal Register** for public comment before distribution to consumers. Another comment suggested that the consumer guide be developed cooperatively with organizations outside FDA. One consumer organization suggested that the consumer guide should be distributed to beneficiaries of public assistance programs to assure that persons with low incomes have access to nutrition information. Another recommendation was that, in addition to English, the guide should be published in other languages.

Although FDA still intends to issue a consumer guide, the agency believes that such a consumer guide should be issued separately from this proposal. Section 2(c) of the 1990 amendments directs FDA to carry out activities that educate consumers about the availability of nutrition information on the label and in labeling of a food and about the importance of such information in maintaining healthy dietary practices. Inclusion of the consumer guide on health claims as a part of these new educational activities will address the issues and concerns that motivated FDA to propose the consumer guide.

Accordingly, FDA believes that it is not necessary for it to respond more specifically to the comments about the consumer guide at this time. Of course, the agency will consider these comments when a guide or other educational material is being prepared.

J. Petitions for Health Claims

Section 403(r)(4)(A)(i) of the act grants any person the right to petition the agency to issue a regulation authorizing a health claim on a substance-disease relationship. Section 403(r)(4)(B) of the act requires that the petition include an explanation of the reasons why the claim that is the subject of the petition meets the requirements of section 403(r) of the act and a summary of the scientific data that support those reasons. The act also states that if the petition relies on a report from an authoritative scientific body of the United States, the agency shall give particular consideration to such report and shall justify any decision rejecting the conclusions of such report (section 403(r)(4)(C) of the act)

The act requires in section 403(r)(4)(A)(i) that, within 100 days of receipt of a petition for a regulation concerning a health claim, FDA must either issue a final decision denying the petition or file the petition for further action. If the agency denies the petition, it is not made available to the public. If FDA files the petition for further action, the agency must either deny it or publish a proposed regulation responsive to the petition within 90 days of filing.

However, the foregoing provisions do not apply to health claims for dietary supplements. Under section 403(r)(5)(D) of the act, as stated above, these claims are subject to a procedure established by regulation by the Secretary of Health and Human Services (and by delegation, FDA).

On March 14, 1991, the agency published a notice in the **Federal Register** (56 FR 10906) that it is developing procedural regulations that will prescribe the types of information needed to support petitions for health claims and the other types of petitions permitted by the 1990 amendments (including petitions concerning nutrient content claims and State petitions for exemption from Federal preemption granted by the 1990 amendments), the format in which the petitions are to be submitted to the agency, and the procedures that the agency will follow in its review of these petitions. The agency requested comments on these issues and on the following:

(1) Criteria that should be used in evaluating health claim petitions;

(2) The extent, manner, and timing that the agency should use to give public notice of petitions; and

(3) The appropriate procedure for establishing regulations on permissible health claims for dietary supplements.

The agency stated that the most efficient use of its resources would be to establish these procedures in final form before considering, or acting on, any such petitions that are submitted to the agency. The agency, therefore, advised that it would likely deny any petition submitted under the 1990 amendments until final procedural regulations are promulgated.

FDA received comments pertaining to petitions for health claims from the food industry, industry trade associations, and consumer organizations. FDA considered the comments, and many of the recommendations contained therein have been incorporated in, or otherwise used in, the development of this section of the proposed rule.

1. Comments

Some comments objected to the requirement for "publicly available evidence" and stated that unpublished research findings, including proprietary data, should be considered in support of proposed health claims. These comments further stated that firms will be able to justify undertaking research and development activities relating to diet/health relationships only if the regulatory framework allows them to recapture, through competitive marketing, some of the expense of research. They stated that, if regulations are adopted requiring that results be made public to substantiate a health

claim, then this substantiation could be used by other companies to make similar claims. The comments pointed out that the original petitioner would lose its competitive edge and thereby its motivation to perform research. Comments also suggested that the petition process should provide for the strictest confidence in the submission and maintenance of proprietary, unpublished studies.

The agency advises that section 403(r)(3)(B)(i) of the act mandates that "publicly available evidence" be used to support the scientific standard for health claims. Moreover, section 403(r)(A)(i) provides for not making a petition available to the public only if FDA decides to deny it without filing it. Consequently, FDA does not have authority to provide the relief the comments seek. The agency will make all information submitted in support of a health claim publicly available when the petition is filed and thus becomes available to the public.

An approved health claim is a description of a substance-disease relationship. It is not brand specific and, therefore, may appropriately be used by any firm whose food product meets the criteria for the claim.

Another comment stated that, in the past, in evaluating substance-disease relationships, the agency has placed too much reliance on findings published in a few peer-reviewed journals, and that the language in section 403(r)(3)(B) of the act; "totality of publicly available scientific evidence," should not be construed to limit evaluation to such reports. Other comments recommended that petitions should be accompanied by extensive literature reviews and include copies of all animal studies and human epidemiological or clinical trials relevant to the proposed health claim.

The agency advises that under proposed § 101.70(f) the petitioner is required to submit copies of all information, published or unpublished, relied upon for the support of the health claim, as well as information related to the claim that concerns adverse effects in individuals. Further, the petitioner must also submit copies of all information relevant to the claim that is pertinent to the U.S. population. The agency is, therefore, proposing to require that a broad array of information be submitted with the petition. Consequently, the agency's review of the proposed topic will not be limited to peer-reviewed publications, although, as suggested in the legislative history (Ref. 1), the agency may give greater weight to a research report published in a peer-reviewed journal because such reports have been subjected to scientific evaluation before publication. The agency intends to give greatest weight, however, to research reports of well-conducted, relevant studies regardless of publication status.

To ensure that submitted information is not biased, one comment recommended that the petition include an assurance statement, such as that required in petitions for the affirmation of the GRAS status of a substance (§ 170.35(c)(1)(v)), whereby the petitioner certifies that the petition contains all favorable and unfavorable scientific data of which he has knowledge. The agency agrees that this requirement is appropriate for a petition that must draw upon the totality of publicly available scientific evidence to support the proposed health claim, and this requirement has been included in the proposed procedural regulations in § 101.70(h).

Several comments addressed format issues for health claims petitions. One comment stated that the format for submission of citizen petitions (§ 10.30) is applicable to health claims petitions.

FDA recognizes the point made in these comments but tentatively concludes that, given the provisions of section 403(r) of the act, it is appropriate to specifically describe the information that should be submitted in support of a health claims petition in a regulation that is separate from § 10.30. The agency believes that a procedural regulation for a health claims petition is necessary so that petitioners will clearly understand what is required, that review will be conducted on an equitable basis, and that the grounds for agency action on the petition will be clearly understood.

A comment stated that the proposed regulations should provide that, for well-substantiated petitions setting forth substance-disease relationships that are widely accepted in the scientific community, the initial agency response time should be reduced from 100 to 60 days, and the agency's proposed regulation should be published within 30 rather than 90 days after the initial response.

The agency's ability to meet timeframes is influenced by many factors such as work priorities and availability of personnel. FDA considers the statutory timeframes for assessing the validity of health claims to be extremely short for evaluating the totality of available scientific evidence on a substance and a disease. It would not be practicable to shorten these timeframes further. The agency does agree that a petition for a claim on a well accepted diet/health relationship would probably be reviewed more expeditiously than one for which scientific agreement is equivocal or marginal.

Several comments recommended procedures for the evaluation of health claim petitions. One recommended the development of a multifactorial scoring system to be used to evaluate health impact based on the product's total nutrient content, the level of nationwide consumption, and the scientific validity of the health claim. This system would incorporate a cut-off limit to determine whether a petition is acceptable. Another suggested criterion was that the new health claim be recognized by reputable health organizations or research centers.

As discussed in section IV.C. of this document, the extremely short timeframes provided under the act for FDA to decide if a health claim is to be authorized make significant input from other health organizations impracticable before a proposed rule is to be issued. However, the agency does expect and encourages other health organizations, public, private, and governmental, to submit comments on all proposed actions on health claims.

With respect to the suggested scoring system, FDA does not believe that such a system would be practicable because of the necessity for the agency to exercise its scientific judgment to give more weight to those studies of greater significance. Such significance may vary greatly from one situation to another, depending upon the nature of the evidence in each study. A scoring system might, under such circumstances, not fairly evaluate the merits of the studies.

One comment pertained to section 403(r)(4)(C) of the act which provides that if a petition for a health claim regulation relies on a report from an authoritative scientific body of the United States, the agency must consider such report and must justify any decision rejecting the conclusions of such report. The comment advised that similar consideration should apply with respect to other reputable scientific data that are submitted in support of the petition.

The agency does not agree. Section 403(r)(4)(C) of the act imposes upon FDA an obligation to justify rejection of conclusions of a report from an authoritative scientific body of the United States. Congress obviously believed that FDA should have strong grounds for not agreeing with such reports because of the high credibility of U.S. Government bodies. However, there is no indication in the legislative history of the 1990 amendments of an intent for FDA to have a similar burden

for reports not generated by such Government bodies. For such situations, the agency is only required to state the reasons for the denial of the recommendation. However, FDA intends to fully and fairly evaluate any scientific reports that are submitted to the agency in support of a health claim. The agency intends to consider such reports as part of the totality of evidence on the substance-disease relationship.

Several comments recommended that the agency establish a distinct and separate procedure (and consequently distinct and separate requirements for petitions) for determining the propriety and validity of health claims for dietary supplements. These comments stated that Congress intended that dietary supplements be considered under a more lenient standard than conventional foods and recommended that health claims for dietary supplements be based on significant scientific evidence and not significant scientific agreement. The comments stated that different standards should be applied to foods and dietary supplements because of FDA's disparate treatment of dietary supplements in the past. Some of these comments recommended that health claims be classified in three categories depending on the abundance of the scientific evidence and strength of scientific support.

FDA recognizes that dietary supplements are not subject to section 403(r)(3) and (r)(4) of the act. However, as explained fully above, FDA has carefully considered the discussion of dietary supplements in both the Senate and House, its obligations under the act, and the question of what standard and procedure are most appropriate to use in assessing and ensuring the validity of health claims for dietary supplements. Based on this consideration, FDA is proposing to apply the same scientific standard to health claims for dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances as for conventional foods because the agency considers this standard to be the appropriate standard for ensuring the validity of all such claims. For the same reasons, as discussed above, FDA finds it appropriate under section 403(r)(5)(D) of the act and section 3(b)(1)(A)(x) of the 1990 amendments to make petitions to authorize claims on dietary supplements subject to the same requirements that apply to petitions for claims for conventional foods. FDA is proposing these requirements for dietary supplements because they will ensure that the agency has the information that it needs to assess the validity of claims for substances in these foods. Because FDA is proposing the same requirements for petitions on substances in dietary supplements as for substances in conventional foods, it is not distinguishing between dietary supplements and conventional foods in proposed § 101.70.

2. General Requirements and Provisions for Petitions

The agency is proposing to establish § 101.70 as the general procedural regulation for petitions for health claims. Section 101.70(a) through (d) address general issues and requirements such as the incorporation of various types of information into the petition and standard agency requirements pertaining to clinical and nonclinical studies submitted to the agency for review. Section 101.70(e) provides that all types of data and information in petitions for health claims are available for public disclosure after a petition is filed except for information that would identify a person or a third party, such as a physician or hospital, involved in a report. FDA is proposing no other exceptions to full disclosure because the statute does not provide for any exceptions, and because, as the agency explained above, it has tentatively concluded that the best way to assure the validity of a claim, either for a nutrient or for substance in a dietary supplement, is on the basis of publicly available scientific evidence. However, when FDA denies a petition before it is filed, the agency is proposing in § 101.70(j)(2) that no part of the petition will be made available to the public. This provision conforms to the requirements of section 403(r)(4)(A)(i) of the act and provides the same protection for petitions for substances in dietary supplements. FDA is also proposing to amend § 20.100, by adding § 20.100(c)(34), to reflect the provisions on the availability of records in proposed § 101.70.

Elsewhere in this issue of the **Federal Register**, FDA is publishing several documents that propose to find that certain substance and disease relationships are not valid. (In this document, FDA is proposing to establish § 101.17 in which the agency will list the topics for which it makes such a determination.) Those determinations are being processed through rulemaking proceedings because the 1990 amendments specifically directed the Secretary of Health and Human Services (and by delegation, FDA) to make the determinations (section 3(b)(1)(A)(vi) and (b)(1)(A)(x) of the 1990 amendments). With such specific direction, the agency believes that it is more appropriate to formalize its determinations through rulemaking rather than informally announcing its findings. However, while this course of action may be practicable for the 10 determinations mandated by the 1990 amendments, FDA does not believe it would be so for the many determinations that the agency may have to make in response to future petitions. Instead, FDA believes that its responses to petitions need to be made in the same manner as other petitions to change its food regulations. Specifically, the agency intends to advise firms of the specific reasons for denials without instituting a rulemaking proceeding.

FDA recognizes that in some circumstances there may be considerable interest in the agency's reasons for issuing denials, and that some firms may want to submit additional data that might result in a different FDA finding. Such firms may wish to consult the public listing of those health claims petitions that have been accepted for filing for issues of particular concern. Although denials of petitions not accepted for filing will not be released to the public, filed petitions will be fully available for public disclosure. Where the agency has denied a filed petition, interested parties may wish to review FDA reasons for denial before submitting an additional petition concerning a health claim.

Section 101.70(f) sets forth the proposed format for a health claim petition. It specifies the types of data and other requirements that the agency believes are necessary to provide for an efficient review and to demonstrate that the proposed substance-disease relationship complies with the requirements established under the 1990 amendments.

As proposed in format item A, the petition must include one or more model health claims that may be used on a food label or in labeling for a food to characterize the relationship of the substance in the food to a disease or health-related condition. This item is included among the petition requirements because FDA has tentatively concluded that it is valuable to include a model health claim in any authorizing regulation. Given the short timeframes under which FDA must review a petition, it would be difficult for the agency to prepare a model claim. Therefore, FDA is proposing to require that a model health claim be submitted as part of the petition.

In proposed format item B, the petitioner is to address how the substance conforms to the requirements in proposed § 101.14(b). These

requirements are discussed in section IV.B. of this document. One requirement is that the use of the substance, or the food ingredient of which the substance is a component, at the levels necessary to justify a claim be demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the act.

For petitions where the subject substance is a component of a food ingredient, the agency is proposing to require that the petitioner compile a comprehensive list of the specific ingredients that could be added to food to supply the substance in the food bearing the health claim. The agency is also proposing to require that, for each ingredient listed, the petitioner demonstrate that the use of the ingredient is safe and lawful under the applicable food safety provisions of the act. This showing can be made by a showing that the use of the ingredient is GRAS, listed as a food additive, or authorized by a prior sanction. Where the GRAS status is addressed in agency regulations (e.g., listed in Part 182 or affirmed in Part 184), the petition can cite the specific regulation. Where the GRAS status is not specifically addressed in agency regulations (e.g., where the GRAS status is based on common use in food prior to January 1, 1958 or based on conformance with the general principles stated in § 170.30(d)), or where there is a prior sanction, the petitioner must demonstrate, to the agency's satisfaction, that this requirement is met.

With respect to the requirement in proposed § 101.14(b)(1) that the U.S. population must be at risk for a disease or condition to permit a health claim, or that the petition submitted by the proponent of the claim otherwise explains the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet, proposed format item C requires that the necessary information be provided. It should be noted that the prevalence of the disease or health-related condition is of greater importance than the extent of the population's inadequate dietary intake of a substance. In particular, there may be data supporting that all or a significant part of the population has, or may have, an inadequate dietary intake of a substance. Such data are of value in justifying authorizing a health claim only in cases where the relationship of inadequate intake of a substance to the condition or disease has been satisfactorily established.

Information on the prevalence of a disease or condition is necessary because data from food intake surveys are commonly interpreted as showing that some segments of the population consume inadequate levels of nutrients. However, such surveys are generally poor predictors of nutritional status. There are several reasons for this apparent inconsistency. It is generally accepted, and controlled studies show (Ref. 19), that consumers who participate in a survey tend to underreport information on food consumption. Further, use of RDAs as criteria for assessing adequate or inadequate nutritional status fails to account for the large safety factor built into the RDAs for adequate nutrient intake by individuals in a population (Ref. 20). In addition, survey data show that a large segment of the population regularly consumes vitamin, mineral, and other dietary supplements that are not adequately recorded in surveys or studies of food consumption (Ref. 21).

For these reasons, the agency has had a longstanding policy that the only reliable means of determining the nutritional adequacy of diets of the population is through the use of clinical and biochemical measures to assess nutritional status. Data from the National Health and Nutrition Examination Survey have frequently been used and generally indicate that the level of nutrient deficiencies is very low or nonexistent for most nutrients. Iron is an exception based on observations of how iron stores in women of childbearing ages and among young children during rapid growth.

Proposed format item C also specifies the requirements to be addressed in the summary of scientific data in support of the claim. This summary must establish that the proposed claim meets the scientific standard provided for in proposed § 101.14(c).

If the claim is intended for a specific group within the population, the petitioner's analysis shall specifically address the dietary practices of such group and shall include data sufficient to demonstrate that the dietary analysis is representative of such group (e .g., adolescents or the elderly).

Proposed format item D requires the submission of analytical data showing the amount of a substance present in representative foods that would be candidates to bear the claim and specifies that the data be obtained using the Association of Official Analytical Chemists (AOAC) methods, where available, or other valid methodology along with submission of the methodology and its validation. Data on the amount of the substance in various foods will enable the agency to evaluate the usefulness of the claim in the context of the total diet.

Proposed format item E specifies the attachments to be submitted with the petition. These attachments include the scientific reports, studies, and other data and literature searches used to support the petition.

Proposed format item F requires that the petitioner include either a claim for a categorical exclusion under § 25.24 or an environmental assessment under § 25.31.

Proposed § 101.70(g) sets forth how the submitted data in the petition are to be organized and identified and permits the petitioner to incorporate by reference any data from an earlier petition.

Proposed § 101.70(h) requires that the petition include a statement signed by the person responsible for the petition that, to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him/her to be pertinent to the evaluation of the proposed health claim.

Proposed § 101.70(i) requires that the petition be signed by the petitioner or by his/her attorney or agent, or (if a corporation) by an authorized official.

The proposed procedures for agency action on the petition in § 101.70(j) (1), (j) (2), and (j) (3) reflect the requirements of section 403(r) (4) (A) (i) of the act. For fairness, FDA is proposing to apply the same procedures in its review of petitions involving substances in dietary supplements. Further, the agency is proposing therein to notify the petitioner of receipt of the petition within 15 days of receipt.

Finally, with respect to petitions, the agency has proposed elsewhere in this issue of the **Federal Register** to amend 21 CFR 5.61 to redelegate from the Commissioner of Foods and Drugs to the Director and Deputy Director of the Center for Food Safety and Applied Nutrition, all the functions of the Secretary concerning petitions for label claims under section 403(r) of the act for both nutrient content and health claims that do not involve controversial issues. For petitions for health claims, such functions consist of the issuance of notices of proposed rulemaking and final rules concerning authorized health claims and the issuance of letters concerning the filing or denial of a petition. These proposed redelegations will facilitate timely agency action on these petitions given the short timeframes for agency action imposed

by the 1990 amendments. The proposed redelegations are similar to those proposed elsewhere in this issue of the **Federal Register** in the proposal concerning nutrient content claims which, like health claims, were designated by section 403(r) of the act to be used on food labels and in labeling only in conformity with regulations promulgated by the agency.

V. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24 that this proposed rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required. The proposed requirements pertaining to health claims on food labeling qualify for a categorical exclusion under 21 CFR 25.24(a) (11) and the proposed requirements pertaining to petitions requesting approval for the use of health claims for specific substances in food qualify for exclusion under 21 CFR 25.21(a) (8).

VII. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

VIII. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 pm., Monday through Friday.

The agency has determined that 90 days is the maximum time that it can provide for the submission of comments and still meet the statutory timeframe for the issuance of final regulations on health claims. Thus, the agency is advising that it will not consider any requests under 21 CFR 10.40(b) for extension of the comment period beyond February 25, 1992. The agency must limit the comment period to no more than 90 days to assure sufficient time to develop a final rule based on this proposal and the comments it receives.

IX. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the provisions of § 100.70 *Petitions for health claims* relating to submission of petitions to FDA will be submitted for approval to the Office of Management and Budget (OMB). These provisions will not be effective until FDA obtains OMB approval. FDA will give notice of OMB approval of these requirements in the **Federal Register** as part of any final rule that is based on this proposal.

X. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. House of Representatives, House Report 101–538, "Nutrition Labeling and Education Act of 1990," June 13, 1990.
2. Congressional Record-Senate, S16607–16612, October 24, 1990.
3. Congressional Record-House, H12951–12955, October 26, 1990.
4. Congressional Record-House, H5836–5845, July 30, 1990.
5. U.S. Department of Health and Human Services, Public Health Service, "The Surgeon General's Report on Nutrition and Health," DHHS (PHS) Publication No. 88–50210 (GPO Stock No. 017–001–00465–1, U.S. Government Printing Office, Washington, DC), 1988.
6. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.
7. U.S. Department of Agriculture and U.S. Department of Health and Human Services, "Nutrition and Your Health: Dietary Guidelines for Americans," 3d ed., Home and Garden Bulletin No. 232, U.S. Government Printing Office, Washington, DC, 1990.
8. Dresser, C. M., National Center for Health Statistics, Interagency memorandum to Marilyn Stephenson, Food and Drug Administration, December 3, 1981.
9. U.S. Department of Agriculture, Human Nutrition Information Service, "Nationwide Food Consumption Survey—1986," NFCS, Continuing Survey of Food Intakes by Individuals, Report No. 86–3, Hyattsville, MD, September 1988, p. 168.
10. Buzzard, I. M., Letter to Virginia Wilkening, Food and Drug Administration, February 12, 1991.
11. Clinical Nutrition Branch, Memo to File: Data Analysis HM1, Percent Daily Reference Value Per Serving, October 16, 1991.
12. Clinical Nutrition Branch, Memo to File: Data Analysis HM2, Presence of Nutrients in Food Categories, October 16, 1991.
13. Clinical Nutrition Branch, Memo to File: Data Analysis HM3, Assessment of Disqualifying Levels of 10, 15, and 20 Percent of the DRV Per Serving, October 16, 1991.
14. Clinical Nutrition Branch, Memo to File: Data Analysis HM4, Assessment of Need for Disqualifying Levels Based on 100 Grams, October 16, 1991.
15. Senate Report No. 493, 73rd Cong., 2nd sess., March 15, 1934. Cited in: Food and Drug Administration, "A Legislative History of the Federal Food, Drug, and Cosmetic Act," vol. 2, pp. 721–3, Food and Drug Administration, Rockville, MD, 1979.
16. Fosmire, G. J., "Zinc Toxicity," The American Journal of Clinical Nutrition, 51:225–227, 1990.
17. Fischer, P. W. F., A. Giroux, and M. R. L'Abbe, "Effect of Zinc Supplementation on Copper Status in Adult Man," The American Journal of Clinical Nutrition, 40:743–746, 1984.
18. Food and Drug Administration, "Compliance Program Guidance Manual," Chapter 21, Program No. 7321.002 (1988–1991), Food and Drug Administration, 1990.
19. Schoeller, D. E., "How Accurate is Self-Reported Dietary Energy Intake?", Nutrition Reviews, 48:373–379, 1990.
20. Food and Nutrition Board, National Research Council, "Recommended Dietary Allowances, 10th ed., chapter 1, National Academy Press, Washington, DC, 1989.
21. Yetley, E. A. and Y. K. Park, "Obtaining Data on Intake of Supplements," in Nutritional Status of the Individual, G. E. Livingston, Ed., pp. 113–123, 1989, Food and Nutrition Press, Inc., Trumbull, CT.
22. Burke Marketing Research, "Analysis: Restaurant Users Focus Group Session," Study BMR# 39–545 conducted for the American Heart Association, Dallas, TX, March 1989.
23. Burke Marketing Research, "Logo/Name Study for American Heart Association," Study BMR# 39–651 conducted for the American Heart Association, Dallas, TX, June 1989.

List of Subjects

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 20 and 101 be amended as follows:

Part 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: Section 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 301, 302, 303, 307, 310, 311, 351, 352, 354–360F, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1); 5 U.S.C. 552; 18 U.S.C. 1905.

2. Section 20.100 is amended by adding a new paragraph (c)(34) to read as follows:

§ 20.100 Applicability; cross reference to other regulations.

* * * * *

(c) * * *

(34) Health claims petitions, in § 101.70 of this chapter.

Part 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

4. Section 101.9 is amended by adding paragraph (k) (1) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(k) * * *

(1) That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom. Information about the relationship of a dietary property to a disease or health-related condition may only be provided in conformance with the requirements of § 101.14 and subpart E of part 101.

* * * * *

5. New § 101.14 is added to read as follows:

§ 101.14 Health claims: general requirements.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Health claim* means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" endorsements, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, that characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include only those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or would be likely to be understood, to assert or direct beneficial relationship between the presence or level of any substance in the food and a health or disease-related condition.

(2) *Substance* means a component of a conventional food or of a dietary supplement of vitamins, minerals, herbs, or other nutritional substances.

(3) *Nutritive value* means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.

(4) *Dietary supplement* means a food, other than a conventional food, that supplies a component with nutritive value to supplement the diet by increasing the total dietary intake of that substance. A dietary supplement includes a food for special dietary use within the meaning of § 101.9(a) (2) that is in conventional food form.

(5) *Disqualifying nutrient levels* means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 11.5 grams (g) of fat, 4.0 g of saturated fat, 45 milligrams (mg) of cholesterol, or 360 mg of sodium, per reference amount commonly consumed, per label serving size, and per 100 g. Any one of the levels, on a per reference amount commonly consumed, a per label serving size, or a per 100 g basis, will disqualify a food from making a health claim.

(b) For a substance to be eligible for a health claim:

(1) The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk, or, alternatively, the petition submitted by the proponent of the claim otherwise explains the prevalence of the disease or health related-condition in the U.S. population and the relevance of the claim in the context of the total daily diet and satisfies the other requirements of this section.

(2) If the substance is to be consumed as a component of a conventional food at decreased dietary levels, the substance must be a nutrient listed in 21 U.S.C. 343(q) (1) (C) or (D), or one that FDA has required to be included in the label or labeling under 21 U.S.C. 343 (q) (2) (A); and

(3) If the substance is to be consumed at other than decreased dietary levels:

(i) The substance must be consumed as a component of a conventional food or of a dietary supplement and contribute taste, aroma, or nutritive value, or any other technical effect listed in § 170.3(o) to the food and must retain that attribute when consumed at levels that are necessary to justify a claim; and

(ii) The substance must be a food ingredient or a component of a food ingredient whose use at the levels necessary to justify a claim has been demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the act.

(c) *Validity requirements.* FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(1) It must be supported by the totality of publicly available scientific evidence (including evidence from welldesigned studies conducted in a manner which is consistent with generally recognized scientific procedures and principles); and

(2) There must be significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims that this support exists.

(d) *General health claim labeling requirements.* (1) When FDA determines that a health claim meets the validity requirements of paragraph (c) of this section, FDA will propose a regulation in subpart E of this part to authorize the use of that claim. If the claim pertains to a substance not provided for in §§ 101.9 or 101.36, FDA will propose amending these regulations to include declaration of the substance.

(2) When a regulation has been established in subpart E of this part providing for a health claim, firms may make claims based on the regulation in subpart E of this part, provided that:

(i) All label or labeling statements about the substance-disease relationship that is the subject of the claim are based on, and consistent with, the conclusions set forth in the summary of scientific information and model health claims provided in regulations in subpart E of this part;

(ii) The claim is limited to describing the value that ingestion (or reduced ingestion) of the substance, as part of a total dietary pattern, may have on a

particular disease or health-related condition;

(iii) The claim is complete, truthful, and not misleading. Where factors other than dietary intake of the substance affect the health benefit, such factors may be required to be addressed in the claim by a specific regulation in subpart E of this part;

(iv) All information required to be included in the claim appears in one place, in the same type size, without other intervening material: Except that the label may bear the statement, "See ___ for information about the relationship between ___ and ___," with the blanks filled in with references to the location of the labeling containing the health claim, the name of the substance, and the disease or healthrelated condition (e.g., "See attached pamphlet for information about calcium and osteoporosis"), with the entire claim appearing on the other labeling;

(v) The claim enables the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet; and

(vi) If the claim is about the effects of consuming the substance at decreased dietary levels, the level of the substance in the food is sufficiently low to justify the claim. To meet this requirement, if a definition for use of the term "low" has been established for that substance under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in Subpart E of this part. If no definition for "low" has been established, the level of the substance must meet the level established in the regulation authorizing the claim; or

(vii) If the claim is about the effects of consuming the substance at other than decreased dietary levels, the level of the substance in the food is sufficiently high and in an appropriate form to justify the claim. To meet this requirement, if a definition for use of the term "high" for that substance has been established under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "high" has been established, the level of the substance must meet the level established in the regulation authorizing the claim.

(3) Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with §§ 101.9 and 101.36.

(e) *Prohibited health claims.* No expressed or implied health claim may be made on the label or in labeling for a food unless:

(1) The claim is specifically provided for in subpart E of this part; and

(2) The claim conforms to all general provisions of this section as well as to all specific provisions in the appropriate section of Subpart E of this part;

(3) None of the disqualifying levels identified in paragraph (a)(5) of this section is exceeded in the food, unless specific alternative levels have been established for the substance in subpart E of this part; or unless FDA has permitted a claim despite the fact that a disqualifying level of a nutrient is present in the food based on a finding that such a claim will assist consumers in maintaining healthy dietary practices, and, in accordance with the regulation in subpart E that makes such a finding, the label bears a referral statement that complies with § 101.13(h) highlighting the nutrient that exceeds the disqualifying level;

(4) No substance, other than one for which a "disqualifying nutrient level" is established, is present at an inappropriate level as determined in specific provisions of subpart E of this part; and

(5) The label does not represent or purport that the food is for infants and toddlers less than 2 years of age.

(f) The requirements of this section do not apply to:

(1) Infant formulas subject to section 412(h) of the Federal Food, Drug, and Cosmetic Act, and

(2) Medical foods defined by section 5(b) of the Orphan Drug Act.

(g) *Applicability.* The requirements of this section apply to foods intended for human consumption that are offered for sale.

6. Subpart E, consisting of §§ 101.70 and 101.71, is added to read as follows:

Subpart E—Specific Requirements for Health Claims

Sec.
101.70 Petitions for health claims.
101.71 Health claims: Claims not authorized.

Subpart E—Specific Requirements for Health Claims

§ 101.70 Petitions for health claims.

(a) Any interested person may petition the Food and Drug Administration (FDA) to issue a regulation regarding a health claim. The petition shall be submitted in quadruplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which any correspondence required by section 403 of the Federal Food, Drug, and Cosmetic Act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of FDA. Any reference to published information shall be accompanied by reprints, or easily readable copies of such information.

(c) If nonclinical laboratory studies are included in a petition, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) If clinical or other human investigations are included in a petition, the petition shall include a statement that they were either conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or were not subject to such requirements in accordance with § 56.104 or § 56.105, and a statement that they were conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(e) All data and information in a health claim petition are available for public disclosure after the notice of filing of petition is issued to the petitioner, except that clinical investigation reports, adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall only be available after deletion of:

(1) Names and any information that would identify the person using the product.

(2) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(f) Petitions for a health claim shall include the following data and be submitted in the following form:

(Date)
Name of petitioner ———
Post office address ———
Subject of the petition ———
Food and Drug Administration, Regulatory Affairs Staff (HFF-204), Office of Nutrition and Food Sciences, 200 C St. SW., Washington, DC 20204.

The undersigned, _____ submits this petition pursuant to section 403(r) (4) or 403(r) (s) (D) of the Federal Food, Drug, and Cosmetic Act with respect to (statement of the substance and its health claim).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. Model health claim. One or more model health claims that represent label statements that may be used on a food label or in labeling for a food to characterize the relationship between the substance in a food to a disease or health-related condition that is justified by the summary of scientific data provided in section C of the petition. The model health claim shall include:

1. A brief capsulized statement of the relevant conclusions of the summary, and

2. A statement of how this substance helps the consumer to attain a total dietary pattern or goal associated with the health benefit that is provided.

B. Preliminary requirements. A complete explanation of how the substance conforms to the requirements of § 101.14 (b). For petitions where the subject substance is a food ingredient or a component of a food ingredient, the petitioner should compile a comprehensive list of the specific ingredients that will be added to the food to supply the substance in the food bearing the health claim. For each such ingredient listed, the petitioner should state how the ingredient complies with the requirements of § 101.14(b) (3) (ii), e.g., that its use is GRAS, listed as a food additive, or authorized by a prior sanction issued by the agency, and what the basis is for the GRAS claim, the food additive status, or prior sanctioned status.

C. Summary of scientific data. The summary of scientific data provides the basis upon which authorizing a health claim can be justified as providing the health benefit. The summary must establish that, based on the totality of publicly available scientific evidence (including evidence from well designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The summary shall state what public health benefit will derive from use of the claim as proposed. If the claim is intended for a specific group within the population, the summary shall specifically address nutritional needs of such group and shall include scientific data showing how the claim is likely to assist in meeting such needs.

The summary shall concentrate on the findings of appropriate review articles, National Institutes of Health consensus development conferences, and other appropriate resource materials. Issues addressed in the summary shall include answers to such questions as:

1. Is there an optimum level of the particular substance to be consumed beyond which no benefit would be expected?

2. Is there any level at which an adverse effect from the substance or from foods containing the substance occurs for any segment of the population?

3. Are there certain populations that must receive special consideration?

4. What other nutritional or health factors (both positive and negative) are important to consider when consuming the substance?

In addition, the summary of scientific data shall include a detailed analysis of the potential effect of the use of the proposed claim on food consumption, specifically any change due to significant alterations in eating habits and corresponding changes in nutrient intake resulting from such changes in food consumption. The latter item shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet.

If the claim is intended for a significant subpopulation within the general U.S. population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group (e.g., adolescents or the elderly).

If appropriate, the petition shall explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet.

Also, the summary shall demonstrate that the substance that is the subject of the proposed claim conforms to the definition of the term "substance" in paragraph (a) (2) of § 101.14.

D. Analytical data that show the amount of the substance that is present in representative foods that would be candidates to bear the claim should be obtained from representative samples using methods from the Association of Official Analytical Chemists (AOAC), where available. If no AOAC method is available, the petitioner shall submit the assay method used and data establishing the validity of the method for assaying the substance in food. The validation data should include a statistical analysis of the analytical and product variability.

E. The petition shall include the following attachments:

1. Copies of any computer literature searches done by the petitioner (e.g., Medline).

2. Copies of articles cited in the literature searches and other information as follows:

a. All information relied upon for the support of the health claim, including copies of publications or other information cited in review articles and used to perform meta-analyses.

b. All information concerning adverse consequences to any segment of the population (e.g., sensitivity to the substance).

c. All information pertaining to the U.S. population.

F. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

Yours very truly,

Petitioner

_____

By _____

(Indicate authority)

(g) The data specified under the several lettered headings should be submitted on separate pages or sets of pages, suitably identified. If such data have already been submitted with an earlier application from the petitioner or any other final petition, the present petition may incorporate it by specific reference to the earlier petition.

(h) The petition shall include a statement signed by the person responsible for the petition that, to the best of his/her knowledge, it is a representative and balanced submission that includes unfavorable information as well as favorable information, known to him/her to be pertinent to the evaluation of the proposed health claim.

(i) The petition shall be signed by the petitioner or by his/her attorney or agent, or (if a corporation) by an authorized official.

(j) *Agency action on the petition.* (1) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner that the petition is undergoing agency review and that the petitioner will subsequently be notified of the agency's decision to file for comprehensive review or deny the petition.

(2) Within 100 days of the date of receipt of the petition, FDA will notify the petitioner by letter that the petition has either been filed for comprehensive review or denied. The agency will deny a petition without reviewing the information contained in C. *Summary of Scientific Data* if the information in B. *Preliminary Requirements* is inadequate in explaining how the substance conforms to the requirements of § 101.14(b). If the petition is denied, the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. A petition that has been denied will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (e) of this section.

(3) Within 90 days of the date of filing, FDA will by letter of notification to the petitioner:

(i) Deny the petition, or

(ii) Inform the petitioner that a proposed regulation to provide for the request use of the health claim will be published in the **Federal Register**. If the petition is denied, the notification will state the reasons therefor, including justification for the rejection of any report from an authoritative Scientific body of the U.S. Government. FDA will

publish the proposal to amend the regulations to provide for the requested use of the health claim in the **Federal Register** within 90 days of the date of filing. The proposal will also announce the availability of the petition for public review.

§ 101.71 Health claims: claims not authorized.

In response to the Nutrition Labeling and Education Act of 1990, FDA has reviewed the evidence on the following topics that Congress specifically asked FDA to evaluate and has concluded that there is no basis for claims about the following:

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27151 Filed 11-26-91; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 101

[Docket No. 91N-0098]

RIN 0905-AD08

Food Labeling: Health Claims; Dietary Fiber and Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that after reviewing the available evidence, it tentatively finds that a basis does not exist on which to authorize the use on foods, including dietary supplements, of health claims relating to an association between ingestion of dietary fiber and reduction in risk of cancer. While data support an association between consumption of fiber-rich plant foods and reduced risk of cancer, FDA tentatively finds that it cannot attribute this effect to the fiber itself. Therefore, FDA specifically requests comments on this topic. FDA has reviewed the relationship between this dietary component and this disease under the provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the 1990 amendments.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0316.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535), which amend the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorize the Secretary of Health and Human Services (and FDA by delegation) to issue regulations authorizing claims on the label or labeling of foods characterizing the relationship between a food component and a disease or health-related condition. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under the act (21 U.S.C. 343(r)(1)(B)).

Published elsewhere in this issue of the **Federal Register** is a proposed rule "Food Labeling: General Requirements for Health Claims for Food" to establish general requirements for health claims on food labels and labeling that characterize the relationship of nutrients, including vitamins or minerals, herbs, or other nutritional substances (referred to generally as "substances") in food to a disease or health-related condition. In this companion document, FDA has tentatively concluded that such claims would only be justified for substances in conventional foods as well as in dietary supplements if the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) supports a claim, and if there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, about such support.

The 1990 amendments also require (section 3(b)(1)(A)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x)) that within 12 months of their enactment, the Secretary shall issue proposed regulations to implement section 403(r) of the act, and that such regulations shall determine, among other things, whether claims respecting 10 topic areas, including dietary fiber and cancer, meet the requirements of the act. In this document, the agency will consider whether a claim on the label or labeling of food or food products on the relationship between dietary fiber and cancer would be justified under the standard proposed in the companion document.

B. Basis for Considering a Claim Relating Dietary Fiber and Cancer

1. Cancer

Cancer accounts for about one of every five deaths and is the second leading cause of death in the United States (DHHS/PHS, 1990). Deaths from cancer numbered more than 475,000 in 1987. The overall economic cost of cancer, including direct health care costs and losses due to morbidity and mortality, was estimated to be $72.5 billion. In addition, the social impact of cancer can be measured in part by potential years of life lost by death before age 65. Potential years of life lost were 18 million for cancer compared to 15 million for heart disease (Ref. 46).

The risk of occurrence of cancer differs markedly for various sites. In 1990, lung cancer accounted for 35 percent of all cancer deaths in men. Colorectal cancer and prostate cancer each accounted for 11 percent of cancer deaths in men. The leading causes of cancer deaths among women were lung cancer (21 percent of cancer deaths), breast cancer (18 percent), and colorectal cancer (13 percent) (Ref. 46).

2. Dietary Fiber

Dietary fiber is comprised of components of plant materials that are resistent to human digestive enzymes (Refs. 12 and 24). These components are predominantly nonstarch polysaccharides and lignin and may include, in addition, associated substances (Ref. 12). To date, the best documented and most widely accepted nutritional role for dietary fibers is for normal bowel function and health (Ref. 24). It is estimated that current dietary fiber intakes of 10 to 15 grams (g) per day (6 to 7 g per 1000 kilocalories) in the United States are less than optimal for meeting needs for normal bowel function and health (Refs. 22 and 24). Significant increases in this level of intake have been recommended frequently (Ref. 24).

Based on currently available analytical methods, dietary fiber is measured both as total dietary fiber and as the subcomponents of soluble and

insoluble fibers (Ref. 24). Until recently, epidemiologic and other human studies were not able to evaluate total dietary fiber intake because the majority of food composition tables contained no values for total dietary fiber content of foods. In addition, no standardized definitions of dietary fiber or dietary fiber components have been agreed upon.

Naturally occurring fibers in food are usually a mixture of insoluble fibers such as cellulose and lignin, soluble fibers such as pectins, gums, and mucilages, and combinations of soluble and insoluble fibers such as hemicelluloses (Ref. 25). The proportions and types of fiber subcomponents vary among foods (e.g., oatmeal contains relatively large amounts of soluble fiber, while whole wheat bread contains relatively large amounts of insoluble fiber). Fiber content also varies within a food item or food group depending on maturity of the plant, storage and ripening conditions, and food processing techniques used, if any.

In evaluating the biological effects and health consequences of total dietary fiber, dietary fiber intake has been expressed as:

(a) As total dietary fiber or as the major fiber subcomponents (soluble and insoluble fibers);

(b) Fiber-containing foods (e.g., whole grains, legumes, fruits, vegetables);

(c) Fiber-rich food isolates (e.g., wheat bran, oat bran, corn bran, soy isolates); or

(d) Isolated and purified fibers (e.g., cellulose, pectins, lignin).

3. Basis for Evaluating a Relationship Between Dietary Fiber and Risk of Cancer

Interest in a possible role of dietary fiber in reducing the risk of cancer was stimulated by Burkitt and Trowell's suggestion that the rarity of cancer of the large intestine in Africa may be the result of a protective effect of dietary fiber (Ref. 5). These authors also suggested that fiber may be protective against other diseases that are common in the west, such as coronary heart disease and colorectal cancer. Subsequently, considerable research has been conducted on the role of dietary fiber and its relationship to risk of cancer at various sites.

Populations consuming diets rich in fiber-containing foods (vegetables, fruits, and grains) have significantly lower rates of cancer of the colon, breast, lung, oral cavity, larynx, esophagus, stomach, bladder, uterine cervix, and pancreas than populations consuming diets low in fiber-containing foods (Refs. 46 and 47). Available evidence also shows that populations consuming diets high in fiber also tend to consume diets that are low in fat and total energy (calories), high in vitamins and minerals (including vitamin A precursors and vitamin C), high in plant foods, and low in animal foods. Thus, it has not usually been possible to separate the effects of dietary fiber from those of other dietary components or a combination of dietary components.

Estimations of the impact of dietary fiber and other dietary components on total cancer incidence have been based on evidence regarding established relationships between dietary factors and cancer risk, the dramatic shifts in site-specific cancer rates among migrants to the United States, secular trends in cancer for which a dietary etiology is likely, and supportive evidence from animal experiments (Ref. 30).

The strongest support for a possible protective effect of fiber-rich diets is for cancers of the colon and rectum (colorectal cancers), the second leading cause of all cancer deaths in the United States (Ref. 46). Most of the epidemiologic associations between dietary fiber and risk of cancer relate to cancer of the colon. Virtually all laboratory animal studies on the topic of dietary fiber and cancer have focused on colon carcinogenesis.

The specific health claim topic described in the 1990 amendments was "dietary fiber and cancer." FDA, however, limited its review of the scientific evidence to cancers of the colon and rectum. This limitation was deemed appropriate because, as noted above, the great majority of epidemiologic and intervention studies have focused on colon cancer, as have virtually all animal studies in this area.

FDA recognizes that some fibers have been reported to modify the biological actions of hormones and thus reduce the risk of hormone-related cancers such as breast cancer (Ref. 22). Lanza et al. (Ref. 22) reviewed studies relating diets rich in fruits, vegetables, or grains and decreased risk of breast cancer, and also discussed mechanisms by which dietary fiber may modify risk of cancer at this site. FDA also recognizes that dietary fiber has also been studied with respect to its possible involvement in risk of stomach, ovarian, and endometrial cancers. Because the number of studies of the association between dietary fiber and cancers at these other sites is limited, review of such studies is not included in this document. The relationship of dietary fiber to cardiovascular disease is addressed in a companion document published elsewhere in this issue of the **Federal Register.** The relationships of antioxidant vitamins and cancer and fat and cancer are addressed in two other companion documents also published elsewhere in this **Federal Register.**

C. Regulatory and Legislative History

1. Early Claims for Dietary Fiber

Claims for health benefits to be derived from consuming fiber-containing foods have been made for over 100 years. Early interest focused on the benefits of wheat bran as a promoter of regular bowel function. Claims for wheat bran on breakfast cereal packages were popular in the early 1900's, and the importance of adding "bulk" to the diet by the addition of dietary fiber was emphasized in advertisements promoting the benefits of certain fibers as aids to digestion and in relieving constipation. Such claims on packages were largely unregulated until after the passage of the act in 1938. Under the act, such claims evidence an intent that the products are to be used as drugs, and therefore, subjected the products to the requirements of drug law. As a result, the use of health-related claims on cereal products virtually stopped until recently.

On November 22, 1941, the agency published regulations that included labeling requirements for "nondigestible carbohydrates" (6 FR 5921). At that time, foods having a high fiber content were valued because decreases in caloric density were achieved when such products were added to foods such as bread. Based on the analytical procedures available at that time, the fibrous plant components of food had to be labeled as "crude fiber," which is compositionally and quantitatively different from dietary fiber.

During the late 1970 s, FDA sought to revise its regulations to include as fiber other fractions of carbohydrates, in addition to crude fiber, that are not digested by human enzymes. In doing so, the agency noted that the scientific evidence linking fiber to health outcomes was limited. In the **Federal Register** of December 21, 1979 (44 FR 75990), the agency stated that "some advocates of higher fiber diets have theorized that the incidence of bowel cancer and other intestinal diseases may be related to the decreased amount of fiber in western diets * * * and that the relationship of dietary fiber to health remains controversial" Currently § 105.66 (21 CFR 105.66) provides for the declaration of nonnutritive substances, but there is no regulation for declaration of fiber.

2. Food Additive Status

Substances that are added to food may be categorized based on their use as generally recognized as safe (GRAS) ingredients, food additives, or substances subject to a sanction or approval granted by the FDA or the United States Department of Agriculture prior to September 6, 1958. The use of substances may be GRAS under the general principles set forth in § 170.30 (21 CFR 170.30), listed as GRAS in part 182 (21 CFR part 182), or affirmed as GRAS in part 184 (21 CFR part 184). FDA's listings of food additives and affirmations that the use of a substance for direct addition to food is GRAS generally include the particular food categories in which (as defined in § 170.3(n)), and specific technical effects for which (as defined in § 170.3(o)), the substance may be used.

"Fiber" is not considered to be either a food category or a technical effect according to the above definitions, and ingredients that are added to food are therefore not regulated as "fiber." However, FDA has regulated a number of isolated or purified fibers for specific technical effects in various food categories. For example, xanthin gum is listed as a food additive for use as a stabilizer, emulsifier, thickener, suspending agent, bodying agent, or foam enhancer (§ 172.695 (21 CFR 172.695)); methylcellulose is listed as a multiple purpose GRAS substance (21 CFR 182.1480); and pectins are affirmed as GRAS for use as an emulsifier, stabilizer, or thickener (§ 184.1588). Guar gum is affirmed as GRAS for specific conditions of use that include those as an emulsifier, formulation aid, firming agent, and thickener (§ 184.1339). Guar gum has not been listed for use as a source of fiber, and under some circumstances, it has been shown to cause esophageal blockage and thus, to be a health hazard. These and many other isolated or purified gums and fibers have no established history of food use or safety as fiber supplements.

3. Dietary Fiber and Cancer as Subjects of Health Claims

Prompted by the use, beginning in 1984, of information on high-wheat bran cereal packages stating that high fiber diets may reduce the risk of cancer, and by issuance of interim dietary fiber recommendations by the National Cancer Institute, FDA proposed in 1987 to amend the food labeling regulations to allow the use of health messages (hereafter, the term "health claim" is used for consistency with section 403(r) of the act) on labels and food labeling (52 FR 28843, August 4, 1987). The agency stated that food labeling could have an important influence on the public s food choices, and that truthful, nonmisleading health claims could increase the consumer's understanding of health benefits that can result from adhering to a sound and nutritious diet. This proposal set forth criteria for the evaluation of health claims.

In the **Federal Register** of February 13, 1990 (55 FR 5176), FDA published a reproposed rule on health claims that withdrew the 1987 proposal and proposed to establish procedures for permitting valid and reliable consumer information on food labels. The agency noted that the 1987 proposal was too ambiguous to be workable in preventing misleading claims. FDA thus proposed to issue tighter requirements for health claims. The agency also proposed to evaluate the scientific evidence on six possible topics for claims, including dietary fiber and cancer.

On November 8, 1990, the President signed the 1990 amendments, that authorize FDA to issue regulations concerning claims on the label or labeling of foods that characterize the relationship between a substance and a disease or a health-related condition. As stated above, this law identified 10 substance-disease topics, including dietary fiber and cancer, that FDA is to consider to determine whether they are appropriate subjects of health claims.

D. Evidence Considered in Reaching the Decision

As noted above, the strongest support for a possible protective effect of fiber-rich diets is for colorectal cancers, major causes of cancer deaths in men and women in the United States. For this reason, FDA limited its review of the scientific evidence to the topic of dietary fiber and cancers of the colon and rectum (colorectal cancers). Most of the epidemiologic associations between dietary fiber and risk of cancer relates to cancer of the colon and virtually all laboratory animal studies in this topic area have focused on colon carcinogenesis.

The agency has reviewed the relevant scientific evidence on dietary fiber and colorectal cancers. The scientific evidence included descriptions of evidence reviewed and conclusions reached in Federal Government documents including "The Surgeon General's Report Nutrition and Health" (Ref. 47), the Department of Agriculture and the Department of Health and Human Services "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 45), and the Department of Health and Human Services' "Healthy People 2000, National Health Promotion and Disease Prevention Objectives" (Ref. 46). The agency also reviewed the evidence and conclusions in other reviews by recognized scientific bodies including the Life Sciences Research Office (LSRO) report on "Physiological Effects and Health Consequences of Dietary Fiber" (Ref. 24), the National Academy of Sciences (NAS) "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 30), the National Research Council's (NRC) "Recommended Dietary Allowances" (Ref. 31), and the World Health Organization's "Diet, Nutrition, and the Prevention of Chronic Diseases" (Ref. 51).

The agency updated these reports by independently reviewing all human studies and all review articles published since the Federal Government documents and other documents mentioned above had completed their reviews of the literature on the relationship of dietary fiber and colorectal cancer. FDA considered animal studies to the extent that they clarified human studies or suggested possible mechanisms of action.

FDA also contracted with LSRO to independently evaluate current evidence since the fiber report LSRO issued in 1987 (Ref. 25). Finally, to ensure that its review of relevant evidence was complete, FDA requested in the **Federal Register** of March 28, 1991 (56 FR 12932), scientific data and information on the 10 specific topic areas including dietary fiber and cancer identified in section 3(b)(1)(A) of the 1990 amendments. The agency reviewed and considered comments submitted in response to the **Federal Register** notice in developing this document.

E. Summary of Comments Received in Response to FDA Request for Scientific Data and Information

Responses to the March 28, 1991 **Federal Register** notice were received from 3 professional organizations, 10 industry and trade associations, the Canadian Government, 1 consumer association, and an individual consumer.

One of the professional organizations urged caution in determining the use of health claims on foods, and another called attention to the need for FDA to use independent judgment with regard to the use of health claims on dietary supplements. A third professional organization pointed out that the protective effect of fiber against cancer cannot be ascribed to dietary fiber alone. The comment stated that the interaction of fiber with other nutrients

in the diet must also be considered. The comment also expressed concern that food label claims would be misunderstood by the public.

Among 10 comments received from dietary supplement or food manufacturers and related trade associations, 7 submitted comments and evidence, including some unpublished studies, that supported their position that health claims on fiber and cancer should be allowed on foods. One acknowledged that although the evidence is usually considered inconclusive, there is enough evidence to support the view that increased consumption of food sources of fiber is associated with reduced rates of cancer (colorectal and breast). All scientific data submitted are discussed in the scientific summary portion of this document.

The Director General, Food Directorate, Health and Welfare, Canada submitted information on the regulatory status of health claims in that country. The Canadian Government is not in favor of health claims on fiber-containing foods because it is difficult to disassociate the effect of fiber from the metabolic effects of fat and energy intake that also are claimed to influence the development of colorectal cancer. Although it has been estimated that cancer incidence can be reduced by 35 percent by dietary changes, "it has been remarkably difficult to identify specific components of the diet that increase risk or provide protection in individuals" (Ref. 28). The comment said that this finding does not diminish the importance of diet as a factor in the maintenance of health but reinforces the importance of the whole diet rather than the contribution of individual components.

II. Review of the Scientific Evidence

A. Federal Government Documents

"The Surgeon General's Report Nutrition and Health" (Ref. 47) reviewed human and animal studies of fiber and colorectal cancer and noted that among epidemiologic studies, international correlation studies are the most consistent source of support for the relationship. The report found that case-control studies provided less consistent support, but that many of the epidemiologic studies were limited by the lack of information about the type of fiber consumed. The report also noted that rodent studies suggest the importance of type of dietary fiber, but the relevance of these animal models to human cancer needs to be determined. The report concluded that "while inconclusive, some evidence also suggests that an overall increase in intake of foods high in fiber might decrease the risk for colon cancer." The role of various types of fiber that differ in their effects on water-holding capacity, viscosity, bacterial fermentation, and intestinal transit time has not been resolved (Ref. 47). The report concluded that current evidence suggests the prudence of increasing consumption of whole grain foods and cereal products, vegetables (including dried beans and peas), and fruits (Ref. 47).

USDA/DHHS' "Nutrition and Your Health, Dietary Guidelines for Americans" (Ref. 45) noted that populations such as those in the United States with diets low in dietary fiber and complex carbohydrates and high in fat, especially saturated fat, tend to have more heart disease, obesity, and some cancers. The guidelines stated that just how dietary fiber is involved is not yet clear, and that the benefit from a higher fiber diet may be from the food providing the fiber rather than from the fiber alone (Ref. 45). The dietary guidelines recommended that the American population choose diets with plenty of vegetables, fruits, and grain products rather than use of fiber supplements. Excessive use of fiber supplements is associated with greater risk of intestinal problems and lower absorption of some minerals.

In "Healthy People 2000," the Public Health Service and the Department of Health and Human Services identified increased consumption of complex carbohydrates and fiber-containing foods by adults as a specific risk reduction objective (Ref. 46). Recommendations included increasing consumption of vegetables (including legumes) and fruits to 5 or more servings daily, and increasing consumption of grain products to 6 or more daily servings. The report noted that dietary patterns with higher intakes of vegetables (including legumes), fruits, and grain products are associated with a variety of health benefits, including decreased risk for some types of cancer (Ref. 46).

There are several unresolved issues related to dietary fiber and cancer prevention (Ref. 46). For example, the role of specific types of fiber has not been delineated. Other natural substances present in plant foods, such as carotenoids, indoles, and flavonoids might also be contributing to the observed protective association for certain cancers (Ref. 46).

B. Other Reviews by Recognized Scientific Bodies

Several other reviews by recognized scientific bodies of the role of diet, nutrition and health have been published recently (Refs. 24, 25, 30, 31, 51, and 52). The conclusions regarding dietary fiber and cancer reached in these reports are similar to those reached in the Federal Government reports above.

An expert advisory committee was convened in 1985 by the Health Protection Branch of the Department of National Health and Welfare of the Canadian Government to advise them on scientific and regulatory issues related to dietary fiber (Ref. 52). While this report did not specifically review the area of fiber and cancer, it did review broad issues related to dietary fiber in foods. The committee noted that the relationship between the physico-chemical properties of dietary fibers and their physiological effects is difficult to evaluate due to the complexity of the interactions of mixed fibers in foods and to, in some cases, the lack of uniformity in testing procedures. The committee also recommended that manufacturers of food products, to which non-native and/or novel fibers have been added to increase dietary fiber content, may be required to provide evidence substantiating the safety and efficacy of these products in terms of accepted physiological effects. Non-native fibers were defined as fibers from traditional foods but not naturally occurring in the foods to which they have been added; novel fibers were defined as those which have not traditionally been part of the human diet. The committee also recommended that manufacturers of products which have been substantially enriched with native fibers should also be prepared to provide proof of efficacy and safety on request.

LSRO concluded in its 1987 report that dietary fiber is an integral part of a healthy diet (Ref. 24). However, it also concluded that the available evidence is not sufficient to support specific, quantitative recommendations on the role of dietary fiber for reducing the risk of specific diseases in the general, healthy population. The report noted that correlational studies using data from different countries have suggested a protective effect of dietary fiber against colon cancer, but that such studies cannot adequately determine whether high fiber intake per se or the low fat intake associated with consumption of fiber-rich foods is responsible for the observed associations (Ref. 24). The report noted

that most international correlational studies are based on the same Food and Agricultural Organization (FAO) data base and thus lacked independence. The LSRO report concluded that studies correlating fiber intake and cancer incidence within a single population generally observed weaker associations than the international studies. In reviewing the case-control studies of fiber intake and colon cancer, the report noted inconsistencies in the results. Nine studies showed fiber-containing foods to provide a protective effect, eight studies showed no effect, and three studies suggested that fiber may be a risk factor for colon carcinogenesis. LSRO concluded (Ref. 24) following a review of animal studies, that only particular types of fiber (especially fiber from wheat bran) are protective against chemically-induced colon cancer in animal models.

The LSRO report (Ref. 24) recommended consumption by the healthy adult population of a wide variety of foods, such as whole-grain products, fruits, and vegetables, leading to a dietary fiber intake range of 20 to 35 g per day (approximately 10 to 13 g per 1000 calories).

The 1989 NAS report "Diet and Health" (Ref. 30) also recommended increased consumption of vegetables, fruits, breads, cereals, and legumes. The report concluded that the evidence for a protective role of fiber in colon cancer was inconclusive. The report noted inconsistency in the results of epidemiological studies, and that animal studies suggested that the type of dietary fiber is important in modulating the effects of a colon carcinogen. The NAS report also noted that the effects attributed to fiber in some studies may actually be produced by some other components of the diet. Thus, even where the evidence is strongest, it has not been possible to adequately separate the effects of fiber from those of other components of the diet (e.g. total calories, fats, vitamins, minerals, and nonnutritive constituents of fruits and vegetables) and nondietary factors (e.g. socioeconomic status) (Ref. 30). The overall assessment of the evidence by the NAS report was as follows: "In general, the evidence for a protective role of dietary fiber per se in coronary heart disease, colon and rectal cancers, stomach cancers * * * is inconclusive." (Ref. 30).

The NRC's "Recommended Dietary Allowances" (Ref. 31) stated that the consumption of diets rich in plant foods, and therefore fiber, is inversely related to the incidence of cardiovascular disease, colon cancer, and diabetes and noted that because an increase in dietary fiber consumption is almost invariably associated with a change in other dietary constituents, it is difficult to establish a clear relationship with dietary fiber alone (Ref. 31). The NRC recommends that a desirable fiber intake be achieved not by adding fiber concentrates to the diet, but by consumption of fruits, vegetables, legumes, and wholegrain cereals, which also provide minerals and vitamins (Ref. 31).

The reports summarized above were in agreement in their recommendations that Americans should increase their intake of fiber-rich foods. The reports are also in agreement in their conclusions that it is not clear if the relationship between fiber-rich foods and lower rates of cancer and other chronic diseases is the result of the fiber content of the foods or of other nutrients contained in these foods. Thus, virtually all recent dietary guidelines encourage the increased consumption of fiber-rich foods rather than fiber.

In its report "Diet, Nutrition, and the Prevention of Chronic Diseases," (Ref. 51), the World Health Organization stated that dietary factors are known to influence the development of a wide range of chronic diseases, including cancer, but the relationships between specific dietary components and cancer are much less well-established than those between diet and cardiovascular disease. The report noted that for populations in developed countries, some epidemiologists estimate that 30 to 40 percent of cancers in men and up to 60 percent of cancers in women are attributable to diet (Ref. 51). Although several studies demonstrated positive associations between the risk of colorectal cancer (primarily colon cancer) and dietary fat, the data relating dietary fiber to colorectal cancer are equivocal. The WHO report concluded that it is not clear whether dietary fiber is protective or whether the apparent effect is due to other food constituents (Ref. 51).

The 1990 Canadian Government document *Nutrition Recommendations—Report of the Scientific Review Committee* (Ref. 28) reviewed the literature on nutrient requirements and on various relationships between diet and disease. The goal of the document was to provide guidance in the selection of a dietary pattern providing essential nutrients, while reducing the risk of chronic disease (Ref. 28). With respect to cancer studies, the document noted that international epidemiologic studies show an inverse relationship between colon cancer mortality and fiber content of diets. The difficulty with epidemiologic studies, the document pointed out, is that they suffer from an inability to "disentangle the effect of the fiber content in the diet from the effect of fat and energy intake" which can influence the development of colorectal cancer (Ref. 28). The document concluded that various studies have provided inconsistent results and some have cast doubt on the beneficial effect of fiber. The Canadian recommendations are to increase present intakes of dietary fiber from a variety of carbohydrates and fiber-rich foods. The addition of large amounts of a single source of purified fiber to the diet was not recommended (Ref. 28).

In 1991, LSRO reviewed scientific studies that have become available since publication of its earlier report (Ref. 24). LSRO (Ref. 25) found no new evidence to support an association between increased intake of dietary fiber and decreased risk of cancer. The report concluded that it remains to be determined whether the observed effects of fiber are due strictly to fiber, to other components of fiber-rich food, to displacement of fat or calories from the diet by fiber, or to a combination of these (Ref. 25).

C. Review of the Scientific Evidence

1. Selection and Evaluation of Studies

a. *Selection of studies.* The criteria used to select pertinent studies required them to be publicly available in English, to provide a description of the study design and results that is adequate to permit an evaluation of the study, to include direct measurements or quantitative estimates of total dietary fiber intake as a single substance or as a component of foods, and to include direct measurement of risk of colorectal cancer (prognostic indicators, incidence, development, prevalence, or mortality).

Several types of human studies provide information on the role of dietary fiber in colorectal cancer. Correlational studies use grouped data to examine the relationship between dietary exposure and health outcome among populations. These studies do not examine relationships among individuals and have traditionally been regarded as useful for generating, rather than testing, hypotheses regarding diet-disease relationships. Analytic epidemiologic studies involve comparisons of individuals and have been regarded as providing the strongest type of observational evidence in human populations. In case-control studies, the relationship of an attribute (in this case,

a dietary component) to a disease is examined by comparing persons who already are diagnosed with cancer (cases) to persons without cancer (controls). A limitation of the case-control study is that diet is assessed in the cases after diagnosis, so that cases may unintentionally overestimate or underestimate dietary intakes of specific foods. Prospective cohort studies compare individuals who have been exposed to a risk factor to those who have not and observe individuals over time to determine if disease develops. In cohort studies, diet is assessed at the beginning of the study before cancer develops.

b. *Evaluation criteria.* FDA evaluated the results of studies in humans and animals against general criteria for good experimental design, execution, and analysis. The strengths and weaknesses of different kinds of epidemiologic studies and the methodologies for dietary assessment relevant to risk of chronic diseases, as well as suggestions on weighing of available evidence, are reviewed and discussed in the proposal on general requirements for health claims (published elsewhere in this issue of the **Federal Register**) and are also reviewed elsewhere (Ref. 30).

The criteria that FDA used in evaluating epidemiology studies included reliability and accuracy of the methods used in food intake analysis and measurement of disease endpoints, choice of control subjects, representativeness of subjects, control of confounding factors (for example, intake of fat and other nutrients; intake of vegetables), potential for misclassification of individuals with regard to dietary intakes, and presence of recall bias and interviewer bias.

The criteria that FDA used in evaluating studies in animals included whether components (for example, fiber) added to experimental diets were within physiological ranges of intake, whether there was control of confounding factors (for example, through use of isocaloric diets), whether the animal species was appropriate as a model for human carcinogenesis in response to dietary modification, and whether the numbers of animals used, the duration of exposures, the periods of observation, and methods used for assessment of disease endpoints, were appropriate.

FDA assessed the weaknesses and strengths of individual studies. FDA then assessed the strength of the overall evidence derived from the Federal Government reports, the other reports cited above, and the update of the scientific literature, using factors including the strength of associations, consistency of findings, specificity of reported associations, evidence for a dose-response relationship, and biological plausibility. FDA's conclusions reflect the strength, consistency, and the degree of concordance among results obtained from a variety of types of studies.

FDA also considered several factors identified by the NAS in its evaluation of the scientific basis for a relationship between intake of dietary fiber and cancer (Ref. 30). The NAS report cautioned that analysis of study results based on measures of total dietary fiber alone could be misleading because of the complex nature of the dietary substances subsumed under the term "fiber." In many studies, no quantitative data were given on the intake of total dietary fiber or of subcomponents of fiber. NAS (1989) also stated that in view of the importance of fat intake and total caloric intake, data from studies that are controlled for energy, fat, and other nutrients are the most useful. Fiber intake is correlated with caloric intake, which in turn is correlated with fat intake. Finally, the report cautioned that homogeneity of dietary fiber intake within a population may make it difficult to detect an effect of high fiber diet on incidence of cancer (Ref. 30).

2. Human Studies

The Federal Government reports and the other reports cited above noted that the effect of fiber-rich foods was best documented relative to risk of colorectal cancer. FDA reviewed all publicly available colon and rectal cancer studies in human subjects published from 1988 to the present. This review was undertaken to determine if more recent data provided additional evidence on an association between dietary fiber and risk of colorectal cancers, and if new results would alter the conclusions of the earlier reports.

a. *Correlational studies.* A brief summary of correlational studies relating to associations between dietary fiber and risk of colorectal cancer reviewed in "The Surgeon General's Report" (Ref. 47) and in reports by other scientific bodies is presented here. Many correlational studies have suggested a protective effect of dietary fiber against colon cancer (Refs. 24 and 47). Twenty-one of 24 correlational studies reviewed in "The Surgeon General's Report" (Ref. 47) identified an inverse association between intake of dietary fiber, cereals, or vegetables and occurrence of colon cancer. Three of the 24 studies showed no effect. One international study (Ref. 26) found an inverse association between colon cancer and total dietary fiber and reported a protective effect of cereal fiber, even after adjustment for intake of fat or meat. Some of these studies also showed correlations between intake of other nutrients and colon cancer. Thus, while patterns of eating foods high in fiber showed good correlation with low colon cancer rates, other dietary components might also be influencing this association (Ref. 47).

Two recent studies (Table 1) have correlated colorectal cancer mortality with population-based dietary intake data. Rosen et al. (Ref. 37) correlated colon cancer mortality rates from 1969 to 1978 with estimates of dietary intake of fiber for 24 counties in Sweden. Dietary fiber intake was calculated from household food expenditure data (excluding foods eaten outside the home) for 1978. Results showed a strong negative correlation (inverse relationship) between dietary fiber and colorectal cancer in both men ($r=-0.75$) and women ($r=-0.67$) ("r" means simple correlation coefficient), and this association was not altered by controlling for fat intake. Rosen et al. (Ref. 37) observed similar correlations for high-fiber breads. No effects of vegetable consumption on colorectal cancer were observed (Ref. 37).

Daily per capita total dietary fiber intake was estimated to be 12 g based on expenditure data. Regional data showed a high intake of milk and fat as well as fiber in areas with low mortality rates from colorectal cancer. A major limitation of correlational studies is that dietaty intakes are not necessarily assessed in the individuals who develop the disease under investigation. This limitation and regional differences in dietary intakes may explain why high intakes of fat, fiber, and milk were associated with low mortality rates from colorectal cancer in the study by Rosen (Ref 37).

Morales Suarez-Varela et al. (Ref. 29) (Table 1) undertook a correlational study of diet and rectosigmoid cancer in Spain. The investigators correlated standardized mortality and morbidity data from rectal and sigmoid colon cancer in 50 Spanish provinces with dietary fiber (type unspecified) consumption estimated from food composition tables of the National Statistical Institute. Consumption of vegetable fats, butter and pork lard, total animal fats, and fiber showed no correlation with provincial morbidity and mortality due to rectal cancer. Sex-specific standardized morbidity ratios for men showed a modest positive correlation (0.3344; $p<0.01$) of fiber consumption with rectosigmoid colon cancer morbidity. These observations are difficult to interpret because the

study combined data from rectal and lower (sigmoid) colon cancer cases.

b. *Case-control studies.* In several recent case-control studies, patients with colon cancer and matched controls were interviewed about previous fiber intake (Table 2). Kune et al. (Ref. 21) (Table 2), in a study of 715 colorectal cancer cases and controls, analyzed data on total fiber, vegetable fiber, and fruit fiber intake. Dietary information covering the previous 20 years was obtained from subjects by interview. Although uncontrolled analysis for total fiber, vegetable, fruit, and cereal fiber gave a negative association with colorectal cancer, the effect was removed when micronutrients, fats, and energy were controlled. By examining interaction effects, the combination of high fiber intake and high vegetable intake was found to be protective, although neither was independently protective. The source of the fiber (cereal, vegetable, or fruit) did not alter the interaction. The types of fiber involved (soluble or insoluble) were not identified (Ref. 21).

Tuyns et al. (Ref. 44) (Table 2) conducted a case-control study of 453 colon cancer patients, 356 rectal cancer patients, and 2,851 population-based controls in 2 Belgian provinces. Cases were asked about their usual food intakes over 1 week before the onset of illness and controls at the time of interview. Only 50 percent of the case series were successfully interviewed. Logistic regression analysis was used to estimate the relative risk of colon and rectal cancer, controlling for age, sex, province, total calories, and other nutrients. Dietary fiber intake was significantly negatively associated with both colon and rectal cancer (i.e., the higher the fiber intake, the lower the incidence of these cancers), and there was a negative linear trend indicative of an intake response (Ref. 44). This trend was not affected by adjustments for calorie intake. However, the low response rate of the cases (50 percent) may have introduced selection bias and substantially reduces the confidence that can be placed in the results.

West et al. (Ref. 48) (Table 2) studied dietary intake in 231 colon cancer cases from the Utah Cancer Registry and 391 controls identified by random digit dialing. A stratified random sample of control individuals within the selected households was chosen to reflect sex, age within 5 years, and county of residence of cases. Food intake was assessed by a food frequency questionnaire for the 2 to 3 years prior to the interview. Interviews were completed for 71 percent of cases and 74 percent of controls. Odds ratios and multiple logistic regression analysis were used to estimate the risk of colon cancer controlling for age, body mass index, and energy intake, but not for other dietary factors. Increased crude fiber intake was associated with a decreased risk of colon cancer for both males and females. Ninety percent confidence intervals were used in the statistical analysis and this finding was significant at the 0.10 level.

A detailed analysis of dietary fiber components was undertaken in a case-control study in western New York of 428 colon cancer cases, 422 rectal cancer cases, and neighborhood controls (Refs. 9 and 10) (Table 2). Cases were identified from hospital pathology reports. Sixty-five percent of colon cancer patients, 54 percent of rectal cancer patients, and 53 percent of eligible controls were interviewed regarding frequency of consumption of foods for 1 year prior to onset of symptoms. Total dietary fiber was classified by source from grain, or fruit, or vegetables, and for each of these, the soluble and insoluble components were identified. Insoluble fiber from each source (grain, fruit, or vegetables) was further classified as hemicellulose, cellulose, or lignin. Conditional logistic regression analysis, with adjustment for fat intake, was used to estimate the impact of total fiber and each of five fiber components from grains and fruit or vegetables on risk of colon and rectal cancer. Separate analyses were performed for males and females. Reduction in risk of colon cancer was associated with intake of grain fiber in both males and females and with fiber from fruit or vegetable sources for males only. Insoluble grain fiber was more strongly associated with reduction in risk of colon cancer than soluble fiber. Analysis of risk of rectal cancer showed a protective effect of fruit or vegetable fibers but not grain fibers. There were no differences in the effects of soluble and insoluble fiber. However, the analysis did not control for other components of fruits and vegetables that might affect cancer risk. Furthermore, the low response rates for cases and controls may introduce selection bias.

Wohlleb et al. (Ref. 50) (Table 2) conducted a small case-control study of colorectal cancer (43 patients and 41 controls) in men at a U.S. Veterans Administration hospital. Demographic traits, medical history, occupational history, use of alcohol and tobacco, and other information were obtained by questionnaire that also collected data about weekly intakes of 55 food items (that is, current diet was surveyed). Consumption of cauliflower (a cruciferous vegetable) was significantly associated with fewer cancers in this study. Consumption of rolled oats appeared as a significant protective factor against colorectal cancer, and other high-fiber foods (wheat bran and unpeeled apples) were apparently protective (Ref. 50).

A case control study conducted in Stockholm, Sweden, involved 452 subjects with colon cancer, 268 subjects with rectal cancer, and a population based control group (Ref. 8) (Table 2). Dietary data for the previous 5 years was obtained by a food frequency questionnaire. Interviews were completed for 76 percent of cases and 87 percent of controls. A protective effect of high fiber intake against colon cancer was found in men (RR = 0.5) but not in women (RR = 1.2). Fiber appeared to be protective against rectal cancer in both sexes (RR for all subjects = 0.5). The data were analyzed controlling for year of birth and protein intake but not for other nutrients. There was an interaction effect observed between protein and fiber intake such that fiber had a greater protective effect in those consuming a low protein diet.

A case-control study performed in Utah (Ref. 40) (Table 2) involved 231 colon cancer cases and 391 controls. Subjects were interviewed about diet for the 2 years prior to diagnosis. Consumption of fruits, vegetables, and grain was estimated by a food frequency questionnarie. Fiber intake was calculated from several food tables, and in some cases actual analysis of foods was performed to allow assessment of the effects of chemically-defined fiber fractions. Body mass index, caloric intake, membership in the Mormon church, and age were controlled for by statistical adjustment. The effect of fiber varied with the chemical type and food source. Intake of fruits and vegetables was negatively related to risk of colon cancer in males and females. Intake of grain fiber was not protective. The effects of neutral detergent fiber or dietary fiber as determined by the method of Bitner were weak and inconsistent. Fiber effects, when detected, were usually of greater magnitude in males. This study is one of the few to examine the effects of several analytically defined fiber fractions. The results suggest that fibers from different food sources have different effects.

Lee et al. (Ref. 23) (Table 2) conducted a case-control study of 132 colon cancer cases and 71 rectal cancer hospital cases in Singapore. Dietary information was obtained about usual diets consumed 1 year prior to the interview.

Intakes of cruciferous vegetables and a high intake of vegetables relative to meats were generally protective against colorectal cancer. Fiber was protective for rectal cancer (OR=0.46; $p<0.05$) but not for colon cancer. Protective effects were reported for cruciferous vegetables (OR=0.50<0.01). The authors urged caution in interpreting their data for rectal cancer, however, because of the small number of cases.

One study examined the dietary patterns of patients with colonic polyps (considered a precursor lesion to colon cancer) and of individuals without polyps. Hoff et al. (Ref. 15) (Table 2) assessed dietary intake from 5-day food records in a case-control study utilizing patients participating in endoscopic screening for colonic polyps. Nutrient intake of patients with and without polyps was compared. Patients were not aware of their polyp status when they completed the food intake records. Results revealed that patients with large polyps consumed significantly less total dietary fiber and less total carbohydrate than patients without polyps. Intake of vitamin C and cruciferous vegetables did not differ significantly among patients with or without polyps, although patients with multiple polyps had a significantly lower intake of cruciferous vegetables and vitamin C compared to patients with only a single polyp. Assessment of diets 1 to 2 years or more prior to onset of symptoms would have provided more useful information.

Benito et al. (Ref. 4) (Table 2) conducted a case-control study of 286 colorectal cancer patients, 295 age and sex-matched community controls, and 203 hospital controls on the Spanish island of Majorca. The participants were given a food frequency questionnaire covering the 6 months prior to the interview. Consumption of high-fiber vegetables was found to have no effect on the risk of colorectal cancer. No data on total fiber or its components were provided. Slattery et al. (Ref. 41) conducted a case-control study correlating diet prior to diagnosis with survival time in colon cancer patients. Dietary information for the 2 to 5 years prior to diagnosis of colon cancer was collected by interview. The highest quartile of fiber intake was associated with decreased survival time.

c. *Prospective studies.* In two recent prospective studies, dietary intakes of individuals were estimated at baseline by mailed questionnaire and then individuals were followed over time for occurrence of disease. Willet et al. (Ref. 49) (Table 3) in a study involving 6 years of followup of 88,751 female nurses (ages 34 to 59 years) found no evidence of a protective effect of intake of total crude fiber on colon cancer. A high intake of crude fiber from fruit, but not from vegetables or cereal, showed a significant protective effect but this effect was not statistically independent of intake of red meat.

Heilbrun et al. (Ref. 13) (Table 3) conducted a nested case-control study of 8,006 Japanese-American men in Hawaii, with 361 controls, 102 cases of colon cancer, and 60 cases of rectal cancers. Dietary intakes of crude fiber were based on a single 24-hour recall collected between 1965 to 1968. Cancer cases consumed an estimated 11.4 to 12.1 g per day of crude fiber while controls consumed 11.6 g of crude fiber per day. Proportional hazards models adjusted for age, and for alcohol intake in the cases of rectal cancer, were used to estimate the relative risk of colon and rectal cancer. The models included all micronutrients, fat, calories, saturated fat, protein, cholesterol, and carbohydrates. Fiber was protective in the low fat group when the cohort was divided into two groups at the median level of fat intake of colon cancer cases. When fat intake was less than 61 g per day, risk of colon cancer decreased as consumption of fiber increased ($p<0.042$).

d. *Meta-analysis of epidemiologic studies.* Trock et al. (Ref. 43) performed a thorough review with reanalysis of data from all English-language epidemiologic studies concerning colorectal cancer and fiber, vegetables, grains, or fruit published from 1970 through 1988. The review included 23 case-control studies, 7 international correlation studies, 8 within-country correlation studies, 2 cohort studies, and 3 time-trend studies. Trock et al. (1990) made an aggregate assessment of the strength of evidence from numerous observational epidemiologic studies and meta-analysis of data from 16 of 23 case-control studies. Both types of analyses indicated that the majority of studies give support for a protective effect of fiber-rich foods against colorectal cancer. Risk estimates based on vegetable consumption were only slightly more convincing than those based on estimates of fiber intake. The authors noted that the data do not permit discrimination of the fiber and nonfiber effects of vegetables (Ref. 43).

e. *Intervention studies.* DeCosse et al. (Ref. 7) conducted a long term, randomized intervention study aimed at reducing rectal polyp recurrence in patients with familial polyposis. Adults patients (n=58) having undergone previous total colectomy for familial polyposis were given daily supplements of vitamins C and E alone or with wheat bran, and rectal polyp number and size was assessed repeatedly over a 4-year period. Fiber appeared to reduce mean polyp size over time, especially if total intake of fiber was calculated as dietary sources plus fiber supplement. Thus, the authors concluded that benign large bowel neoplasia was inhibited by intakes of grain fiber supplements greater than 11 g per day. It is not known whether the results of this study can be applied directly to the much more common clinical situation of sporadic colonic polyps.

f. *Mechanistic studies.* The mechanisms by which fiber may affect colonic carcinogenesis are unknown. Proposed mechanisms include effects of fiber to:

(a) Dilute fecal bile acids which may have growth promoting effects on small adenomas;

(b) Reduce fecal mutagenicity;

(c) Alter fecal bulk;

(d) Increase fecal transit time;

(e) Alter colonic mucin;

(f) Change fecal pH; and

(g) Alter colonic cell proliferation.

Newer hypotheses have focused on the role of microbial fermentation in cancer prevention (Ref. 22). A number of studies have been performed in attempts to test which of these potential mechanisms may affect tumorigenesis.

FDA reviewed a number of studies that examined hypothesized risk factors for colon cancer such as cell turnover, fecal bile acids, and fecal mutagens. Such studies are helpful in determining possible mechanisms of action for effects of fiber or fiber-rich foods on carcinogenesis. Fiber type and amount can be carefully controlled in animal and human mechanistic studies. As a result, it should be possible to distinguish effects of fiber from effects of other components of fiber-rich foods.

Reddy et al. (Ref. 35), in a study involving supplementing the diet with a mixture of high-fiber oat and whole wheat bread, found a significant decrease in fecal secondary bile acid concentration and decreased fecal mutagenicity with increased fiber intake in the form of high-fiber bread.

Reddy et al. (Ref. 34), in a dietary intervention study, instructed subjects to eat a high fiber, low fat, low meat diet, similar to the "Pritikin"-type diet. The dietary intervention increased stool weight and decreased bile fecal acid concentration (effects that are thought to be protective against colon carcinogenesis). The interpretation of the study was complicated by significant weight loss in the subjects

and major dietary changes other than alterations in dietary fiber. The study design did not use a contemporaneous control group and did not attempt to crossover treatments.

In a well-designed study, Reddy et al. (Ref. 33) fed wheat bran, cellulose, or oat bran to human subjects in a randomized crossover design. Both wheat bran and cellulose reduced fecal mutagenicity, fecal bile acid concentration, and fecal neutral sterol concentration. These are all considered positive changes toward reducing colon cancer risk. Oat bran, however, did not significantly alter these parameters compared to those measured with the baseline "normal" diet.

Allinger et al. (Ref. 3) instructed subjects to increase their intake of fruits, vegetables, and grains, eliminate meat and eggs, and consume only fermented, rather than fresh, dairy products. The change in diet was conducted in three "shifts" (March, May, and August) to attempt to control for seasonal variability. The total dietary change resulted in increased fecal weight and decreased soluble fecal deoxycholic acid (both thought to be favorable changes for reduced risk of colon cancer). Because of the combined dietary approach, it cannot be determined whether the additional fiber or the other changes in the diet were responsible for the observed alterations in the fecal parameters.

Johansson et al. (Ref. 18), in another study utilizing the same subjects and diets, as Allinger et al. (1990), examined changes in fecal bacterial enzyme activities in response to the dietary modifications. The dietary change decreased the activity of three fecal bacterial enzymes considered to be important in colonic carcinogenesis. Most of the effect was apparently the result of dilution by increased stool volume. Moreover, the importance of these bacterial enzymes in the development of human colon cancer is unknown. It cannot be determined whether the additional fiber or the other changes in the diet were responsible for the observed alterations in the fecal parameters.

Alberts et al. (Ref. 2) examined rectal cell proliferation in a trial of wheat bran supplementation (13.5 g per day) in patients in whom colons were removed for treatment of colon cancer. Seventeen patients (aged 54 to 70 years), at high risk of recurrent colorectal cancer, participated in the 8-week study. Rectal cell proliferation was assessed by two methods both pre- and post-diet intervention. One method of assay showed a significant mean decrease in rectal cell proliferation after 2 months of wheat bran supplementation while the other showed no change.

Kashtan et al. (Ref. 19) found that 100 g of oat bran decreased fecal pH significantly in normal volunteers, while lesser quantities of oat bran did not produce significant reductions in fecal pH. Psyllium and wheat bran did not affect fecal pH. The importance of fecal pH in colon cancer has not been determined.

In a study by Friedman et al. (Ref. 11), human colonic cells were incubated in vitro with psyllium or bile salts. Small decreases in the cytotoxicity of the bile salts were noted with the addition of psyllium, and other alterations in cell growth were seen when various short chain fatty acids (products of bacterial digestion of fiber in the large intestine) were added. However, adding ungraded psyllium to a cell culture is not reflective of the bacterial metabolism of this material which occurs in the colon in vivo. No rationale is provided to relate the concentrations or relative proportions of short chain fatty acids added to the culture to the products of actual bacterial digestion of psyllium in vivo. Thus, the in vitro conditions in this study may not be physiological.

3. Animal Studies

As mentioned previously, most laboratory animal studies of dietary fiber and cancer have focused on colon cancer. Results of numerous animal studies are reviewed by LSRO (Ref. 24), in The Surgeon General's Report. (Ref. 47), and in "Diet and Health" (Ref. 30). Recent reviews include those (Refs. 17 and 32).

Effects of dietary fiber on colon carcinogenesis in animals are frequently studied following exposure of the animals to a compound such as 1,2-dimethylhydrazine (DMH) which is known to be carcinogenic to the colon. The animals are then fed varying amounts and types of dietary fibers and subsequent effects tumorigenesis are observed. The carcinogen is usually given weekly via a tube into the stomach or injection for a 5- to 10-week period. Tumors begin to develop within 2 to 3 months following completion of carcinogen treatment.

The 1987 LSRO (Ref. 24) report notes that studies using animal models to examine the role of various types of dietary fiber in the development of carcinomas of the colon provide conflicting results. One of the factors that has a major effect on the results of carcinogenesis studies is the type of dietary fiber fed to the animals. Many studies have shown that not all fiber types reduce experimental colon cancer. Dietary soybean bran and rice bran showed no effect on DMH-induced colon carcinogenesis in rats, while oat bran had an enhancing effect. Corn bran had either an enhancing effect or no effect on colon carcinogenesis, while 10 percent guar gum was shown to enhance tumor development. Most studies with wheat bran show an inhibitory effect. The 1987 LSRO (Ref. 24) report states that both the physical and chemical properties of a fiber source are probably important in determining its effects. Of all fiber types studied, the authors considered wheat bran to have the most consistent inhibitory effects on colonic tumor development.

Many factors besides the type of fiber fed were noted to affect the outcome of these studies, including the type and dose of carcinogen given, the sex and strain of animal, the total duration of the study, and whether the fiber was fed during the initiation phase (while carcinogen is being given) or during promotion (after completion of carcinogen treatment).

"The Surgeon General's Report" (Ref. 47) noted that wheat bran was found to be protective in most but not all animal studies. Results of animal studies of fibers such as corn bran, rice bran, oat bran, pectin, and guar gum were much less consistent. Some studies showed a protective effect, more tended to show a tumor-enhancing effect, and others showed no effect. "The Surgeon General's Report" (Ref. 47) concluded that the relevance of these animal models to human cancer needs to be determined.

The NAS, in "Diet and Health" (Ref. 30) cited a diversity of results (protection, enhancement, no effect) for nonhuman carcinogenesis studies of various types and amounts of fiber. The report concluded that the type of fiber is very important in determining its effects on colon carcinogenesis. NAS (Ref. 30) also noted that wheat bran has the most consistent inhibitory effect.

Animal studies published since 1987 in which animals were fed defined diets containing cellulose, wheat bran, or psyllium are reviewed briefly below.

Roberts-Anderson et al. (Ref. 36) fed 10 percent cellulose, 10 percent psyllium, or a fiber free diet to rats both during and after administration of a chemical carcinogen. Both fiber treatments reduced tumor incidence. Rats in the psyllium group gained considerably less weight than control rats, and the duration of the study was significantly shorter than most published tumorigenesis studies. The number of rats exposed to the carcinogen was also smaller than usual for studies of this type.

Heitman et al. (Ref. 14) fed rats 0, 5, or 15 percent cellulose during the phases of initiation or promotion or both. Cellulose at 5 or 15 percent showed statistically significant protective effects if fed during both initiation and promotion. Other combinations of cellulose feeding (promotion only, etc.) produced reductions that were not statistically significant. The authors correlated the antitumor effects of cellulose with its ability to inhibit DMH-induced cell replication during initiation. This study suggests a protective effect for cellulose when fed during both initiation and promotion.

Three recent studies evaluated the effect of wheat bran on colon carcinogenesis. Calvert et al. (Ref. 6) fed 10 percent wheat bran or wheat bran with bile salts added (sufficient to eliminate its effects on bile salt dilution) to rats during the promotion phase, after they had been exposed to the chemical carcinogen DMH. Wheat bran consistently reduced tumor incidence and multiplicity in this study. Added bile salts did not diminish this effect, suggesting that bile salt dilution is not the mechanism of the observed antitumor effect. Tatsuta et al. (Ref. 42) noted no effect of wheat bran on tumor development in their study. Wheat bran was fed during both initiation and promotion. Sinkeldam et al. (Ref. 39) fed 9 or 17 percent wheat bran to rats on low, medium, or high fat diets. Diets were consumed during both initiation and promotion. The 17 percent wheat bran diets eliminated the tumor enhancing effect of increasing levels of fat. If fat levels were moderate or low, 9 percent wheat bran enhanced tumorigenesis, while 17 percent wheat bran was inhibitory.

Thus, three recent studies with wheat bran report inconsistent effects on colon carcinogenesis. Differences in the timing of the feeding of wheat bran (promotion phase only versus initiation and promotion phases) or fat levels may partly explain these inconsistencies.

4. Other Relevant Information

Concerns have been raised about potential risks of ingesting isolated or purified forms of fiber (Ref. 24, 25, and 52). Side effects and possible adverse health effects of high intakes of dietary fiber have also been hypothesized by NAS (NAS, 1989). Excessive consumption of fiber supplements may result in more intestinal problems or poor absorption of trace minerals than would be expected from a high-fiber diet (Ref. 25). Safety concerns about more novel sources of fiber (e.g., gums and isolated sources of fibers) when consumed in large amounts or when consumed in nonfood forms have also been raised (Ref. 52). However, high dietary intakes of foods with naturally-occurring fiber have generally not been found to have adverse health effects (Ref. 24 and 30).

5. Conclusions

Federal Government documents (Ref. 47) and the other referenced reports from recognized scientific bodies (Refs. 24, 25, and 30) concur that the evidence for a protective effect of dietary fiber in colon carcinogenesis is inconclusive. However, they do note the association of dietary patterns high in plant foods to reduce risk of cancer and other chronic diseases.

Of two recently reported correlational studies, one compared colorectal cancer mortality in Sweden with population-based dietary fiber intake data and found a strong negative correlation between intake of dietary fiber and colorectal cancer mortality in men and women, Rosen et al. (Ref. 37). In a second study, Morales Suarez-Varela et al. (Ref. 29) found no correlation between fiber intake and rectosigmoid cancer morbidity or mortality among 50 Spanish province Spain.

Dietary fiber is extremely heterogenous in nature (Refs. 12 and 24) and fiber-rich foods differ significantly in the amounts and types of fiber components they contain. The limited amount of analytical data on dietary fiber and various components of dietary fiber have impeded research on its health effects (Ref. 22).

Human studies on effects of dietary fiber intake and risk of cancer of the colon and rectum have differed in classification of dietary fiber (i.e., source, type, components) and in measurement of dietary intake (e.g., 24-hour recall, food frequency). The results of these studies have also differed. Of two recent case-control studies that were adequately controlled for other known components of fruits and vegetables, one study, Kune et al. (Ref. 21) reported no effect of dietary fiber per se but found an interaction such that those consuming diets high in fiber and vegetables experienced a reduced risk of colorectal cancer. Tuyns et al. (Ref. 44) reported a protective effect of dietary fiber and an intake response relationship.

Three other recent case-control studies did not control for micronutrients in vegetables and fruits. The results of these studies were inconsistent. West et al. (Ref. 48) reported an association of crude fiber with reduced risk of colon cancer. Freudenheim et al. (Refs. 9 and 10) observed no association of total fiber with colon cancer, but grain fiber was protective in men and women, and fruit and vegetable fibers were protective in men only. The same study showed fruit or vegetable fiber to be protective for rectal cancer (statistically significant only in men) regardless of soluble or insoluble components. In contrast to the results reported for colon cancer, grain fiber consumption was not associated with risk reduction in rectal cancer. De Verdier et al. (Ref. 8) reported that fiber was protective in men only, but an interaction was observed such that a low protein and high fiber diet led to a reduction in risk of colon and rectal cancer. Because none of these studies controlled for nutrients or other components in fruits and vegetables, it is not possible to determine if observed effects were due to fiber or to nonfiber components of fruits and vegetables.

Among two recently completed prospective studies, Willet et al. (Ref. 49) reported no effect of crude fiber or components when consumption of red meat was controlled. Heilbrun et al. (Ref. 13) reported no effect of dietary fiber on colon or rectal cancer. However, fiber was protective in those subjects with a fat intake below the median for the group as a whole.

A number of studies have examined effects of dietary fiber on possible risk factors for colorectal cancers. Such studies have examined effects of specific types of fibers on hypothesized risk factors for colorectal cancer. Generally favorable effects of some types of fibers on such factors have been reported. The actual risk factors for colorectal cancer are still incompletely understood, however. Thus, the significance of favorable effects produced by fiber feeding on particular parameters such as secondary bile acid concentration, fecal mutagenicity, fecal weight, fecal deoxycholic acid, and activity of fecal bacterial enzymes is not clear at this time. Additional studies are needed to establish which, if any, of these factors affect the development of human colon cancer.

Thus, evidence that has become available since the publication of the Federal Government and the other major reviews by recognized scientific bodies does not provide a basis for altering the conclusions of these documents which note a reduced risk for colon cancer with diets high in fiber-containing foods but not for fiber in isolation.

Results of studies of colon carcinogenesis in animals must be interpreted cautiously. Colon cancer is induced in animals by relatively

infrequent exposures to large doses of a known, potent carcinogen, while in human colon cancer, carcinogen exposure is presumably long-term, possibly continuous, and arises from as yet unidentified carcinogens. In animal studies, different types of fiber produce widely varying results. Animal sex, strain, carcinogen dose, and other aspects of study design profoundly influence the results. Fiber in general shows no consistent protective effect. Wheat bran shows the most consistent protective effect, but even among wheat bran studies results are not completely consistent.

Human studies are just beginning to examine effects of specific types of fiber. Data currently available, however, are insufficient to conclude whether fiber itself, specific components of fiber, or some other components of diets rich in fruits, vegetables, and grains are the factors responsible for the risk reduction observed in some studies. Nor has it been established what type or amount of fiber is necessary for a protective effect. The mechanism of fiber's effects, if any, is also unknown. For all of these reasons, a specific relationship between dietary fiber and decreased risk of cancer has not been demonstrated. However, a relationship between vegetables, fruits, and grains that contain fiber and other nutrients and a reduced risk for cancer has been demonstrated.

III. Tentative Decision Not To Propose a Health Claim Relating Dietary Fiber to Decreased Risk of Cancer

FDA limited its review of the scientific evidence relating ingestion of dietary fiber and cancer to the topic of dietary fiber and risk of colorectal cancer. This limitation was deemed appropriate because the great majority of epidemiologic and intervention studies have focused on colon cancer, as have virtually all animal studies in this area. The strongest support and largest volume of evidence for a possible protective effect of fiber-rich diets is for colon and rectal cancers (colorectal cancers), the second leading causes of cancer deaths in the United States (Ref. 46). Relationships between dietary fiber and risk of cancer at other sites (for example, breast, stomach, endometrium, and ovaries) have been less extensively examined but are currently the focus of considerable research effort (Refs. 47, 30, and 25).

FDA has tentatively concluded, based on the totality of the evidence, that there is not a sufficient basis to authorize a health claim for dietary fiber and reduction in risk of cancer. Numerous human and animal studies have examined the possible role of dietary fiber intake in reducing the risk of developing colon cancer. Most correlational and many (but not all) case-control studies show that diets high in fiber-containing foods (whole grains, fruits, and vegetables) are associated with a reduced risk of colorectal cancer. Prospective epidemiologic studies are few in number and give mixed results. Animal studies indicate that certain types of dietary fiber are important in modulating the effects of chemical carcinogens.

There is substantial evidence that fiber-rich foods and diets high in fiber-rich foods, including whole grains, fruits and vegetables, are associated with reduced risk of colorectal cancer. These diets differ, however, in levels of many nutrients and in types of dietary fiber, making it difficult to ascribe the observed nutrient and disease relationship to a single nutrient. Overall, the available data are not sufficient to demonstrate that it is the total dietary fiber, or a specific fiber component, or specific vitamins and minerals (singly or interactively) that are related to reduction of cancer risk.

A major limitation in designing and evaluating research studies has been the need for better defined measures of dietary fiber and standardized descriptions for source, type, and amount of dietary fiber (Ref. 24). Dietary fibers are a heterogeneous family of compounds that vary considerably in chemical composition, physical characteristics, and biological effects (Refs. 12 and 24). Processing of foods and fiber sources may also alter the inherent characteristics of the fiber (Ref. 24). The commonly used analytical methodologies often do not detect many of the characteristics that vary among fibers and that may be related to biological function (e.g., particle size, chemical composition, or water-holding capacity) (Refs. 12 and 24). Analytical methods also do not differentiate between source or type of fiber. This lack of ability to detect many of the differences that exist among fibers and the general lack of clear evidence as to the mechanisms of action of fibers have raised questions as to the ability of commonly used analytical measures of dietary fiber to adequately predict biological actions of specific fibers (Refs. 12 and 24).

Another problem in evaluating the relationship of dietary fiber intakes to risk of chronic diseases such as cancer is the lack of reference food composition data on the fiber content of foods. Consequently, most human studies have described dietary intakes in terms of amounts of fruits, vegetables, or other food groups rather than as total dietary fiber intakes; or have used measures of the crude fiber content of foods rather than total dietary fiber to estimate fiber intakes. Not only do measures of crude fiber variably underestimate intakes of total dietary fiber, but they also are not necessarily reflective of the various combinations of types of fiber normally present in foods. The seriousness of this limitation varies by type and objective of study, but inappropriate and inadequate estimates of dietary fiber intakes can limit the ability to detect a fiber/cancer relationship in some studies. This limitation affects, then, the ability to link dietary fiber intakes to cancer risk.

In summary, the currently available scientific evidence is not sufficiently conclusive or specific for fiber per se to justify use of a health claim relating intake of dietary fiber to reduced risk of cancer. Federal government (Refs. 25 and 47) and other reviews by recognized scientific bodies (Refs. 24, 25, 30, and 31) are consistent in agreeing that it is difficult to separate the effects of fiber from those of other dietary components present in high fiber foods or in dietary patterns high in plant food. As noted above, the evidence that has become available since publication of these reports is consistent with these conclusions and is, therefore, not sufficient to alter the earlier conclusions. Thus, FDA has tentatively concluded, based on the totality of the scientific evidence, that there is not significant scientific agreement among experts qualified by training and experience to evaluate such a relationship, as to the independent and specific role of dietary fiber or fiber components in reducing the risk of cancer, particularly colon cancer.

Virtually all recent dietary guidelines for Americans have encouraged the increased consumption of fiber-rich foods, including whole grain cereals, fruits, and vegetables. This recommendation is also consistent with available scientific evidence which shows that changes in dietary patterns can play a significant role in reducing risk of colorectal cancer, other cancers, and other chronic diseases (Refs. 30, 47). FDA has supported and continues to support these recommendations and to encourage dietary guidance consistent with the recommendations.

This raises a dilemma, however, for which FDA is requesting comment. To encourage and help consumers to meet dietary guidance recommendations, it would be useful to have appropriate dietary information at point of purchase. The use of health claims on foods

(including dietary supplements) to inform consumers of these recommendations, however, is problematic because it is not clear what qualifying and other criteria are necessary to adequately define eligible foods for such a health claim. As described in companion documents on "General Principles for Health Claims" and in requirements for "Mandatory Nutrition Labeling," the fiber content of foods (including dietary supplements) as measured by the Association of Official Analytical Chemists method for dietary fiber is proposed to serve as the basis for nutrition labeling of fiber content and, consequently, for determining whether foods and supplements qualify for health claims. Yet as discussed above, the correspondence between analytical fiber content and biological responses is not established. Thus, health claims that derive from this basis could be misleading. Congress, in the 1990 amendments, specified that FDA evaluate nutrient and disease relationships. Dietary fiber was specified as one nutrient for evaluation. Yet, FDA has tentatively concluded that the available evidence that is supportive of food patterns containing fiber-rich foods cannot be extrapolated to a specific fiber effect at this time.

Given the public health significance of cancer, specifically colon cancer, and given the general dietary guidance to increase consumption of fruit and vegetables and whole grain products which are rich sources of dietary fiber and other nutrients, FDA is requesting comments on how to best inform consumers of these issues.

Specifically should the agency permit a claim on the label or in labeling such as: "Diets high in fruit, vegetables, whole grains are associated with a reduced risk of cancer of the lower bowel and cardiovascular disease;" or alternatively "Research has shown that populations who consume diets that contain several servings each of fruit, vegetables, and whole grains have a decreased risk of certain forms of cancer and cardiovascular disease;" or "Choose diets with plenty of fruit, vegetables, and whole grains to help lower your risk of cardiovascular disease and certain forms of cancer." If such statements should be permitted, what criteria should be used to identify foods that are eligible for such statements? For example, should such statements be limited to fresh fruit, vegetables, and milled whole grains, or should processed foods derived from these producers be also included? What measure should the agency adopt to assure that consumers are not misled as to the benefit of consuming a specific product?

The use of such claims on fruit, vegetables, and whole grains raises the issue of authority to permit claims for food as well as nutrients. FDA specifically requests comments on whether it has the authority and should allow health claims on foods as well as nutrients. FDA also requests information on how to develop regulatory criteria for such a program. If FDA were to permit such claims, what qualifying and disqualifying criteria should be used to determine eligibility for a claim, and what methods or criteria should be used for regulatory monitoring and compliance? Additionally, FDA requests comments on what criteria could be used to develop a health claim for foods that would provide truthful and not misleading messages to consumers that changes in dietary patterns are related to reductions in cancer risk.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

VI. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR Part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. Section 101.71 is amended by adding paragraph (a) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(a) Dietary fiber and cancer (insert cite and date of publication in the **Federal Register** of the final rule).

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

TABLE 1.—DIETARY FIBER AND COLORECTAL CANCER: CORRELATIONAL STUDIES

Study	Type and location	Design	Methods	Results	Comments
Rosen et al., 1988 (Ref. 37).	Correlational Sweden	Cancer mortality rates from 1969-1978 and dietary practices were studied in 24 countries.	Dietary fiber was calculated based on food expenditures for 1978. Population providing food expenditure data was a random sample of 5,760 households. All food expenditures for 2 weeks were recorded.	High intake of cereal fiber was protective against colorectal cancer for both males, females. A negative correlation between milk consumption and colorectal cancer was found.	Food eaten in restaurants and food wastage were not accounted for. Estimates were based on food expenditure rather than on consumption.
Morales Suarez-Varela et al., 1990 (Ref. 29).	Correlational, Spain	Correlated mortality rates from rectal cancer (including sigmoid colon) with dietary practices, including dietary fiber intake.	Study covered period from 1977-1985. Consumption of various diet components obtained from Natl. Statistics Institute publications. Components examined were total lipids, animal fats, vegetable fats, butter and pork lard, margarine, fiber, and alcohol.	No significant correlations were established between animal fat, vegetable fat, total lipids, or fiber and morbidity and mortality.	Data for rectal and sigmoid colon cancer were combined.

TABLE 2.—DIETARY FIBER AND COLORECTAL CANCER: CASE CONTROL STUDIES

Study	Type and Location	Subjects	Methods	Results	Comments
Benito et al., 1990 (Ref. 4).	Case control, Majorca	286 cases of colon cancer (including rectal cancer); 295 community controls matched for age, sex; 203 hospital controls.	Subjects given food frequency questionnaire covering 6 months prior to interview.	Increased risk of colon cancer found for higher consumption of fresh meats; protection associated with high intake of cruciferous vegetables. Fourfold increase in risk of colorectal cancer found for high consumption of fresh meat, dairy products, and cereals combined with low intake of cruciferous vegetables.	The study examined effects of foods rather than fiber.
De Verdier et al., 1990 (Ref. 8).	Case control, Sweden	452 cases of colon cancer, 268 cases of rectal cancer, 624 controls matched for age.	Dietary data obtained by food frequency questionnaire covering previous 5 years. Method of fiber calculation was not specified.	Those consuming high fiber, low protein diets had lowest risk of colorectal cancer. Fiber was protective against colon cancer for males. Fiber was protective for rectal cancer for both males and females.	Data analysis was not controlled for micronutrients or fats.
Freudenheim et al., 1990 (Ref. 9).	Case control, Western New York.	428 colon cancer cases (223 males, 205 females); 422 rectal cancer cases (145 males, 277 females); 428 community controls (223 males, 205 females).	Participants interviewed regarding frequency of consumption of foods for 1 year prior to onset of symptoms. Fiber was part of normal diet (calculated by Southgate's tables or Lanza and Butrum).	Colon cancer risk decreased with intake of grain fiber for males and females, and with fiber from fruits and vegetables for males. Insoluble grain fiber was associated with reduced cancer risk more strongly than soluble fiber. Risk of rectal cancer was reduced in those consuming more fruit or vegetable fiber but not grain fiber.	Data analysis was not controlled for micronutrients or fat.

TABLE 2.—DIETARY FIBER AND COLORECTAL CANCER: CASE CONTROL STUDIES—Continued

Study	Type and Location	Subjects	Methods	Results	Comments
Hoff et al., 1986 (Ref. 15).	Case control,	155 men and women (78 with colonic polyps and 77 without polyps.	Subjects were participating in colon polyp endoscopic screening project. They recorded food intake for 5 consecutive weekdays. Bread was analyzed, gravimetrically, for total fiber. Fiber in other dietary components estimated by use of computerized Norwegian food composition data base.	Intakes of fiber was significantly less and total carbohydrate lower in patients with large polyps vs. those without polyps. Differences in intake of cruciferous vegetables, vitamin C, animal protein were not significant. Patients with large polyps consumed significantly more fat than patients without polyps. A lower intake of vitamin C or cruciferous vegetables correlated with the presence of multiple polyps.	Individuals were unaware of their polyp status when completing dietary information, a major strength of the study. Shows a protective effect of dietary fiber and total carbohydrates. Cruciferous vegetables and vitamin C intakes were protective against multiple polyp development.
Kune et al., 1987 (Ref. 21).	Case control, Melbourne, Australia..	392 colon cancer patients; 323 rectal cancer patients 727 community controls.	Patients were identified over a 1-year period. Usual diet, covering previous 20 years, was determined by interview with dietitian. Seasonal variations in diet were accounted for. Cancer patients were interviewed postoperatively in the hospital. Nutrients analyzed for included protein, fat, fiber, energy, **β carotene and vitamin C.**	Variables not contributing to, or contributing very little to, variation in colorectal cancer risk included fats; carbohydrates; fiber from pulses, nuts, seeds; fruit; cereals; energy; retinol in the diet; meats; and milk products (not milk drinks). Combination of high fiber, high vegetable diet was protective against colorectal cancer.	Difficult to interpret interaction effects. Type of fiber (soluble vs insoluble) was not analyzed.
Lee et al., 1989 (Ref. 23).	Case control, Singapore, China.	132 colon cancer patients; 71 rectal cancer patients—all hospital based 426 controls selected from other wards of the same hospital.	Dietary intake was calculated from food frequency questionnaire, providing information of usual dietary intake one year prior to interview. Fiber intake calculated from investigator's own determinations of fiber in local foods, as well as from food composition tables.	Colon cancer: significant protective effect from cruciferous vegetables. No significant effect of dietary fiber. High meat/low vegetable intake was a risk factor. Rectal cancer: significant protective effects noted for cruciferous vegetables, total vegetables, **β-carotene, and total dietary fiber.**	Number of cases (especially of rectal cancer) was small. Cruciferous vegetable intake and a high vegetable to meat intake ratio cited as most strongly protective factors. Fiber protective only for rectal cancer.
Slattery et al., 1989 (Ref. 41).	Case control, Utah	410 colon cancer cases. Combines patient data from 2 previous studies.	Dietary data obtained by food frequency questionnaire within 6 months of diagnosis. Data collected referenced 2-5 yrs before diagnosis of colon cancer. Crude dietary fiber calculated from prediagnosis food intake. Base diet was precancer diagnosis.	Highest quartile of crude fiber intake correlated with ↑ risk of death. No clear intake response effect.	Uses crude dietary fiber.

TABLE 2.—DIETARY FIBER AND COLORECTAL CANCER: CASE CONTROL STUDIES—Continued

Study	Type and Location	Subjects	Methods	Results	Comments
Slattery et al., 1988 (Ref. 40).	Case control, Utah	231 cases of colon cancer 391 controls: 185 males & 206 females. Cases and controls were all caucasians. Controls selected by random digit dialing.	Subjects were interviewed about diet 2 years prior to diagnosis. Dietary fiber intake calculated from some direct food analyses or from tables. Values computed for neutral detergent fiber, dietary fiber, and crude fiber based on food frequency questionnaire interview.	Significant dose-response risk reduction for crude fiber in males. Weak inconsistent effect for neutral detergent fiber. No effect of dietary fiber (analyzed by method of Bitner) or grain fiber. Data for females was similar, but 95% confidence intervals included 1.0. Significant intake-response risk reduction for fruit fiber in males. Lesser effect for vegetables, no effect for grain fiber. In females, vegetables showed a significant protective effect. Fruit fiber followed a dose response but 95% confidence intervals included 1.0. Data adjusted for calorie intake age and elevated body mass index (risk factors for colon cancer in this study) and Mormon church membership.	This study is one of the few published studies that examined the effect of several analytically defined fiber fractions on colon cancer risk. Crude fiber was the fraction most strongly associated with risk reduction. The authors note that the number of cases limits the ability to be more detailed about fiber types (sugar composition, etc.) or monitor differing effects on proximal vs. distal colon.
Tuyns et al., 1987 (Ref. 44).	Case control, Belgium	818 cases of colon or rectal cancer; 2851 controls in 2 provinces of Belgium with differing dietary habits.	Patients asked about usual weekly intake for 1 week before onset of illness or at time of interview for controls. Total dietary fiber was calculated at 17.5–22.8 g/day (Southgate tables).	Significant ↓ risk of colorectal cancer with ↑ fiber consumption in both sexes and in both provinces. When adjusted for calorie intake, dose response was stronger. Also noted was a protective dose response for "polysaccharides" (starch) when adjusted for calorie intake.	Overall, showed a protective effect of total fiber.
West et al., 1989 (Ref. 48).	Case control, Utah	231 colon cancer cases: 112 males and 119 females. 391 controls: 185 males and 206 females from same community.	Food intake from subject's diets assessed by a food frequency questionnaire for the 2–3 yrs prior to interview. Fiber calculated from USDA data base and analyses of grocery foods. Data not controlled for micronutrient or fat intake.	This study reports a statistically significant ($p<0.10$) effect of crude fiber on reducing risk of colon cancer in males and females, after adjusting for age, body mass index, and energy intake. A modest intake response effect was seen for both sexes.	Apparent fiber effect may have been due to other factors in fruits and vegetables. 90% confidence intervals used in statistical analysis.
Wohlleb et al., 1990 (Ref. 50).	Case control, Arkansas.	Male VA patients: 43 with resected colorectal cancer 41 elective surgery patients.	Self administered questionnaire used to estimate approximate weekly intake of 55 food items (surveyed present diet), selected to estimate intakes of fat, fiber, vegetables, and meat. Total food consumption not recorded; did take weight and height measurement.	Study showed protective effect of wheat bran and cauliflower. Luncheon meats associated with increased risk.	Study does not examine fiber per se. Small sample size.

TABLE 3.—DIETARY FIBER AND COLORECTAL CANCER: COHORT STUDIES

Study	Type and location	Subjects	Methods	Results	Comments
Heilbrun et al., 1989 (Ref. 13).	Cohort study, records reviewed retrospectively. Hawaiian Japanese.	Subjects chosen from a group of 8,006 Hawaiian Japanese. 102 colon cancer cases; 60 rectal cancer cases.	Subjects followed for cancer occurrence for 17-20 yrs. Subjects consumed usual diet. Fiber calculated from a single 24 hr. recall taken upon entry into study in 1965-1968. Range of calculated dietary fiber intake was 1.3-43.2 g/day. Method of calculating dietary fiber not clear from text.	No effect of dietary fiber on relative risk of colon cancer in entire cohort. When group was divided in half (based on median fat intake) fiber conferred a significant protective effect only in the "low fat" half of the cohort. Vegetables/fruits also showed protective effect.	Authors consider results "preliminary" because limited #'s of cases precluded definitive analysis of fat effect. As in many other DF studies, fruits and vegetables also showed a protective effect. Only one 24 hour dietary recall (15 years before end of study) interview used to assess fiber intake. This may not accurately assess habitual diet.
Willet et al., 1990 (Ref. 49).	Prospective cohort	88,751 subjects (female nurses, 30-55 years old) available for follow up; 150 cases of adenocarcinoma of colon.	Study of the relationships between intakes of meat, fat, and fiber and colon cancer. Follow up since 1976. Dietary questionnaire used to estimate fiber from usual diets. Used crude dietary fiber or Southgate tables.	No evidence for protective effect of crude dietary fiber on colon cancer. High intake of crude fruit fiber, but not vegetable or cereal fiber, was protective. However, adjusted for red meat consumption, the effect disappeared.	

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21 CFR PART 101

[Docket No. 91N-0099]

RIN 0905-AB67

Food Labeling: Health Claims; Dietary Fiber and Cardiovascular Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that after review of the available evidence, it tentatively finds that a basis does not exist on which to authorize the use on foods, including dietary supplements, of health claims relating to the association between dietary fiber and cardiovascular disease. While an association appears to exist between consumption of fiber-rich foods and reduced risk of cardiovascular disease, FDA tentatively finds that it cannot attribute this effect to the fiber itself. Therefore, FDA specifically requests comments on this topic. FDA has reviewed the relationship between this dietary component and this disease under the provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the 1990 amendments.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0316.

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535), which amended the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorize the Secretary of Health and Human Services (the Secretary) to issue regulations authorizing nutrient content and health claims on the label or labeling of foods. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)).

Published elsewhere in this **Federal Register** is a proposed rule to establish general requirements for health claims that characterize the relationship of nutrients, including vitamins and minerals, herbs, or other nutritional substances (referred to generally as "substance" to a disease or health related condition on food labels and in labeling. In this companion document, FDA has tentatively determined that such claims would only be justified for substances in dietary supplements, as well as in conventional foods, if the agency determines, based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The 1990 amendments also require (section 3(b)(1)(A)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x)) that within 12 months of their enactment, the Secretary shall issue proposed regulations to implement section 403(r) of the act (21 U.S.C. 343), and that such regulations shall determine, among other things, whether claims respecting 10 topic areas, including dietary fiber and cardiovascular disease, meet the requirements of the act.

In this document, the agency will consider whether a claim on food or

food products, including dietary supplements as well as conventional foods, on the relationship between dietary fiber and cardiovascular disease would be justified under the standard proposed in the companion document entitled "Food Labeling: General Requirements for Health Claims for Food: Proposed Rule."

B. Basis for Considering a Claim Relating Dietary Fiber and Cardiovascular Disease

1. Cardiovascular Disease

Cardiovascular disease is a major public health problem in the United States. Coronary heart disease (CHD) is the most common, most frequently reported, and most serious form of cardiovascular disease. CHD and stroke kill nearly as many Americans as all other diseases combined. Cardiovascular disease, primarily CHD is also among the leading causes of disability. These facts remain true despite the dramatic decline over the past 15 years in the death rate from cardiovascular disease: 35 percent for all cardiovascular disease, 40 percent for CHD, and more than 50 percent for stroke (Ref. 64). Changes in lifestyles, risk factor reduction, and medical intervention are major contributors to this decline (Ref. 64).

In order to be consistent with the magnitude of the public health problem and with the conclusions of the Federal government and other reports from recognized scientific bodies such as the National Academy of Sciences (NAS) and the Life Sciences Research Office (LSRO) (Refs. 40, 48, 63, 65, and 66), the focus of this document is CHD rather than the broader area of cardiovascular disease. CHD is not only considered to be the most common and most serious, but is also the earliest form of cardiovascular disease, frequently producing symptoms and health problems in middle-aged adults (Ref. 48). Despite a declining death rate from CHD since the mid 1960's, CHD still accounts for more deaths than any other disease or groups of diseases (Ref. 63). More than 1.25 million heart attacks occur each year (two-thirds occur in men), and more than 500,000 people die as a result (Ref. 63). In the United States, it is very common for significant pathogenesis of CHD to occur without easily detectable symptoms (Ref. 66). Thus, the total affected population is considerably larger than the statistics on death and illness would indicate. In addition to its impact on the nation's health, CHD costs the U.S. economy over $50 billion annually (Ref. 63).

2. Dietary Fiber

Dietary fibers are comprised of components of plant materials that are resistent to human digestive enzymes (Refs. 39 and 46). These components are predominantly nonstarch polysaccharides and lignin and may include, in addition, associated substances (Ref. 46). To date, the best documented and most accepted nutritional role for dietary fibers is for normal bowel function and health (Refs. 39, 49, and Canadian comments: FDA Docket No. 91N-0099). It is generally assumed that current fiber intakes in the United States of 10 to 15 grams (g) per day (6 to 7 g per 1,000 kilocalories (kcal) are less than optimal for meeting these needs (Refs. 36 and 39). Significant increases in this level of intake have been recommended frequently (Ref. 39).

Based on currently available analytical methods, dietary fiber is frequently measured as total dietary fiber and as the subcomponents of soluble and insoluble fibers (Ref. 39). Until recently, epidemiologic and other studies were not able to evaluate total dietary fiber intake because the majority of food composition tables contained no values for total dietary fiber content of foods. In addition, no standardized definitions of dietary fiber or dietary fiber components have been agreed upon.

Naturally occurring fibers in food are usually a mixture of the insoluble fibers such as cellulose and lignin; soluble fibers such as pectins, gums, and mucilages; and combinations of soluble and insoluble fibers such as hemicelluloses (Ref. 40). The proportions and types of fiber subcomponents vary among foods (e.g., oatmeal contains relatively large amounts of soluble fiber, and whole wheat bread contains relatively large amounts of insoluble fiber), and fiber content also varies within a food item or food group depending on the maturity of the plant, storage and ripening conditions, and food processing techniques used, if any.

In evaluating the biological effects and health consequences of dietary fiber intake, dietary fiber intake has been expressed as:

(a) Total dietary fiber or as the major fiber subcomponents (soluble and insoluble fibers);

(b) Fiber-containing foods (e.g., whole grains, legumes, fruits, vegetables);

(c) Fiber-rich food isolates (e.g., wheat bran, oat bran, corn bran, soy isolates); or

(d) Isolated and purified fibers (e.g., cellulose, pectins, lignin).

3. Relationship of Dietary Fiber and Cardiovascular Disease: Theoretical Basis

Many risk factors contribute to the development of cardiovascular disease, and specifically to CHD. There is general agreement that elevated blood cholesterol levels are one of the major "modifiable" risk factors in the development of CHD (Refs. 63 through 66). Federal government and other review (Refs. 48 and 63 through 66) have concluded that there was substantial epidemiologic and clinical evidence to indicate that high blood levels of total cholesterol and low density lipoprotein cholesterol (LDL-cholesterol) are reliable indicators of the development, severity, and rates of atherosclerosis (inadequate circulation of blood to the heart due to narrowing of the arteries) and constitute a major contributor to CHD (Refs. 48 and 63 through 66). Factors that decrease total blood cholesterol and LDL-cholesterol also tend to decrease the risk of CHD. Thus, it is generally accepted that total blood cholesterol and LDL-cholesterol levels can predict the risk of developing CHD, and that dietary factors affecting blood cholesterol levels are related to CHD (Refs. 48 and 63 through 66).

Populations with relatively low serum cholesterol levels tend to have dietary patterns that are low in fat, especially saturated fat and cholesterol, and that are relatively high in fiber-rich foods (e.g. fruits, vegetables, and whole grain cereals) (Refs. 48 and 63 through 66). Because of the relationship between serum cholesterol and CHD, all current dietary guidelines in the United States recommend dietary patterns that are likely to lower serum cholesterol levels: Reductions in dietary intakes of fat, saturated fat, and cholesterol and increases in intakes of vegetables, fruits, grain products, and cereal products (Refs. 48, 62, 63, and 66).

The association between dietary patterns rich in fibercontaining foods and lower levels of serum cholesterol is the theoretical basis for consideration of the appropriateness of a health claim for dietary fiber and reduced risk of developing CHD. Various beneficial health effects, including effects on lipid (fat) metabolism, have been suggested for fiber-containing foods and for dietary fiber, particularly the soluble dietary fiber component (Ref. 40). For these reasons, FDA limited its review of the relationship of dietary fiber and cardiovascular disease to dietary intake of soluble fiber effect on blood lipid levels and to risk of developing CHD. Based on conclusions from Federal

government reviews, total blood and LDL-cholesterol were accepted as valid indicators of risk of developing CHD. This focus is most consistent with current dietary guidelines for the U.S. population (Refs. 48 and 62 through 66).

(The relationship of dietary fiber to cancer is addressed in a companion document published elsewhere in this issue of the **Federal Register**. The relationship of cardiovascular disease to lipids and to omega-3 fatty acids are also addressed in companion documents published elsewhere in this **Federal Register**.)

C. Dietary Fiber: Regulatory and Legislative History

1. Early Claims for use of Dietary Fiber

Health attributes for fiber-containing foods have been claimed for over 100 years. Early interest focused on the benefits of wheat bran as a promoter of regular bowel function. Health claims for wheat bran on breakfast cereal packages became popular in the early 1900's, and the importance of adding "bulk" in the diet by the addition of dietary fiber appeared in advertisements that promoted the benefits of certain fibers as aids to digestion and to help relieve constipation. Such health claims on packages were mostly unregulated until after the act deemed products that carried such claims to be drugs and, therefore, subject to requirements of drug law. As a result, the use of health claims on food products virtually stopped until recently.

In 1941, the agency published regulations that included labeling requirements for "non-digestible carbohydrates" (6 FR 5921). At that time, foods having a high fiber content were valued because, when added to foods such as bread, lower caloric density was achieved. Based on the analytical procedures available at that time, the fibrous plant components of food had to be labeled as "crude fiber."

During the late 1970's, FDA sought to revise its regulations to include as fiber other fractions of carbohydrates, in addition to crude fiber, that are not digested by human enzymes. In doing so, the agency noted that the scientific evidence linking fiber to health outcomes was limited. In the **Federal Register** of December 21, 1979 (44 FR 75991), the agency stated that "* * * the relationship of dietary fiber to health remains controversial." Current § 105.66 (21 CFR 105.66) provides for the declaration of nonnutritive substances, but there is no regulation for declaration of fiber.

2. Food Additive Status

Substances that are added to food may be categorized based on their use as generally recognized as safe (GRAS) ingredients, food additives, or substances subject to a sanction or approval granted by the FDA or the United States Department of Agriculture (USDA) prior to September 6, 1958. The use of substances may be GRAS under the general principles set forth in § 170.30 (21 CFR 170.30), listed as GRAS in part 182 (21 CFR part 182), or affirmed as GRAS in Part 184 (21 CFR part 184). FDA's listings of food additives and affirmations that the use of a substance for direct addition to food is GRAS generally include the particular food categories in which (as defined in § 170.3(n)), and the specific technical effects for which (as defined in § 170.3(o)), the substance may be used.

"Fiber" is not considered to be either a food category or a technical effect according to the above definitions, and ingredients that are added to food are therefore not regulated as "fiber." However, FDA has regulated a number of isolated or purified fibers for specific technical effects in various food categories. For example, xanthin gum is listed as a food additive for use as a stabilizer, emulsifier, thickener, suspending agent, bodying agent, or foam enhancer (§ 172.645 ((21 CFR 172.695)); methyl cellulose is listed as a multipurpose GRAS substance ((21 CFR 182.1480)); and pectins are affirmed as GRAS for use as an emulsifier, stabilizer, or thickener (§ 184.1588). Guar gum is affirmed as GRAS for specific conditions of use that include those as an emulsifier, formulation aid, firming agent, and thickener (§ 184.1339). Guar gum has not been listed for use as a source of fiber, and under some circumstances, it has been shown to cause esophageal blockage and thus to be a health hazard. These and many other gums and fiber sources have no established history of food use, or safety as fiber supplements.

3. Dietary Fiber as Subjects of Health Claims

Prompted by the use (beginning in 1984) of information on high-bran cereal packages that high fiber diets may reduce the risk of cancer and by issuance of interim dietary fiber recommendations by the National Cancer Institute, FDA proposed in the **Federal Register** of August 4, 1987 (52 FR 28843), food labeling regulations to allow the use of health messages on labels and food labeling. The agency stated that food labeling could have an important influence on the public's food choices, and that truthful, nonmisleading health messages could increase consumer's understanding of the health benefits that can result from adhering to a sound and nutritious diet. This proposal set forth criteria for the evaluation of health claims.

In the **Federal Register** of February 13, 1990 (55 FR 5176), FDA published a reproposed rule that revoked the 1987 proposal and proposed to establish procedures permitting valid and reliable consumer information on food labels. The agency noted that the previous proposal was too ambiguous to be workable in preventing misleading claims. FDA thus proposed to tighten the requirements for health claims. The agency also proposed to evaluate the scientific evidence on six possible topics for health claims, including dietary fiber and cardiovascular disease.

On November 8, 1990, the President signed the 1990 amendments, which authorize FDA to issue regulations concerning claims on the label or labeling of foods that characterize the relationship between a substance and a disease or a health-related condition. As stated above, this law identified 10 substance-disease topics, including dietary fiber and cardiovascular disease.

D. Evidence Considered in Reaching the Decision

FDA has reviewed all relevant scientific evidence on dietary fiber and its effects on serum cholesterol. The scientific evidence reviewed by the agency included the summary, conclusions, and recommendations of all recent Federal government comprehensive reviews and dietary guidelines on this topic area: "The Surgeon General's Report on Nutrition and Health" (Ref. 63), the National Cholesterol Education Program's (NCEP) "Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults" (Ref. 65), the NCEP "Population Panel Report" (Ref. 66), the USDA and DHHS' "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 62), and the DHHS' "Healthy People 2000, National Health Promotion and Disease Prevention Objectives" (Ref. 64).

The agency also reviewed the evidence and conclusions in other nongovernmental documents: The LSRO report on "Physiological Effects and Health Consequences of Dietary Fiber" (Ref. 39), the National Research Council's (NRC) "Diet and Health, Implications for Reducing Chronic Disease Risks" (Ref. 48), the NRC's "Recommended Dietary Allowances"

(Ref. 49), and World Health Organization's (WHO) "Diet, Nutrition, and the Prevention of Chronic Diseases" (Ref. 71).

The agency updated these reports by independently reviewing all human studies and all reviews published since the Federal government and other authoritative documents completed their reviews of the literature. FDA considered animal studies to the extent that they helped explain possible mechanisms of action. FDA also contracted with LSRO to independently evaluate current evidence since their 1987 fiber report. A summary of the LSRO report, "Dietary Fiber and Cardiovascular Disease" (Ref. 40) is included in this review.

Finally, to ensure that its review of relevant evidence was complete, FDA requested, in the **Federal Register** of March 28, 1991 (56 FR 12932), scientific data and information on the 10 specific topic areas identified in section 3(b)(1)(A) of the 1990 amendments. Dietary fiber and cardiovascular disease were among the 10 subjects for which the agency requested information.

E. Summary of Comments in Response to FDA Request for Scientific Data and Information

FDA received 1 comment in response to the February 13, 1990 reproposed final rule and 19 comments in response to the notice in the **Federal Register** of March 28, 1991 (56 FR 12932), concerning dietary fiber and CHD health claims.

One comment from a representative of industry was received in response to the reproposed final rule. Based on the findings of several authoritative documents and a review of additional references published since 1988, the comment suggested that the currently recommended low fat/low cholesterol diet could be made more effective in lowering blood cholesterol and risk of CHD by the inclusion of soluble fiber.

Of the 19 comments received in response to the March 28, 1991 notice requesting scientific data on dietary fiber and cardiovascular disease (under Docket No. 91N-0099), 13 were from industry; 4 from professional organizations; 1 from a consumer; 2 from health professionals; 2 from scientists; and 1 from the Government of Canada. The industry comments included primarily literature reviews and unpublished studies, which were included in FDA's science review of the scientific evidence. One food company did not support health claims on dietary fiber and risk of developing heart disease because of the multifactorial nature of the disease and the seriousness of the disease and suggested that medical intervention is required for proper diagnosis and monitoring of heart disease. All other industry and trade submissions supported the use of health claims.

Of the six comments from professional organizations, three submitted research reports generally supporting a health claim. Another called attention to the need for caution to avoid consumer misunderstanding. One comment pointed to the need to consider the overall diet context. Another took the position that the data on fiber and cardiovascular diseases are insufficient to support a claim.

The citizen comment included a literature search but no comment about the health claim issue.

The two comments from health professionals were divided. Although both provided data supporting their individual position, one was in favor of health claims and the other was not.

The Director General, Food Directorate, Health and Welfare, Canada, submitted information on the regulatory status of health claims in that country. The Canadian government is not in favor of health claims on fiber-containing foods because it is difficult to disassociate the metabolic effects of complex carbohydrates and the low fat content of these diets from those of dietary fiber. The comment said that this finding does not diminish the importance of diet as a factor in the maintenance of health but reinforces the importance of the whole diet rather than the contribution of individual components. Interactions between nutrients and between nutrients and nonnutrient components of the diet probably alter the likelihood of disease.

II. Review of Scientific Evidence

A. Federal Government Documents

Several Federal government documents (Refs. 62 through 64, 66, and 67) have concluded that the evidence for a role of dietary fiber in lowering the risk of cardiovascular disease, and more specifically CHD, is inconclusive.

The Surgeon General's Report (Ref. 63) comprehensively reviewed human and animal studies on CHD and blood cholesterol and noted that an extensive body of evidence supported by epidemiologic, metabolic, and animal studies has established the relationship among intake of saturated fat, high blood cholesterol, and increased rates of CHD (Ref. 63). The report also noted that based on ecological studies in several countries, dietary intakes that are high in starch (e.g., 60 to 70 percent of calories), such as those in Asian countries, are associated with low plasma cholesterol and a low rate of CHD. These diets tend to be high in fiber, lower in energy, and very low in fat, especially saturated fat and cholesterol. Several short-term clinical studies that were reviewed showed an association between water-soluble fiber fractions, such as oat bran, guar gum, and pectin, and cholesterol-lowering effects in hypercholesterolemic subjects (Refs. 7, 22, and 32). The report concluded that current evidence suggests the prudence of increasing consumption of whole grain foods and cereal products, vegetables (including dry beans and peas) and fruits (Ref. 63).

The recommendations of the NCEP (Refs. 65 and 66) are based on the goals of reducing blood cholesterol, and low density lipoprotein (LDL) cholesterol in particular, and providing a diet that is nutritious and palatable (Ref. 65). The LDL-cholesterol levels are directly correlated with risk for CHD (Ref. 65). The NCEP report concluded that changing American eating patterns will help lower blood cholesterol levels, thus reducing the risk of developing CHD. In this regard, the panel recommended lowering the intake of dietary saturated fatty acids, total fat, and cholesterol, and increasing the intake of fruits, vegetables, whole grain products, and legumes. These food items will help meet nutritional needs for minerals, vitamins, dietary fiber (including soluble fiber), and complex carbohydrates (Ref. 66).

The USDA/DHHS report "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 62) concluded that dietary fiber is important for proper bowel function and to reduce symptoms of chronic constipation, diverticular disease, and hemorrhoids. It stated that "populations like ours with diets low in dietary fiber and complex carbohydrates and high in fat, especially saturated fat, tend to have more heart disease * * *" (Ref. 62). The dietary guidelines noted the possibility that the benefit from a diet with more fiber may be from the food or component of the food providing the fiber rather than from the fiber alone. The USDA/DHHS dietary guidelines recommended choosing a diet with plenty of vegetables, fruits, and grain products.

In "Healthy People 2000," the Public Health Service and DHHS identified increased consumption of complex carbohydrates and fiber-containing foods by adults as a specific risk reduction objective (Ref. 64). Recommendations included increasing consumption of vegetables (including legumes) and fruits to five or more servings daily, and increasing

consumption of grain products to six or more daily servings. The report noted that dietary patterns with higher intakes of vegetables (including legumes), fruits, and grain products are associated with a variety of health benefits, including decreased risk for some types of cancer (Ref. 65). It was also noted that the association between diets high in complex carbohydrates (and fiber) and reduced CHD and diabetes mellitus is difficult to interpret because such diets tend to be lower in energy (calories) and fats, especially saturated fat and cholesterol. "Further research is needed to clarify whether the effect of dietary fiber on blood lipids is an independent effect, and if so, to quantify the relationship. (Ref. 64).

B. Other Review From Recognized Scientific Bodies

Several other comprehensive reviews from recognized scientific bodies on the role of nutrition and health have been published in recent years (Refs. 39, 40, 48, 49, and 71). The conclusions reached in these reports are similar to those reached in the Federal reports noted above.

In 1985, the Department of national Health and Welfare, Health Protection Branch, of the Canadian government convened an expert advisory committee to evaluate dietary fiber issues (Ref. 46). This committee noted that the relationship between the physico-chemical properties of dietary fibers and their physiological effects is difficult to evaluate partly due to the complexity of the interactions of mixed fibers in foods and in some instances, lack of uniformity in testing procedures. They recommended that manufacturers of food products to which nonnative and/or novel fibers have been added to increase dietary fiber content may be required to provide evidence substantiating the safety and efficacy of these products in terms of accepted physiological effects. Nonnative fibers were defined as fibers from traditional foods but not naturally occurring in the foods to which they have been added; novel fibers are those which have not traditionally been part of the human diet. They also recommended that manufactures of products which have been substantially enriched with native fibers should also be prepared to provide proof of efficacy on request. They noted that evidence is lacking that commercially produced products containing some of these materials will, when consumed, produce effects that the public has come to expect of fiber containing foods. They recommended more research to elucidate physiological forles of dietary fiber.

LSRO, in its 1987 report entitled "Physiological Effects and Health Consequences of Dietary Fiber" (Ref. 39), concluded that dietary fiber is an integral part of a healthy diet. However, LSRO stated that the available evidence is not sufficient to support specific, quantitative recommendations on the role of dietary fiber for the prevention of specific diseases in the general, healthy population. LSRO recommended, therefore, that a wide variety of fiber-rich foods be consumed, such as whole grain products, fruits, vegetables and legumes, because of the diversity of effects of various components of dietary fiber. The report stated that the foods eaten in the amounts suggested would provide about 20 to 35 g of dietary fiber per day (approximately 10 to 13 per 1,000 kcal) for the healthy, adult population (Ref. 39).

The 1989 NRC, NAS report, "Diet and Health—Implication for Reducing Chronic Disease Risk" (Ref. 48) reviewed epidemiologic and clinical studies and noted that increased consumption of fiber-rich foods was associated with a lower risk of developing CHD and other diseases. Diets providing 45 g of dietary fiber from fresh fruits, vegetables, and legumes (Refs. 20, 23, and 29), and with an isocaloric replacement of either sugar or bread with a mixture of vegetables providing 40 g per day of dietary fiber (Ref. 21), were associated with lower blood cholesterol levels. The NAS report concluded that although epidemiologic and clinical studies indicate that a diet consisting of complex carbohydrate and high-fiber foods may be associated with a lower risk of CHD, colon cancer, diverticulosis, hypertension, or gallstone formation, there is "no conclusive evidence that it is dietary fiber, rather than the other components of vegetables, fruits, and cereal products, that reduces the risk of those diseases" (Ref. 48). The NAS report recommended increased consumption of vegetables, fruits, breads, cereals, and legumes (Ref. 48).

The WHO report "Diet, Nutrition, and the Prevention of Chronic Diseases" (Ref. 71), stated that dietary factors are known to influence the development of a wide range of chronic diseases, including CHD. The report stated, the "affluent" type of diet that often accompanies economic development is energy (calorie)-dense. People consuming these diets characteristically have a high intake of fat (especially saturated fats) and free sugars and a relatively low intake of complex carbohydrates (from starchy, fiber-containing foods)." All of these factors influence serum cholesterol and their combined effects "may be important in modifying the rate of progression of atherosclerosis."

Based on direct experimental evidence concerning the association between dietary fiber, stool bulk, and intestinal transit time, WHO recommended a lower limit of intake of 16 grams per day of dietary fiber (nonstarch polysaccharides) and an upper limit of 24 g per day. This goal is consistent with an intake of about 27 to 40 g per day of total fiber, which includes other fiber components (Ref. 71).

The 1991 LSRO report "Dietary Fiber and Cardiovascular Disease" (Ref. 39) reviewed epidemiological studies since LSRO's 1987 report and found no new evidence to support reduced risk of CHD from an intake of dietary fiber and particularly soluble fiber. LSRO found that studies suggest that soluble fiber is hypocholesterolemic, while insoluble fiber is not. "Whether the observed effects result strictly from the fiber or from other components of the fiber-rich food or to a combination of these remains to be determined. (Ref. 39). The report also noted that it is also not known if a fiber present in a food is the same as when it has been extracted and purified.

C. Review of the Scientific Evidence: Evidence for an Association Between Intake of Soluble Dietary Fiber and Coronary Heart Disease

All of the government and other reviews by recognized scientific bodies cited above reviewed the evidence for an association between the intake of dietary fiber and CHD, one of the major cardiovascular diseases. It has been established that appropriate dietary intervention, resulting in lower serum total cholesterol, can reduce the incidence of CHD and hence the incidence of cardiovascular disease (Ref. 66; companion document on proposed rules for Health Claims: Lipids and Cardiovascular Disease). The review of studies that follows will also focus, as in the Federal government and other reviews by recognized scientific bodies, on evidence for the beneficial effects of dietary fiber, specifically soluble dietary fiber, on lowering blood total and LDL-cholesterol levels with the ultimate outcome of reduced risk of developing CHD.

The comprehensive government and other reviews by recognized scientific bodies concluded, based on evidence presented to date, that dietary patterns that included fiber-rich foods were associated with lower levels of blood

cholesterol and hence lower rates of CHD. Additionally, these reports suggested that if fiber has an effect on serum cholesterol levels, it is probably related to the soluble dietary fiber component, rather than to total, or insoluble, dietary fiber. However, these reports also noted the lack of evidence that would substantiate that it is the soluble fiber component of these foods, rather than some other concomitant change in nutrient intake or weight control, that is the responsible agent for these associations. For this reason, the nutrition guidelines that have been promulgated have emphasized changes in dietary patterns rather than specifically focusing on changes in soluble fiber intakes.

The agency, therefore, concluded that to provide adequate support for a role for dietary fiber, and in particular soluble dietary fiber, in reducing the risk of CHD, the updated evidence would need to specifically show that soluble dietary fiber at some specific level in the total diet has an effect.

1. Criteria for Selection of Human Studies

The agency evaluated all human data published after 1987, the time at which the NAS report (Ref. 48) completed it's review of the scientific evidence. The criteria that the agency used to select pertinent recent studies required that the studies:

(1) Present primary data and adequate descriptions of study design and methods;

(2) Be available in English;

(3) Include estimates, or enough information to estimate, soluble dietary fiber intakes;

(4) Include direct measurement of blood total cholesterol and other blood lipids related to CHD;

(5) For intervention studies, be conducted for a long enough duration to reasonably assure stabilization of blood lipids (greater than or equal to 3 weeks duration); and

(6) Be conducted in persons who generally represent the healthy U.S. population (adults with blood total cholesterol levels less than 300 miligrams (mg) per deciliter (dl).

2. Criteria for Evaluation of Human Studies

FDA evaluated the results of studies against general criteria for good experimental design, execution, and analysis. The criteria that the agency used in evaluating these studies included reliability and accuracy of the methods used in nutrient intake analysis, including measurements of total dietary soluble fiber and total dietary fiber; measurement of study endpoints (i.e., blood total cholesterol and other blood lipids related to CHD); and general study design characteristics, including randomization of subjects, appropriateness of controls, selection criteria for subjects, attrition rates (including reasons for attrition), potential for misclassification of individuals with regard to dietary intakes, presence of recall bias and interviewer bias, recognition and control of confounding factors (for example, intake of saturated fat and other nutrients, monitoring body weight, and control of weight loss), appropriateness of statistical tests and comparisons, and statistical power of the studies.

The availability of information on the total dietary fiber and total dietary soluble fiber content of baseline, treatment and control diets; the soluble fiber content of the test substance; and nutrient intakes were deemed highly desirable. In many cases, analytical or calculated values were not given for total fiber or for total soluble fiber components of the test diet, although in some cases, it was possible to roughly estimate soluble fiber values above baseline levels from available data on the amount and type of test material added to the diet.

Several research reports were based on studies of only a few weeks duration. To ensure that results were not reflective of transient changes, such as failure of blood cholesterol levels to stabilize to the dramatic changes in dietary patterns that occur with the introduction of large amounts of test substances, studies with treatment periods of less than 3 weeks were not considered in the agency's evaluation of scientific evidence.

The agency excluded studies that were published in abstract form because they lacked sufficient detail on study design and methodologies, and because they lacked necessary primary data. Studies using special population groups, such as insulin-dependent diabetics, individuals with very high serum cholesterol (mean greater than 300 mg per dL), children with hypercholesterolemia, and persons who had already experienced a myocardial infarction were also generally not weighed heavily because the relevance of health claims for the general healthy U.S. population is the key question. (Descriptions of all available studies are, however, included in Table 1).

3. Summary of Human Studies

Responses of blood cholesterol levels to dietary treatment are affected by many factors, including initial (baseline) blood cholesterol levels and dietary factors (i.e., the level of saturated fat and cholesterol in the diet) (Refs. 48, 65, and 66). Previous reviewers have generally concluded that in persons with relatively higher baseline levels of blood cholesterol, responses to treatment protocols tend to be of larger magnitude than is seen in persons with more normal blood cholesterol levels (Refs. 48, 65, and 66). For this reason, FDA separately evaluated studies on mildly to moderately hypercholesterolemic individuals (persons with elevated blood total cholesterol levels of 200 to 300 mg per dL) and normocholesterolemic individuals (persons with normal blood total cholesterol levels, less than 200 mg per dL). Since dietary intakes of saturated fat and cholesterol may also affect blood cholesterol levels, FDA also separated its review of studies on the basis of whether fiber effects are being evaluated as part of a "typical" American diet (approximately 37 percent of calories from fat, 13 percent of calories from saturated fat, and greater than 300 mg of cholesterol daily), or whether the test protocols are incorporated into a Step I or similar (e.g., American Heart Association) dietary regimen (less than 30 percent of calories from fat, less than 10 percent of calories from saturated fat, and less than 300 mg cholesterol daily). Detailed summaries of the reviewed studies are in Table 1.

a. *Hypercholesterolemics: "typical" or "usual" diets.* In two metabolic ward studies of 3 weeks duration (Refs. 3 and 4), soluble fiber intakes of 7 to 8 g per day were associated with reductions of 8 to 12 percent in blood total cholesterol level as compared to baseline levels. In both studies, groups experienced some weight loss (approximately 2 to 3 pounds) during the study period. In one study (Ref. 4), blood total cholesterol levels were measured several times throughout the study. The lowest values were observed at an intermediate time; that is, the initial drop in blood cholesterol levels was followed by a trend towards return to baseline levels at the end of the 3-week test period.

In a randomized, controlled, intervention study where subjects were free-living, Van Horn et al. (Ref. 69) assigned 80 men and women (25 to 76 years; serum cholesterol of 213 to 285 mg per dL) to either a control group (regular diet) or a test group which consumed their regular diet plus a cereal providing 2 g of soluble fiber daily. After 4 weeks of intervention, the test group, as compared to the control group, had significantly different dietary intakes for a number of nutrients, including higher intakes of soluble and total fiber, and

lower intakes of saturated fat and cholesterol. Blood total cholesterol and LDL-cholesterol levels in the test group decreased by 6 percent and 9 percent, respectively, with no change in the control group.

Kahn et al. (Ref. 25), in a randomized, controlled, intervention study added four muffins containing a total of 6 g of soluble fiber to the daily diets of 16 free-living men and women. After 3 weeks, there were no significant differences in total blood cholesterol levels between test and control groups.

Kesaniemi et al. (Ref. 27), in a randomized, self-controlled, cross-over, intervention study, monitored 34 free-living men (serum cholesterol 223 to 238 mg per dL) who consumed a low fiber diet (3 soluble fiber daily) or a high fiber diet (13 g soluble fiber) for 8 weeks. When consuming the high fiber diet, blood total and LDL-cholesterol levels decreased significantly (5 percent and 7 percent, respectively). The high fiber group consumed significantly higher levels of vegetables, cereal, fruits, and berries, compared to the low-fiber group.

Kestin et al. (Ref. 28), in a randomized, double-blind controlled, cross-over study, fed diets containing 6, 7, or 10 g of soluble fiber per day to 24 men (29 to 61 years; serum cholesterol 186 to 293 mg per dL) for 4 weeks. The sources of soluble fiber varied among test groups. Compared to baseline, subjects consuming 10 g of soluble fiber per day had a significant decline in blood total cholesterol (5 percent), with the decrease mainly in the LDL-cholesterol fraction. The other levels of soluble fiber did not cause significant lowering of serum cholesterol.

In a 12-week randomized, double-blind, cross-over intervention study with two 6-week test periods and a 3-week washout between treatments, Lo and Cole (Ref. 43) fed diets containing 13 or 24 g total dietary fiber per day to 12 men and 8 women (27 to 60; serum cholesterol of 210 to 279 mg per dL). The difference in total dietary fiber intakes between the two protocols was due to the addition of soy fiber to the test diet. (Soy is a relatively rich source of soluble dietary fiber). The effects on blood cholesterol differed depending on order of dietary treatment. If soy-enriched diets were fed first, blood total and LDL-cholesterol levels decreased by 8 percent and 7 percent, respectively, compared to baseline. A significant decline (5 percent) in the LDL-cholesterol levels of the placebo group is also observed. However, when soy-enriched diets were fed after the base diet, there was no effect on blood cholesterol levels. Thus, most changes in blood cholesterol levels occurred during the first 6 weeks of treatment, regardless of diet group.

The effect of beta-glucan, a particular type of soluble fiber, was evaluated in a randomized, cross-over, intervention study by McIntosh et al. (Ref. 44). Twenty-one men (30 to 59 years; serum cholesterol 209 to 270 mg per dL) received a diet containing either 8 or 1.5 g added beta-glucan daily for 4 weeks. Total soluble fiber intakes from the two diets were held constant at 13 g per day. Treatment order has an effect, with the group receiving the beta-glucan-enriched diet first showing no changes in serum total cholesterol, while those consuming this diet as the second dietary protocol showed a decline in blood cholesterol levels.

The effectiveness of high dietary fiber on the blood cholesterol levels of men who had already suffered heart attacks was studied by Burr et al. (Ref. 13). In a 2-year intervention study, over 2,000 men (mean age 56 years) were randomly assigned to several diet groups. One group was given advice to decrease fat intake to less than 30 percent of calories and to increase the ratio of polyunsaturated fat to saturated fat. Another group was advised to increase cereal fiber intake to 18 g per day. There were no significant differences in total mortality or in blood cholesterol levels between these groups.

Bulk laxatives (e.g., psyllium) or gums have been used in several study protocols as sources of supplemental soluble dietary fiber. Stewart et al. (Ref. 55), in an intervention study, compared blood cholesterol levels of 175 elderly (mean age 77 years) who had consumed a bulk laxative rich in soluble fiber for at least 1 month with those who had not been users of these products. The period of use of the bulk fiber supplement ranged from 1 month to 1 year. Those taking greater than 15 g of supplemental soluble fiber per day had a 4 percent lower total blood cholesterol level than those taking less than 8 g of supplemental soluble fiber per day. The use of supplemental fiber without specification as to amount versus no use of supplemental fiber was not associated with any differences in blood cholesterol levels.

In a controlled intervention study, McIvor et al. (Ref. 45) gradually increased the soluble fiber intakes of 8 obese men and women with noninsulin dependent diabetes (ages 45 to 50 years; mean serum cholesterol 222 mg per dL) by increasing consumption of granola bars enriched with a concentrated source of soluble fiber. Up to 22 g of supplemental soluble fiber were consumed per day in addition to that contained in subject's usual diets. After 6 months, serum total cholesterol levels did not differ significantly from baseline levels.

Superko et al. (Ref 56), in a randomized, single blinded, cross-over study, evaluated the relative effects of two different types of an isolated soluble fiber source on blood cholesterol levels of 50 men (39 to 63 years; serum cholesterol of 205 to 282 mg per dL). The fiber supplement added approximately 10 of soluble fiber daily to the regular diet. Although differences were observed in blood cholesterol levels after 4 weeks, at the end of 8 weeks there was no significant difference between the fiber supplement and the placebo groups.

Twenty-six men (30 to 65 years; serum cholesterol 188 to 314 mg per dL) consumed their regular diets and also consumed either a bulk laxative rich in soluble fiber or a placebo prior to each meal for 8 weeks in a randomized, parallel, double-blinded, placebo-controlled, intervention study (Ref. 8). The fiber supplement added approximately 8 to 9 g of soluble fiber to the regular dietary intake. From baseline, the group on the soluble fiber-enriched protocol had a significant decrease in blood total cholesterol (15 percent) and LDL-cholesterol (20 percent).

In summary, several studies were reviewed in which conventional foods high in soluble fiber (e.g., beans or oatmeal) or enriched with soluble fibers (baked goods with added wheat, barley, or oat brans) (Refs. 3, 4, 13, 25, 27, 28, 43, 44, and 69) were used to increase the soluble fiber intakes of subjects. The study durations ranged from 3 weeks to 8 weeks, except for one 2-year study which was of limited value since it did not provide information on soluble fiber intakes (Ref. 13). Although information on total intakes of soluble fiber was not always provided, there was enough available information to make crude estimates of intake. These estimates suggested that, under study conditions used, intakes of soluble fiber above 6 to 12 g per day were generally associated with reductions in blood total and, when measured, LDL-cholesterol levels. The potential for differences in effectiveness among different sources of dietary fiber when total intakes are similar was suggested by two studies (Refs. 27 and 28) and by the equivocal results from several isolated sources of soluble fiber (Refs. 8, 45, 55, and 56).

Several studies used isolated sources of soluble fiber (psyllium and guar gum) either under standard pharmacological conditions in bulk form with meals (Refs. 8 and 55) or incorporated into

baked goods (Ref. 45) to increase soluble fiber intakes. Duration of studies ranged from 8 weeks to 1 year. Generally, much higher intakes of soluble fiber were achieved (15 or more per day) with use of supplements as compared to foods (approximately 2 to 12 g daily). One study of 6 months duration (Ref. 45) showed no effect on blood cholesterol levels, although the small sample size (n=8) may lack adequate statistical power. Another study showed rather small changes in blood cholesterol levels (4 percent) with 175 subjects consuming high (15 g or more) versus low (less than 8 g) of supplemental soluble fiber for 1 month to 1 year. Use versus nonuse of supplements showed no relationship to blood cholesterol levels. A third study showed 15 and 20 percent reductions in blood total and LDL-cholesterol after consuming 8 to 9 g of supplemental fiber for 8 weeks (Ref. 8). Finally, results of a fourth study suggested that effects may be transient (Ref. 56), with effects observed at 4 weeks disappearing by the end of 8 weeks.

b. *Hypercholesterolemics: Step 1 diets.* In several studies, the relative effectiveness of Step 1 diets (less than 30 percent calories as fats, less than 10 percent calories as satuated fat, and less than 300 mg cholesterol daily) with and without added soluble fiber were evaluated. In a metabolic ward study, Anderson et al. (Ref. 5) fed Step 1 diets containing 9 g soluble fiber per day to 10 men (40 to 70 years; serum cholesterol 200 to 320 mg per dL) for 3 weeks. The baseline diet contained 3 g soluble fiber daily. There were no significant decreases in total blood cholesterol following consumption of the high fiber diet, but LDL-cholesterol decreased significantly from baseline levels (8 percent decline).

Little et al. (Ref. 42), in a controlled intervention study, examined the effect of 4 types of dietary intervention on blood total cholesterol levels of 184 free-living men (58 to 61 years; serum cholesterol 240 to 267 mg per dL). After 8 weeks, declines in serum cholesterol were the same (approximately 5 percent) for both a low fat diet alone and for a low fat, high fiber diet (total dietary fiber of 40 to 45 g per day; no data on soluble fiber). The authors suggested that low fat rather than increased levels of dietary fiber were responsible for changes in serum cholesterol.

Demark-Wahnefried et al. (Ref. 16), in a randomized intervention study, monitored blood cholesterol levels in 81 men and women (20 to 65 years, mean baseline serum cholesterol of 271 mg per dL) consuming one of four dietary protocols for 12 weeks: Step 1 diet alone, Step 1 diet plus added soluble fiber from 50 g of oat bran, regular diet plus 50 g of oat bran, and regular diet plus 42 g of processed oat bran. Declines in serum cholesterol occurred in all groups. Blood cholesterol levels of groups consuming diets containing the higher soluble fiber (approximately 4 g added soluble fiber daily) did not differ from groups on a dietary regimen modified only in fat and cholesterol content.

Levin et al. (Ref. 37), in a randomized, double-blind, intervention study, followed 58 men and women (21 to 70 years; baseline serum cholesterol of 235 to 245 mg per dL) who consumed a Step 1 diet for 8 weeks followed by 16 weeks of treatment with a placebo or concentrated soluble fiber source. The total soluble fiber intake of the test diet was estimated at 15 g per day compared to intakes of 6 to 8 g daily on the Step 1 diet alone. The group consuming the high soluble fiber diet showed a significant decrease in total and LDL-cholesterol (6 and 9 percent, respectively) from baseline.

Several studies examined the effect of type of fiber on blood cholesterol levels. Keenan et al. (Ref. 26), in a randomized, controlled, double-blind, intervention study with cross-over, used a 6-week pretreatment period to adapt subjects to a Step 1 diet. Then, holding total soluble fiber intakes constant at approximately 6 to 7 g per day, the relative effectiveness of wheat versus oat cereals as the fiber-enriching source were compared. Effects on blood cholesterol levels varied, depending on the order of feeding of the diets supplemented with oat bran or wheat cereal. Interpretation of results was further complicated by the fact that the control group showed an initial decline in blood cholesterol levels followed by a return to baseline at the end of the study.

Bell et al. (Ref. 12), in a randomized, double-blind controlled, intervention study, compared the effects of three diets containing corn flakes (control), pectin-enriched, or psyllium-enriched cereals. Fifty-eight subjects (24 to 69 years; serum cholesterol 227 to 229 mg per dL) consumed Step 1 diet for 6 weeks followed by 6 weeks on the cereal plus Step 1 diets. Total soluble fiber intake for the three diets was relatively constant at 6 to 8 g per day. Blood total and HDL-cholesterol was decreased significantly (6 percent) on the psyllium-enriched but not the pectin-enriched diet.

Several studies evaluated the effectiveness of beta-glucan, a particular type of soluble fiber found in oat products. In a randomized, controlled, intervention study, 351 men and women (20 to 60 years, serum cholesterol 200 to 300 mg per dL) were assigned to one of three dietary regimens: regular diet, Step I diet, or Step I diet plus the addition of about 10 g total dietary fiber (7 to 8 g soluble fiber as beta-glucans) (Ref. 10). There was variable weight loss among treatment groups. No data were provided on total soluble fiber content of the diets. After 8 weeks, reductions in blood total and LDL-cholesterol (decreases of 8 and 10 percent, respectively) were greater with the Step I diet than with no dietary change. Somewhat higher reductions (decreases of 12 to 15 percent) were observed when beta-glucans were added to the Step I diet.

In a randomized, single-blind, controlled intervention study, 148 men and women (30 to 65 years; serum cholesterol 230 to 319 mg per dL) consumed Step 1 diets with either zero or 5 to 7 g of soluble fiber added by incorporation of various types of cereal products (Ref. 15). After 6 weeks, groups consuming diets containing 4 to 6 g of beta-glucan had significant declines in blood total cholesterol (7 to 10 percent) and LDL-cholesterol (10 to 16 percent) as compared to baseline. Blood total cholesterol levels of groups consuming diets containing 1 to 2.4 g daily of beta-glucan did not differ significantly from baseline.

In summary, in the 4 studies with hyperlipidemics consuming diets low in fat, saturated fat, and cholesterol, the addition of soluble fiber to the diets produced equivocal results on blood cholesterol levels, ranging from no effect (Refs. 16 and 42) to 6 to 9 percent declines in blood cholesterol levels when 15 g of soluble fiber per day were consumed for 16 weeks (Refs. 5 and 37). Source of soluble fiber was evaluated in four studies (Refs. 10, 15, 12, and 26). Results were equivocal in one study and suggestive of a source or specific type of soluble fiber component effect in the other studies.

c. *Normocholesterolemics: "typical" or "usual" diets.* Van Horn et al. (Ref. 65), in an epidemiological cross-sectional survey, evaluated baseline dietary assessment and blood cholesterol data from the Coronary Artery Risk Development in Young Adults (CARDIA) study. Dietary intakes were assessed by diet history. Of the over 5,000 men and women (18 to 30 years; normal blood cholesterol levels), there was an inverse and statistically significant correlation between total dietary fiber intake and blood total

cholesterol and LDL-cholesterol levels. Many other nutrient intakes were also correlated with blood cholesterol levels. No data were given on soluble fiber intakes.

Seven men with normal blood cholesterol levels (mean 187 mg per dL) consumed their regular diets for 3 weeks followed by the addition of a supplemental source of soluble fiber for an additional 3 weeks (Ref. 1). The added soluble fiber intake was estimated at 16 to 19 grams per day. Blood cholesterol levels decreased during the pretreatment diet phase. After 3 weeks of supplemental soluble fiber intake, total blood cholesterol levels decreased 16 percent from the level at the end of the pretreatment phase.

Gold and Davidson (Ref. 19), in a double-blind, intervention study, provided 2 muffins containing test fibers (oat bran, wheat bran, or wheat/oat bran combination) to 72 male and female medical students (25 to 37 years; mean blood cholesterol 178 mg per dL) for 4 weeks. Subjects were assigned to one of three treatment groups, depending on soluble fiber intake from the muffins. Group mean supplemental soluble fiber intakes were 2.5, 0.9, and 0.33 g per day. Supplemental total dietary fiber was held constant at about 5 g per day. No data were given on baseline dietary fiber intakes. After 4 weeks, the group consuming 2.5 grams per day of supplemental soluble fiber had significantly lower blood total (5 percent) and LDL-cholesterol levels (9 percent) as compared to baseline levels.

In a controlled, cross-over, intervention study, Taneja et al. (Ref. 58) provided isaqbol husks as supplemental soluble fiber (20 to 22 grams per day) to 11 Indian girls, 16 to 18 years (mean serum cholesterol 182 mg per dL) for 3 weeks. The higher fiber intake was associated with a significantly lower blood total cholesterol level (7 percent) compared to the low fiber diet.

Thirty-four men and women college students (mean age 27 years; normal cholesterol) consumed formula diets standardized to reflect the fat and other macronutrient components of U.S. diets (Ref. 35). Various fiber sources and levels of soluble fiber were added by consuming breads and cereals. Dietary protocols in which soluble fiber intakes were 5 or more per day were associated with reduced levels of blood cholesterol; whereas soluble fiber intakes of 3 g or less per day did not show significant changes in blood cholesterol levels.

Swain et al. (Ref. 57), in a randomized, double-blind, cross-over, intervention trial, fed diets containing 4 or 15 g of soluble fiber per day for 6 weeks added as supplementary oat and wheat bran to subject's regular diets. Both the high and low fiber diets were associated with statistically significant decreases in blood total cholesterol levels as compared to baseline.

In a randomized, single-blind, intervention study to evaluate the effect of beta-glucan, a type of soluble fiber, on blood cholesterol levels, Newman et al. (Ref. 50), provided cereal and baked goods to 14 free-living men (35 years or older; serum cholesterol 141 to 247 mg per dL). Treatment diets were consumed for 4 weeks following 4 weeks of pretreatment with the normal diet. Pretreatment diets contained approximately 5 to 7 g of total dietary fiber. The total dietary fiber content of treatment diets was held constant at approximately 45 g of total dietary fiber; these diets, however, differed considerably in beta-glucan content. The high beta-glucan group also consumed less total fat than the control group. At the end of the 4-week treatment period, the blood cholesterol levels of the high beta-glucan group did not differ significantly from baseline. The blood total and LDL-cholesterol levels of the low beta-glucan group, despite high total dietary fiber intakes, were significantly higher than baseline levels.

In summary, for studies in persons with blood cholesterol levels in the normal to borderline or mild risk levels and consuming their regular diets, and within the context of the study conditions, results tended to show declines in blood cholesterol levels with intakes of soluble dietary fiber (Refs., 1, 19, 35, 57, and 58). One study controlled nutrient intakes by use of formula diets and results generally suggested a dose response to soluble fiber intakes (Ref. 35). Generalization to regular dietary patterns needs to be done cautiously. A study on beta-glucans, however, did not show an effect of this fiber in persons with normal blood cholesterol levels (Ref. 50).

d. *Normocholesterolemics: Step 1 diets.* Van Horn et al. (Ref. 68), in a randomized, intervention study controlled with crossover, stabilized 236 free-living men and women (serum cholesterol 163 to 247 mg per dL) on a Phase II American Heart Association diet (low fat, low saturated fat, low cholesterol). Test diets contained 4.2 g of added soluble fiber. After 8 weeks on the test diet, there were no significant differences in total serum cholesterol levels between groups, although blood cholesterol levels were significantly lower in the test group as compared to the control group at the interim 4-week time.

In a randomized, double-blind, placebo-controlled, parallel intervention trial, 75 men and women (mean blood cholesterol approximately 200 mg per dL) consumed a placebo test fiber for 8 weeks while also consuming a Step 1 diet (Ref. 11). The Step 1 diet provided approximately 6 g of soluble fiber per day; the test fiber supplement provided an additional 8 to 9 g of soluble fiber daily. After 20 weeks on the test diet, blood total and LDL-cholesterol levels were significantly reduced from baseline (4 percent and 8 percent, respectively). A subgroup of 30 subjects continued the intervention for 8 more weeks. Total and LDL-cholesterol levels tended to increase towards baseline in the supplemented group and to increase above baseline in the placebo group. The authors reported excellent compliance of the test substance throughout the study period.

In summary, only two studies were available in which the effect of soluble fiber on blood cholesterol levels was evaluated in persons with normal to mildly elevated levels and consuming diets low in total fat, saturated fat, and cholesterol. Results were equivocal but in both cases seemed to be transient since interim values were lower than final values. This occurred, despite the report of excellent compliance in consuming the test material in one study (Ref. 11).

4. Biological Mechanisms

Several mechanisms have been proposed to explain the claimed hypocholesterolemic effect of soluble fiber. These mechanisms have been reviewed in detail elsewhere (Refs. 17, 34, and 39) and will be briefly summarized here.

a. *Gastrointestinal events.* Dietary fibers affect different aspects of gastrointestinal function, resulting in interference in nutrient absorption and diffusion, altered hormonal responses, and production of short chain fatty acids. "These events could act individually or collectively to decrease serum cholesterol" (Ref. 2). However, effects on gastrointestinal functioning have not been studied adequately in the human body.

Studies outside of the body show that viscous fibers can influence the accessibility of absorbable nutrients to the mucosal surface. There are a variety of demonstrated and potential influences of high dietary fiber intake on both intraluminal and mucosal intestinal physiology that may affect the rate and extent of absorption of nutrients, including dietary lipids and cholesterol.

Dietary fiber may influence nutrient and cholesterol availability in its interaction with digestive enzymes, possibly leading to decreased efficiency of digestion and limited diffusion of absorbable products in the intestinal lumen. In rats, soluble fibers delay gastric emptying and interfere with nutrient exposure to digestive enzymes and absorptive surfaces of the small intestine. Viscous fibers, such as guar gum, show marked influence on lipid digestion in dogs. These fibers decrease the grinding and digestive action of the stomach, allowing poorly digested food to pass into the midintestine, leading to delayed lipid digestion.

Interaction between dietary fiber and the intestinal surface has not been studied adequately in humans. Vahouny and Cassidy (Ref. 75) noted that the effects of various fibers, especially viscous fiber preparations, on the activities of mucosal-associated digestive enzymes have not been consistent.

b. *Binding or sequestering bile acids.* Of all the theories proposed to explain the effects of dietary fiber on serum cholesterol that have been seen in some studies, the theory that fiber binds or sequesters bile acids has received the greatest attention and most extensive evaluation (Ref. 17). Dietary fats, or lipids, are first emulsified in the stomach and then are transferred to the upper part of the small intestine where they are hydrolyzed by pancreatic lipase. The hydrolysis products eventually dissolve in bile acids to form micelles. The micelles are broken at the intestinal wall, and the lipid hydrolysis products are absorbed into the body (Ref. 74). Specific dietary fibers are thought to bind or sequester circulating bile acids, thus interfering with micelle formation required for dietary cholesterol absorption, and thus altering or modifying lipid digestion and absorption. Increased excretion of bile acids in feces results in the conversion of liver cholesterol to bile acids, which eventually leads to decreased serum cholesterol and LDL-cholesterol levels.

In an effort to confirm this hypothesis, Story (Ref. 73) observed that the effects of dietary fiber on bile acid excretion are inconsistent and are not large enough to account for observed changes in serum cholesterol. "However, in some cases (e.g., oat bran in hypercholesterolemic humans), a substantial change in bile acid excretion has consistently accompanied the hypocholesterolemic effects. Clearly, this is not the sole mechanism involved for all sources of dietary fiber and our initial hypothesis concerning adsorption-excretion is not valid for all situations" (Ref. 73).

c. *Effect of fiber fermentation products.* Dietary fibers are partially fermented by bacteria in the human colon. Some of the fermentation products formed include short chain fatty acids, such as acetate, propionate, and butyrate. Short chain fatty acids are almost completely absorbed from the colon. Propionate is extracted by the liver and has been shown to lower plasma cholesterol in rats. In vitro studies in rat liver cells have shown that propionate decreases cholesterol synthesis, but only if acetate is used as a cholesterol precursor (Ref. 72). Venter et al. (Ref. 70) showed that dietary propionate fed to baboons raised total cholesterol, although metabolic effects of dietary propionate may not be the same as propionate derived from microbial fermentation of dietary fiber in the colon.

d. *Summary.* There are several mechanisms proposed (interference with gastrointestinal functions, binding of bile acids, and fiber fermentation) to explain the effects of soluble fiber on serum cholesterol found in some short-term studies. Not only is the mechanism unknown, but it has not been determined if it is the soluble fiber itself, the presence of beta-glucan (the major component of soluble fiber), or some other component in the diet that accounts for the observed effects.

5. Conclusions

Earlier reviews by the Federal government and other recognized scientific bodies generally concluded that diets rich in water-soluble fiber fractions were associated with cholesterol-lowering effects in humans (Refs. 48, 65, and 66). They further noted that high fiber diets are often associated with low fat diets and it is difficult to differentiate the effects of the two nutrients, although the net effect is beneficial and soluble fiber in relatively large amounts may serve as a useful adjunct to low saturated fat and low fat diets. The recent update by LSRO (Ref. 40) noted that recent data reflect results from earlier studies in that results suggest soluble fiber but not insoluble fiber may have cholesterol-lowering properties. Some types of soluble fiber, e.g., betaglucan, may be more effective than other types, although the data are extremely limited at this time. Animal studies are generally supportive. This report also notes that it is not clear whether the observed effects result strictly from the fiber or from other components associated with consumption of fiber-rich foods. The report also noted that there are no data to indicate that a fiber present in a food is the same as when it has been extracted and purified.

FDA reviewed over 30 human studies published in the last several years. Under the study conditions, many studies observed a decline in blood cholesterol levels with increasing intakes of soluble fiber. Most studies, however, were of very short duration and, therefore, cannot confirm long-term benefits from high soluble fiber diets. Indeed, questions of long-term effects were raised by the observation of an initial decline in blood cholesterol levels followed by a return upwards towards baseline in some of the longer studies, even when authors reported excellent compliance for consumption of test substances.

There was some evidence suggesting that different types of soluble fiber have different effects. Additionally there was some evidence of a dose response, although the evidence for this is very limited. There were, however, major design flaws in many of the studies which make it difficult to reach firm conclusions. The objectives of many study protocols seemed to be to evaluate the effectiveness of relatively large amounts of a single type of food or fiber source rich in soluble fiber (e.g., oatmeal, baked beans, oat bran) rather than to look at total soluble dietary fiber intakes or to specifically identify the chemical and physical characteristics of soluble fiber that are most effective in lowering blood cholesterol levels. By adding large amounts of foods to diets (e.g., addition of 1 to 2 cups of baked beans daily), these dietary changes were often accompanied by lower calorie intakes and weight loss. Since weight loss alone can lower blood cholesterol levels, this becomes a serious confounder for interpreting study results. Frequently, also, nutrient intakes, particularly those nutrients related to serum cholesterol levels (saturated fat, total fat, cholesterol) varied among treatment and control groups, again confounding interpretation of results. Information on total soluble fiber intakes is not always provided. Results from studies with crossover designs were often particularly confusing since treatment order effects were often observed.

The LSRO update report (Ref. 40) noted that the recent studies represented, to large degree, a repeat of earlier studies. FDA reached a similar conclusion. Based on the totality of the evidence, FDA has determined that the conclusions of the reports reached by the earlier Federal government and other reviews by recognized scientific

bodies provide an insufficient basis to support a health claim relating soluble fiber intake to reductions in blood cholesterol levels and, ultimately, to reduced risk of developing CHD. It is still not clear whether observed reductions in blood cholesterol levels on short-term studies are due to changes in other nutrients intakes and/or to concomitant weight loss. The potential for adaptation and loss of effectiveness with time remains an unanswered question. And, most importantly, the data suggest that some but not all components of dietary soluble fiber may be most effective. Evidence to date is too limited to be able to clearly identify the characteristics of effective soluble fibers.

III. Tentative Decision not to Propose a Health Claim Relating Dietary Fiber to Decreased Risk of Cardiovascular Disease

FDA limited its review of the scientific evidence relating to ingestion of dietary fiber and cardiovascular disease to the topic of soluble dietary fiber and risk of developing CHD. These limitations were deemed appropriate because the previous Federal government and other reviews by recognized scientific bodies had focused on these areas and the majority of research efforts to date have focused on these areas.

FDA has tentatively concluded, based on the totality of the evidence, that there is not a sufficient basis to authorize a health claim for dietary soluble fiber and reduction in risk of developing CHD. Numerous human studies have examined the possible role of dietary fiber intake in CHD. Many correlational studies show a relationship between diets high in plant foods (fruits, vegetables, and grains) and reduced rates of cardiovascular disease. There are a number of dietary intervention studies which are generally conducted for short-time periods, and often with fairly large changes in dietary patterns. Most of these studies show short-term benefits in serum cholesterol lowering with diets high in soluble dietary fiber. However, these studies are often also characterized by other concomitant changes which could also affect blood cholesterol levels, including weight loss and changes in other nutrients intakes which affect blood cholesterol levels. Studies of longer duration (6 weeks to 6 months) tend to be limited in number and results are more equivocal. The relationship of type of soluble fiber as currently measured by commonly used methods such as those of the Association of Official Analytical Chemists is not clear.

It is clear that diets high in soluble fiber-rich foods, including whole grains, fruits, and vegetables, are associated with reduced risk of developing CHD. These diets differ, however, in the levels of many nutrients and in types of dietary soluble fiber making it difficult to ascribe observed nutrient and disease relationships to a single nutrient. Overall, the available data are not sufficient to demonstrate that it is the total soluble dietary fiber, or a specific measurable and quantifiable subcomponent, that is related to lower blood cholesterol levels.

A major limitation in designing and evaluating research studies has been the need for better-defined measures of dietary fiber and standardized descriptions for source, type, and amount of dietary soluble fiber (Ref. 39). Dietary fibers, including soluble fibers, are a heterogeneous family of compounds that vary considerably in chemical composition, physical characteristics, and biological effects (Ref. 39). Processing of foods and fiber sources may also alter the inherent characteristics of the soluble fiber. The commonly used analytical methodologies often do not detect many of the characteristics that vary among fibers and that may be related to biological function (e.g., particle size, chemical composition, or water-holding capacity) (Ref. 39). Analytical methods also do not differentiate between source of fiber. This lack of ability to detect many of the differences that exist among fibers and the general lack of clear evidence as to the mechanisms of action of fibers have raised questions as to the ability of commonly used analytical measures of dietary fiber to adequately predict biological actions of specific fibers (Refs. 12 and 24).

Another problem in evaluating the relationship of dietary fiber intakes to the risk of chronic disease such as CHD is the lack of reference food composition data on the fiber content of foods. Consequently, most human studies have described dietary intakes in terms of amounts of oatmeal, or oat, or wheat brans. In many studies, total soluble dietary fiber intake, or even the soluble fiber content of the test material, was not described.

In summary, the currently available scientific evidence is not sufficiently conclusive or specific for soluble fiber to justify use of a health claim relating intake of dietary soluble fiber to reduced risk of CHD. Federal government (Refs. 63 and 66) and other reviews by recognized scientific bodies (Refs. 39, 40, and 48) are consistent in agreeing that it is difficult to separate the effects of fiber from those of other components present in high fiber foods or in dietary patterns high in plant food. As noted above, the evidence that has become available since publication of these reports is consistent with these conclusions and is, therefore, not sufficient to alter the earlier conclusions. Thus, FDA has tentatively concluded, based on the totality of the scientific evidence, that there is not significant scientific agreement among experts qualified by training and experience to evaluate such a relationship, as to the independent and specific role of dietary soluble fiber in reducing the risk of CHD.

FDA recognizes that CHD is a leading cause of morbidity and mortality in the United States and that changes in dietary patterns can play a significant role in reducing risk of CHD. Virtually all recent dietary guidelines for Americans have encouraged the increased consumption of fiber-rich foods, including whole grain cereals, fruits, and vegetables. FDA has supported and continues to support these recommendations and to encourage dietary guidance consistent with the recommendations. This raises a dilemma, however, for which FDA is requesting comment. To encourage and help consumers to meet dietary guidance recommendations, it would be useful to have appropriate dietary information at point of purchase. The use of health claims on foods (including dietary supplements) to inform consumers of these recommendations, however, is problematic since it is not clear what qualifying and other criteria are necessary to adequately define eligible foods for such a health claim. Congress, in the 1990 amendments, specified that FDA evaluate nutrient and disease relationships. Dietary fiber was specified as one nutrient for evaluation. Yet, FDA has tentatively concluded that the available evidence that is supportive of changes in food patterns cannot be extrapolated to a specific fiber effect at this time.

Given the public health significance of CHD and given the general dietary guidance to increase consumption of fruits and vegetables and whole grain products which are rich sources of dietary fiber, including soluble fiber, and other nutrients, FDA is requesting comments on how best to inform consumers of these issues.

Specifically, should the agency permit a claim on the label or in labeling such as "Diets high in fruit, vegetables, and whole grains are associated with a reduced risk of cancer of the lower bowel and cardiovascular disease"; or

alternatively "Research has shown that populations who consume diets that contain several servings each of fruit, vegetables, and whole grains have a decreased risk of certain forms of cancer and cardiovascular disease; or "Choose diets with plenty of fruit, vegetables, and whole grains to help lower your risk of cardiovascular disease and certain forms of cancer." If such statements should be permitted, what criteria should be used to identify foods that are eligible for such statements? For example, should such statements be limited to fresh fruit, vegetables, and milled whole grains, or should processed foods derived from these produces also be included? What measure should the agency adopt to assure that consumers are not mislead as to the benefit of consuming a specific product? FDA is requesting comments on whether it has the authority and should allow health claims on foods as well as nutrients.

Based on the studies reviewed in this document, serum cholesterol responses were affected by a number of factors: Initial serum cholesterol level, base diet, self-initiated changes to base diet (particularly to changes in intake of saturated fat and polyunsaturated fat) during the test period, body weight, exercise, medications, general health, and other lifestyle variables. These confounding factors, which were generally not well controlled within many of the individual studies and which make cross-study comparisons difficult, made it impossible to draw conclusions about the relationship of soluble fiber to serum cholesterol levels.

1. Safety of Fiber Supplements

Concerns have been raised about the potential for risk from isolated or purified forms of fiber (Ref. 39). Side effects and possible adverse health effects of high intakes of dietary fiber have also been hypothesized by NAS (Ref. 48). Excessive consumption of fiber supplements may result in more intestinal problems or poor absorption of trace minerals than would be expected from a high-fiber diet (Ref. 40). Fiber sources, such as psyllium seed, guar gum, pectin and other gums, are not listed as GRAS substances for use as a fiber supplement.

The agency is concerned about changing consumption patterns associated with the development and introduction into the marketplace of new sources of dietary fiber, along with increased use of fiber sources as food ingredients or as supplements of fiber. FDA intends to update its GRAS regulations for sources of fiber in the near future. To deal with this issue, the agency intends to initiate a review of the existing types of isolated dietary fibers and their use as a broad class of foods to identify and assess scientific information on the safety of this use. This review will include consideration of the biological effects of different fibers, the extent to which such effects are significantly different for subclasses of dietary fiber, and whether biological effects are significantly altered by chemical or physical changes and by processing. FDA may use the results of this or other reviews to develop a new strategy for assessing food safety.

2. Significant Scientific Agreement

The Federal government and other authoritative reports reviewed consistently concluded that while dietary patterns high in fiber-rich foods were associated with lower levels of serum cholesterol and decreased risk of CHD, the effect of soluble dietary fiber could not be separated from the effects of other dietary factors, i.e., lower contents of saturated fatty acids and cholesterol and higher intakes of fiber, potassium, and vitamins and minerals. The data that has become available since those reports were completed, as reviewed here by FDA and also as independently reviewed by outside experts (Ref. 40), do not provide sufficient evidence to warrant modifying or changing the conclusions reached earlier by the authoritative reports. Thus, FDA concludes that there is not sufficient scientific agreement, among experts qualified by experience and training, to support a health claim for dietary fiber and cardiovascular disease.

3. Public Health Importance

It is clear that cardiovascular disease, and particularly CHD, are major public health problems in the United States. There is also general agreement that dietary patterns that will lower serum cholesterol levels will also lower risk of these diseases. Dietary patterns high in fiber-containing foods; low in fats, saturated fats, and cholesterol; and associated with maintenance of desirable body weights are also associated with decreased risk of CHD. This association is the basis for the numerous dietary guidelines that recommend these types of dietary patterns. FDA has consistently supported these dietary guidelines and continues to do so. (With the proposed changes in the mandatory nutrition labeling regulations (see companion document published elsewhere in this issue of the **Federal Register**), consumers should be better able to obtain the information needed to select foods to help them meet these goals.)

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

VI. Comments

Interested persons may, on or before (February 25, 1992), submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 am and 4 pm, Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. Section 101.71 is amended by adding paragraph (b) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(b) Dietary fiber and cardiovascular disease (insert cite and date of publication in the **Federal Register** of the final rule).

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-M

Table 1

Dietary fiber and cardiovascular disease: Effects of soluble fiber on blood cholesterol in humans.

Study	Study Design	Subjects	Methods	Results	Comments
Abraham and Mehta, 1988 (Ref. 1)	Intervention, controlled diet	7 men, free living, with normal blood cholesterol (mean 187 mg/dL; range 132-240 mg/dL)	Subjects consumed controlled meals, based on usual diet, for 3 weeks followed by 3 weeks with psyllium (PSY) husks added to control diet in form of muffins, cookies, fruit drinks, and peanut butter. Gradual ↑ of psyllium starting with 7 grams/day to 21 g/day. Estimated soluble fiber (SF) intake from PSY - 16-19 g/day. Base diet: 30% kcals (kilocalories or Calories) from fat; 16% from protein; 54% kcals from carbohydrate. Cholesterol intake 300-400 mg/day. P/S = 1; total dietary fiber (TDF) 17 g/day.	After 3 weeks, total or serum cholesterol (TC) ↓16% (calculated) (significant (S)); LDL and HDL cholesterols also ↓ significantly. Subjects with the highest baseline serum cholesterol had the greatest TC reductions.	Subjects' cholesterol values were not stabilized, as the authors reported, when psyllium intervention was started. There was no control group during the intervention period. No data on body weight. The short test period limits ability to generalize to long term effects.
Anderson et al., 1988 (Ref. 8)	Intervention, randomized, parallel, double blinded, placebo controlled	26 men, ages 30-65; free living; normo- and hypercholesterolemic (188-314 mg/dL)	Subjects consumed regular diet for 2 weeks followed by adding psyllium (Metamucil) or cellulose (control), 3 times a day before meals (3.4 g fiber source/meal), to meals for 8 weeks. Dietary intakes monitored with 24-hour random records. 10.2 g/day of PSY provided an estimated 8-9 g of SF. Base diet: 40% kcals from fat; 20% kcals from protein; 40% kcals carbohydrate; <300 mg/day of dietary cholesterol.	From baseline, soluble fiber from psyllium: TC ↓15% (S); LDL ↓20% (S), and LDL/HDL ratio ↓15% (S). There were also significant differences between the placebo group and the psyllium group. No effect of PSY on HDL.	Psyllium was provided as an adjunct to the regular diet. Steady decline in TC over 8-week test in PSY group. No effect on body weight. Authors report compliance was excellent.
Anderson et al, 1990 (Ref. 4)	Intervention, randomized, self-controlled study on a metabolic ward	24 males, hypercholesterolemic, 37-69 years old. No hypocholesterolemic medications were allowed. 5 subjects exceeded desirable body weight by ≥ 20%.	Subjects consumed typical "American" diet for 7 days as a control period. Diet provided 38% kcals as fat; 19% kcals as protein; 43% kcals as carbohydrate; 420 mg dietary cholesterol; total kcals: 1729-1981/day. After 7 days subjects randomized into 3 groups for 21-day test period: Group A (n=6) received a single serving of canned beans (227 g) at noon, Groups B and C (n=9 each) received 2 divided servings of canned beans (227 g and 182 g, respec-tively). TDF / SF Control diet: 13 g / 4 g Diets A and B: 23 g / 8 g Diet C: 23 g / 7 g	Total Serum cholesterol: ↓ 8-11.6% (S) compared to baseline control period in all three test groups. Overall, the LDL/HDL ratio remained similar to control ratios for groups A, B, and C. The interim TC values were lower (↓13-17% decrease from baseline) than the final values.	Each group experienced some weight loss (approximately 3 pounds). Calorie intakes were approximately 1800 kcals/day. TC was increasing towards baseline at end of 3-week test period. Short test period is a limitation of study design.

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Anderson et al, 1990 (Ref. 6)	Intervention, randomized, self-controlled, cross-over on metabolic ward	12 men; 46-70 years old; hypercholesterolemic (210-326 mg/dL); body mass indices of less than 30; 5 subjects had evidence of cardiovascular disease	Subjects, randomized into 2 groups, consumed typical "American" diet for 2 weeks in addition to test or control cereal followed by crossover to other cereal for 2 weeks. Base diet provided 41% kcals as fat; 20% kcals as protein; 43% kcals as carbohydrate; 355 mg dietary cholesterol. One group started with addition of 56 g oat bran cereal to the diet; the other consumed 56 g of cornflakes (control). Total dietary fiber (TDF) and total soluble fiber (TSF) were: TDF / TSF Oat bran cereal: 21 g / 7.4 g Cornflakes: 15 g / 4.5 g	Oat bran diet: ↓ TC 5.4% (S) compared to the corn flakes diet. LDL was lowered by 8.5%, and HDL was not significantly lowered.	The intake of carbohydrates, protein, fat and cholesterol were nearly identical in the two groups. Total dietary fiber varied between the two diets. No change in body weight. Short duration of test is a limitation.
Anderson et al, 1990 (Ref. 5)	Intervention, self-controlled, metabolic ward	10 men, ages 40-70 years; mild to high hypercholesterolemia (200-320 mg/dL); 13 enrolled. 3 dropped out: 2 for reasons unrelated to the study, 1 for non-compliance.	Subjects consumed a controlled diet for 7 days (control period) followed by a 3-week test period. Base diet: 30% kcals from fat; 15 kcals from protein; 55% kcals from carbohydrate; 450 mg/day dietary cholesterol; TDF 25 g/day. The test diet consisted of refined wheat bakery products, high in soluble fiber and fruits and vegetables. TDF / TSF Bakery diet: 25 g / 9 g Baseline diet: 25 g / 3 g	No significant decrease in serum cholesterol on bakery diet; 8 had ↓TC; 2 had ↑TC. Significant (8%) ↓ in LDL. No significant change in the LDL/HDL ratio from control period.	Total fat was controlled but the P/S (poly-unsaturated fat/saturated fat ratio) increased somewhat in the bakery diet. Short time allowed for end-point measures to stabilize to the base diet; the subjects showed a ↓ in TC and ↓LDL during the 7-day control period. Constant body weight maintained by adjusting energy intake.
Anderson et al., 1991 (Ref. 3)	Intervention, randomized, controlled, metabolic ward study	21 men*, ages 38-73 years; hypercholesterolemic (total serum cholesterol: 190 to 347 mg/dL). Body mass indices less than 28.7; no medication for hypercholesterolemia. 1 subject failed to complete study. *14 men had hypertension, CHD, or CVD	Subjects consumed "typical" American diet for 7 days as a baseline (control), then randomized to oat bran (110 g oat bran/day) or wheat bran (40 g wheat bran/day) diets for 21 days; control and treatment diet identical in energy content, and nutrients, differing only in soluble fiber soluble fiber (oat bran) and insoluble fiber (wheat bran). Baseline diet: 41% of kcals from fat, 16% protein, 43% from carbohydrate, 450 mg cholesterol, 14 g/day TDF, 3 g/day SF. Brans were incorporated into muffins and cereals. TDF / SF (bran) g/day / TSF (diet) Baseline diet: 14 / / 5-6 Oat bran: 34 / 7.6 / 13.4 Wheat bran: 34 / 1.3 / 7.8	TC % / LDL % / HDL % OB: ↓12.8* / ↓12.1* / ↑7.4 WB: ↓4.4 / ↓5.5 / ↓3.1 *significant from baseline There was no change in the LDL-HDL ratio in OB group. No effect on HDL in either group.	Authors state the purpose of their study is to compare the effects of soluble fiber (from OB) and insoluble fiber (from WB) keeping TDF constant. Significant weight loss in both groups (about 1 kg from control values).

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Aro et al., 1984 (Ref. 9)	Intervention, double blind, crossover with placebo	14 men, ages 30-64, free living; severely hypercholesterolemic (301-402 mg/dL) and hypertriglyceridemia	Study designed with two 12-week crossover periods with an initial 4-week period on placebo diet and a 4-week washout between test periods. Subjects consumed normal diet (not defined); no dietary records were kept. Guar gum granules were mixed with water and taken before means; same for placebo. Placebo - wheat flour prepared similar to guar. Guar gum, 15 g/day (estimated 10.5 g soluble fiber) was added to baseline diet; it was consumed in 5-gram doses, after mixing with water, before the 3 main meals.	Guar gum: TC ↓ significantly after 6 weeks (15.3%) and by 8.2% between weeks 6 and 12 as compared to baseline. Most of the ↓ was in LDL (22% after 6 weeks and 14% after 12 weeks). Significant ↑ in mean TC from 6 to 12 weeks of guar gum supplementation. LDL/HDL ratio significantly lower in guar than placebo group. Placebo group experienced ↓ in LDL over the 12 weeks. No significant difference in TC and LDL between treatment and control after 12 weeks.	Weight maintained during the study; no dietary information given; no information on TDF or total SF intakes. Authors reported good compliance. The authors suggest that the attenuated effect of guar over time may reflect compensatory mechanisms in the body.
Beling et al, 1989 (Ref. 10)	Intervention, randomized, controlled	351 men and women, ages 20-60, hypercholesterolemic (total serum cholesterol between 200 and 300 mg/dL); not greater than 50% ideal body weight. 433 enrolled; 351 completed; attrition rates for groups 1,2, & 3 were 17%, 15%, and 24%, respectively. Major reason for attrition was inability to attend classes.	This was an 8-week study with 3 groups: Group 1: no dietary change Group 2: Step I diet, which was introduced during the first 4 weeks of the study and continued for 8 weeks Group 3: Step I diet, which was introduced during the first 4 weeks of the study, plus 2 oz oat cereal, which was added for weeks 5 through 8. Oatcor™, a concentrated oat bran cereal, was provided in 2 packets (1 oz each) to be consumed as a snack or cereal. The oat bran provided 10.6 g total dietary fiber per day; 7-8% total beta-glucans by weight. Group % kcal - SFA 0 Tx 1 12 10-11 2 11 6 3 12 7 (SFA = saturated fatty acids) % kcal - fat 0 Tx 1 38 34-36 2 34 23 3 37 25-26 Total Dietary Fiber 0 Tx 1 12 12-14 2 12 18-19 3 9 15-16	Total Serum Cholesterol (% Change from baseline) Group 4 wks 8 wks 1 ↓ 2 ↓ 2 2 ↓10 ↓ 8 3 ↓12 ↓12 LDL - cholesterol (% change from baseline) 1 ↓ 3 ↓ 5 2 ↓11 ↓10 3 ↓12 ↓15 HDL - cholesterol (% change from baseline) 1 ↓ 1 ↓ 1 2 ↓ 6 ↓ 3 3 ↓ 8 ↓ 8	Variable weight loss by treatment: group 1: 2 lbs; group 2: 4 lbs, and group 3: 6 lbs. There was no data on soluble fiber in diets. Not everyone responded similarly; both positive and negative responders and variation in magnitude of effect within treatment groups. Study was unblinded.

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bell et al., 1989 (Ref. 11)	Intervention, randomized, double blind, placebo controlled, parallel	75 men and women, 50th-90th percentile cholesterol (mean for placebo group was 162 mg/dL; for test group, 207 mg/dL); free living	This was a 20-week study with 12 weeks on step 1 diet, followed by 8 weeks of test fiber or placebo (cellulose). Psyllium (Metamucil powder) (3.4 g/meal) was taken 3 times a day before meals. Dietary intake was assessed with 3-day food records at weeks -6, 0, 8 and 16. Step 1 Diet: Fat 27-38% kcals SFA 7-10% kcals Cholesterol 160-200 mg/day T. Dietary Fiber 19-22 g/day Soluble Fiber 6 g/day Psyllium provided an estimated 8-9 g soluble fiber.	TC ↓4.2% (S) from baseline and ↓4.8% (S) from placebo; LDL ↓7.7% from baseline and ↓8.2% (both S) from placebo. LDL/HDL ratio: ↓10% from placebo and baseline (S). 30 subjects continued the intervention for 8 more weeks. Total and LDL cholesterol in the psyllium group tended to increase during the additional 8 weeks in both groups. TC values ↑ above baseline in placebo group; test group: TC ↑ but was still 7.7% lower than the placebo, but only 1.5% lower than baseline.	Psyllium was given as an adjunct to the diet, not in food form. Step 1 diet did not lower serum cholesterol significantly different in baseline TC values. Long term effectiveness remains a question based on evidence in this study of ↑ cholesterol during weeks 8-16 on psyllium. Both TC and LDL values ↑ above baseline in the placebo group; in test group TC ↑ and was only 1.5% lower than baseline, LDL ↑ and was 5% lower than baseline. Compliance was excellent in both groups.
Bell et al., 1990 (Ref.12)	Intervention, randomized, double-blinded, controlled	58 men; 24-69 years old; free living; with mild to moderate hypercholesterolemia (mean range 227-229 mg/dL)	Subjects consumed a Step 1 diet for 6 weeks; then randomly assigned to pectin-enriched, psyllium-enriched cereal, or corn flakes (control) groups for additional 6 weeks. Three-day dietary intake records taken at -6, 0, and +6 weeks. Cereals were added to Step 1 diet. NCEP step 1 diet: 30% kcals as fat, 55% carbohydrates, 15% protein; approx. 200 mg/day cholesterol. Total Dietary Fiber Baseline / Week 6 (g/ day) Placebo 22 / 19 Pectin 21 / 16 Psyllium 23 / 22 Total Soluble Fiber Baseline / Week 6 (g/day) Placebo 7 / 6 Pectin 8 / 6 Psyllium 8 / 8	Total Cholesterol Diet Phase % from baseline / Cereal Phase % from diet phase Placebo ↓ 4 / ↑ 0.4 Pectin ↓ 4 / ↓ 2 Psyllium ↓ 3 / ↓ 6 * * significant from baseline and placebo LDL - cholesterol Diet Phase % from baseline / Cereal Phase % from diet phase Placebo ↓ 4 / ↓ 0.4 Pectin ↓ 5 / ↓ 4 Psyllium ↓ 4 / ↓ 6 * HDL - cholesterol Diet Phase % from baseline / Cereal Phase % from diet phase Placebo ↓ 6 / ↑ 2 Pectin ↓ 6 / ↑ 3 Psyllium ↓ 4 / ↓ 2	Excellent compliance reported. Dietary intakes were approximately same among groups, except for total dietary fiber. No change in weight.
Burr et al., 1989 (Ref.13)	Intervention on effects of diet on secondary prevention of myocardial infarction (MI), randomized, controlled	2.033 men, all recovered from MI; mean age 56 years; free living	A 2-year study. Three groups: (1) advice given to ↓ fat intake to 30% of calories and ↑ the P/S ratio to 1.0; (2) advice given to ↑ fatty fish intake to 2 servings/week; (3) advice given to ↑ cereal fiber (not defined) to 18 g/day. Cereal fiber intake in group 3 was twice that in subjects not given fiber advice. Normal diet of subjects was not defined.	No significant difference in total mortality between those given fiber advice and those not given fiber advice. No significant changes in serum cholesterol attributable to fiber advice.	Fiber is not separated into soluble and insoluble components; no assessment of confounding factors, including intakes of other nutrients (e.g., SFA), was provided.

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Davidson et al., 1991 (Ref. 15)	Intervention, randomized, single-blinded, controlled. Purpose to evaluate the effectiveness of soluble fiber fraction, beta-glucan, in lowering serum cholesterol.	156 men and women, aged 30-65, randomized; 148 completed; free living hypercholesterolemic (230-319 mg/dL) with multiple risk factors. Data from only 140 were used, 8 dropped because of lack of compliance. Dropouts: placebo (3), OB-56 (2); OM-28(1); OM-84(1), and OB-84(1).	NCEP Step 1 diet given 8 weeks before randomization to test diet and during the test period. 6 weeks of intervention with oatmeal (OM)or oat bran (OB) in 28 g, 56 g or 84 g servings. 28 g farina as a control. After intervention 6 weeks of follow-up with no supplementation. Step 1 diet: fat: <30% kcal SFA: <10% kcals Groups TDF TSF OM 28 g 16 6 OB 28 g 17 6 OM 56 g 14 5 OB 56 g 20 7 OM 84 g 19 7 OB 84 g 22 7 Farina 28 g 15 0 4-day food records at baseline, week 3,6,12.	Group g. β Glu % TC % LDL 1. OM 28 1.2 -3.9 -5.8 2. OB 28 2.0 -2.7 -4.7 3. OM 56 2.4 -2.7 -3.5 4. OB 56 3.6 -9.5* -15.9* 5. OM 84 4.0 -7.1* -10.1* 6. OB 84 6.0 -6.9* -11.5* 7. FA 28 0.0 +0.6 +0.6 OM=oatmeal OB=oat bran FA=farina Glu=glucan * Only these changes are significantly different from baseline. The groups showed a decrease in total cholesterol and LDL at the higher levels of oat intake.	Lacked control group for each level of oats consumed. Body weight were stable.
Demark-Wahnefried et al., 1990 (Ref. 16)	Intervention, randomized	81 men and women, 20-65 years, hypercholesterolemic (mean of 271 mg/dL), free-living: 13 dropped out.	12 weeks of intervention on oat bran or processed oat bran cereal. Individuals given oat bran (OB) supplements, OB cereal, and a recipe book for fat-modified diets. One group consumed regular diet and did not get recipes. 50 g oat bran per day (estimated 3.7 g soluble fiber) as add-on to test group. 50 g OB and 42.5 g processed cereal had same amount beta-glucan. Diets: Group 1: low fat, low cholesterol diet Group 2: low fat, low cholesterol diet plus 50 g OB Group 3: regular diet plus 50 g OB Group 4: regular diet plus 42.5 g processed oat bran	Although there was a significant drop in serum cholesterol with all groups, there was no significant difference in the final serum cholesterol between any of the four groups. The low fat, low cholesterol control diet alone had the most marked drop in cholesterol (↓17%) from baseline.	Drop out rate is very high (16%). The study size is small; power to detect changes between groups is limited. Variable weight loss among group with the group consuming low fat diet plus oat bran experiencing the greatest weight loss (4-5%). Calorie intake varied from a mean of 1600 Cal/day for low fat, low cholesterol diet to 1900 Cal/day for oat bran. % changes from baseline in saturated fatty acids ranged from 22% for OB group to 51% for low fat, OB group.
Glassman et al., 1990 (Ref. 18)	Intervention	36 children with type IIa cholesterolemia (mean of 257.0 mg/dL).	8 months on Step 1 diet (10% kcals from SFA) (n=14); 1 month washout period, then 8 months on NY Medical Center modified saturated fat diet (fat 10% of kcals) and added soluble fiber from psyllium (PSY) (n=36). PSY was mixed with water twice a day. Children age 7 and older consumed 10 g psyllium (8-9 g soluble fiber estimated) per day; younger children consumed 2.5 g/day (estimated 2-2.5 g SF).	Total cholesterol and LDL ↓ significantly (18% & 23%, respectively) in test group on NY diet with psyllium. Total cholesterol and LDL decreased 6.7 & 8.8% (NS) on step 1 diet for the same duration. Nine obese children lost weight (2.8 kg).	Primary type IIa cholesterolemia is an inherited condition which causes extremely high serum cholesterol levels in children through a metabolic error in the breakdown of cholesterol. The study is not blinded, and there is no placebo.

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Gold and Davidson, 1988 (Ref. 19)	Intervention, double blind	72 male and female medical students; 25-37 yrs old; free-living; normal cholesterol (mean 178 mg/dL)	This was a 4-week intervention study. Subjects consumed 2 muffins/day that contained test fibers (muffins were provided) along with their regular diet. 3-day food records were submitted. Subjects randomized into 3 groups and received muffins made with either oat bran, wheat bran, or a wheat/oat bran combination. Added soluble fiber (S.F.) and dietary fiber (D.F.) from muffins: S.F.* / D.F. (g) oat bran 2.5 / 5.0 oat/wheat 0.9 / 5.3 wheat bran 0.33 / 5.5 *estimated	Oat bran: TC ↓5%* and LDL ↓9% *significant from baseline S.F. from combined oat/wheat and wheat: TC no change; LDL no significant decrease.	No assessment of the dietary intake before or during the test period. No data on total dietary fiber or total soluble fiber intakes in baseline and treatment diets.
Kahn et al., 1990 (Ref. 25)	Intervention, randomized, controlled.	16 men and women, age 51-54, hypercholesterolemic (215-314 mg/dL); some were diabetic. Free living	One group began immediate intervention on oat bran for 3 weeks; other group was the untreated control for 3 weeks, then they started the intervention for 3 weeks. This was followed by a 6-week washout period during which blood samples were taken. Test subjects consumed 80 g oat bran (estimated 6 g soluble fiber) per day, added to the diet as oat bran muffins (4 per day). Each muffin provided 112 Calories and 20 g oat bran. Subjects' usual diets were not assessed.	All groups, including the control group, had ↓ TC but there was no significant change in serum cholesterol values when the test group was compared to the control group. Results showed a significant ↓ in total cholesterol by 8% and LDL cholesterol by 10% from baseline when individual values were examined.	No dietary assessment before or during test. Subjects experienced some weight loss.

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Keenan et al., 1991 (Ref. 26)	Intervention, randomized, controlled, double blind with crossover	145 men and women, ages 20-70; free living; hypercholesterolemic (207-267 mg/dL). 15% dropout after randomization.	Study designed with 3 periods (6 weeks each period): period 1: step 1 diet; periods 2 & 3: test periods. Test products were provided. 3 groups: control, wheat, and oat. The control group consumed step 1 diet for entire study period. 4-day food records were collected in week 5 of each period; baseline dietary intake taken by self-administered food frequency questionnaire. Step 1 diet: fat calories: <30% SFA calories: <10% Cholesterol: 240 mg/day 2 ounces of oat bran cereal and 2 ounces of ready-to-eat wheat cereal were test fibers. Oat bran: (3 g SF/day); Wheat cereal (1 gram SF/day)	Total cholesterol and LDL decreased in all groups during step 1 period (↓2.5-4%). Oat-wheat group had a further ↓ in TC of 2% (NS) on oat cereal, followed by a 6% ↑ in TC on wheat cereal. The wheat-oat group had no change in TC on wheat and a 3% decrease on oat. Control group had significant increase in TC back to baseline during test periods. Women under 50 found resistant to oat bran intervention. Control: Step 1 — TSF 6.8 g/day, % Change in TC* ↓2.5-4; Step 1 — TSF 6.2, % Change in TC* +; Step 1 — TSF 6.0, % Change in TC* + Oat-Wheat: Step 1 — TSF 6.7 g/day, % Change in TC* ↓2.5-4; Oat — TSF 7.7, % Change in TC* N.S.; Wheat — TSF 6.1, % Change in TC* ↑ 6 Wheat-Oat: Step 1 — TSF 5.8 g/day, % Change in TC* ↓2.5-4; Wheat — TSF 6.0, % Change in TC* N.S.; Oat — TSF 7.4, % Change in TC* ↓ 3 *Compared to beginning of respective treatment period.	Placebo was needed for diet only group. Control group initially dropped TC and then returned to baseline making it difficult to use as a control. Variability among groups in serum cholesterol levels at beginning of treatment periods.

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Kesaniemi et al, 1990 (Ref.27)	Intervention, randomized, self-controlled, crossover	34 men, free living, normal serum cholesterol (223-238 mg/dL). Helsinki, Sweden; 3 were mildly hypertensive, 3 had gallstones, 1 had history of myocardial infarction, and 1 had maturity onset diabetes mellitus.	Purpose of study to evaluate cholesterol metabolism on high and low mixed-fiber diets. A 16-week study: 8-week low fiber period and an 8-week high fiber period. Diets for both groups were self selected. High fiber diet consisted of unpurified corn products, fruits, vegetables, salads, berries, fiber-cereal (made with oat flakes and guar gum and pectin) and graham biscuits (fortified with bran and carrots). Low fiber diet: avoid eating unpurified cereal products, vegetables, salads, fruits and berries. Low fiber period: 11.6 g per day mean intake total fiber (3 g of which is viscous fiber) High fiber period: 26.2 g per day mean intake total fiber (12.8 g of which is viscous fiber) 7-day food records were kept during week 8 of study.	High fiber diet: TC ↓5%, HDL ↓8% and LDL ↓7%. (all statistically significant)	Dietary intakes of total carbohydrate, energy and protein intake were lower on high-fiber diet. Fat intake did not differ significantly between the groups, but the high fiber diet did contain less total fat, with a higher polyunsaturated to saturated ratio. The high fiber group consumed significantly higher levels of vegetables, cereal, fruits, and berries, compared to the low-fiber group.
Kestin et al., 1990 (Ref. 28)	Intervention, randomized, double blind, controlled with crossover. Purpose to compare separate effects of three cereal brans (wheat, rice, oat) on plasma lipids	24 men, 29-61 years, mild to moderate hyper-cholesterolemia (186-293 mg/dL)	3-week control period prior to test; 4 weeks on each of 3 test diets; no washout. Test fibers, oat bran, wheat bran, rice bran, were provided as bread and muffins; control - low fiber white bread. Fiber supplements were added to individual's normal diet. **Test fibers:** Oat bran: 95 g/d; 5.8 g of soluble fiber per day. Rice bran: 60 g/d; 2.9 g of soluble fiber per day. Wheat bran: 35 g/d; 2.6 g of soluble fiber per day. **Base diet:** % fat calories: 31-37 % SFA calories: 12-13 Cholesterol: 250-300 mg/day TDF: Baseline: 11.2 g/day Test diet: 21 g/day SF: OB diet: 10.3 g/day RB diet: 7.2 g/day WB diet: 6.8 g/day Baselin: 5.7 g/day	Oat bran diet: TC ↓ 5% (significant) compared to baseline. The decrease was mainly in the LDL fraction; HDL increased from baseline in all bran diets. Rice and wheat brans did not cause significant lowering.	The amounts of soluble fiber and insoluble fiber in the three test diets were varied while total fiber was held constant. The oat bran group had higher soluble fiber than the rice, wheat or baseline.

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Lampe et al., 1991 (Ref. 35)	Intervention, controlled, crossover	34 men and women (college students), normal cholesterol; free-living; mean age 27.1 years	Three fiber types (wheat bran, vegetable fiber, sugar beet fiber) were supplements to a controlled liquid base diet for three weeks each, with ≥10-day washout between test periods. Fibers were provided as breads and cereals. Base diet: liquid formula diet providing 35-37% of kcals as fat; 12-14% kcals as saturated fat; 558 mg cholesterol/day; fiber free. Wheat bran: 10 g and 30 g/day (1.1 g and 2.6 g soluble fiber (SF), respectively) Vegetable fiber: 10 g and 30 g (2.7 g and 5.2 g SF) Sugar beet: 30 g (8.2 g SF)	TDF g/day / SF / change from baseline %TC Fiber free 2 1 ↓3 10 g WB 11 1 ↓4 30 g WB 29 3 ↓1 10 g VF 15 3 ↓4 30 g VF 37 5 ↓8* 30 g SBF 30 8 ↓14* WB = wheat bran; VF = vegetable fiber SBF = sugar beet fiber *Statistically significant Changes in LDL were similar.	Effect of fiber in a liquid base diet may not reflect fiber effect in regular foods. SFA and cholesterol intakes were higher on fiber free than test diets. Short test periods.
Levin et al., 1990 (Ref. 37)	Intervention, randomized, double blind	58 men and women, 21-70 years old, free living; mildly hypercholesterolemic (235-245 mg/dL)	8 weeks of diet therapy on a step 1 diet (25% kcals as fat; P:S 1.0; cholesterol <200 mg/day, TDF 21-23 g/day; TSF 6.5-8.5 g/day) followed by 16 weeks treatment with psyllium (Metamucil) or cellulose as placebo. PSY or cellulose were consumed in fluids twice a day before meals. TSF in PSY (10.2 g/day) group an estimated 15 g/day.	Psyllium diet: TC ↓6% and LDL ↓9% (both significant) from baseline; placebo group, no change.	The psyllium group showed a small drop (not statistically significant) in dietary fat intake, while the placebo showed no change. There was some weight loss in the psyllium group. Subject compliance was 95%.
Little et al., 1990 (Ref. 42)	Intervention, controlled	184 men, ages 58-61; free living, treated for hypertension and hypercholesterolemia (240-267 mg/dL)	8-week intervention with five groups: Group 1: no dietary change Group 2: high fiber Group 3: low sodium Group 4: low fat (25% cal) Group 5: low fat, high fiber Fiber was not defined. Total dietary fiber, including soluble and insoluble, was 40-45 g/day.	Low fat diet: TC ↓4.7% (S) compared to baseline; Combination low-fat, high fiber diet: TC ↓4.1% (S) compared to baseline; LDL was not ↓ significantly in either diet group and TC lowering for these two groups were not different from each other. High fiber diet: TC ↑1% (NS).	Changes in serum cholesterol were same for low fat diets and for low fat and high fiber diet. Authors suggest low fat was the effective nutrient.

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Lo and Cole, 1990 (Ref. 43)	Intervention, randomized, double blind, crossover	12 men, 8 women ages 27-60; free living; normo- and hypercholesterol-emic (210-279 mg/dL)	12-week study: two 6-week test periods with additional 3-week rest between periods. Soy cotyledon fiber, made into cereal and bread, was supplemented in 3 divided portions to the subjects' normal diet. Soy: 15 g dietary fiber: 4.3 g of soluble fiber and 13 g of insoluble fiber per day placebo supplements: 4-5 g dietary fiber, 1.2 g soluble fiber, 3 g insoluble fiber. Dietary intake assessed from 3-day dietary records. Diets: Placebo / Soy % kcals fat: 32 / 36 Cholesterol: 290 mg / 270 mg TDF: 13 g / 24 g	After first 6 weeks: Soy group: TC ↓8% (S), LDL ↓7% (S). Placebo group: TC ↓2%, LDL ↓5% (S). After crossover, subjects on soy had a non-significant reduction of cholesterol. The greatest cholesterol reduction occurred within the first six weeks.	This study has a placebo group, is double-blinded and randomized. Fat intake in the two groups were borderline significantly different; neither the saturated nor polyunsaturated intakes are measured. The authors did not keep total dietary fiber constant between the groups. Results varied by order of treatment.
McIntosh et al., 1991 (Ref. 44)	Intervention, randomized, crossover; purpose - to compare barley vs wheat foods and their influence on serum cholesterol levels.	21 men, aged 30-59; free living, mild to moderately to high cholesterol (209-270 mg/dL); South Australia	3-week baseline period followed by 4 weeks on each diet. No washout between test periods. Barley and wheat foods were provided. Barley (high in β-glucan) was tested against wheat; dietary intake assessed from 24-hour recall every third day throughout study. Barley diet: 38 g DF, 13 g SF, 25 g insoluble fiber (IF), 8 g β-glucan. Wheat diet: 38 g DF, 13 g SF, 25 g IF, 1.5 g β-glucan. Base diet: 31-35% kcals as fat, 25-26% kcals as saturated fat, P/S 1.6. TDF: 21 g/day; SF: 7 g/day.	Compared to baseline: barley: ↓TC about 2% and LDL ↓1% (both NS); wheat: TC ↑4% and LDL ↑6%. The group consuming barley during the first test period had no difference in serum total cholesterol, then a small increase in cholesterol on wheat. Those consuming wheat first, then barley showed increased serum total cholesterol, then decreased cholesterol on barley.	The authors, in their analysis, controlled statistically for the P/S and fibers. Results difficult to interpret since wheat was used as a control. Comparison to baseline cholesterol shows only a slight effect of barley on TC. The authors account for the difference in response between groups by suggesting that 4 weeks was too short a test period.
McIvor et al., 1985 (Ref. 45)	Intervention, controlled	8 men and women, obese, ages 45-50, with non-insulin dependent diabetes, free living; normal cholesterol (mean 222 mg/dL).	6-month intervention with gradual phase-in of guar gum within first 4-8 weeks. Guar gum added to subjects' normal diets in granola-type bars. Ss began with 1 granola bar/day and increased to 4 bars/day. These were eaten with meals. Control group consumed granola bars without guar gum; no dietary assessment of normal diet. Guar gum intake: up to 32 g/day (4.8 bars/day - each bar had 6.6 g guar gum and estimated 22 g SF).	After 6 months, serum total cholesterol was not significantly different from baseline. LDL and HDL components were not discussed.	Diet was not monitored.

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Newman et al., 1989 (Ref. 50)	Intervention, randomized, single blind; purpose - to compare barley with wheat sources of fiber.	14 men, 35 years or older, free living, normal serum cholesterol 141-247 mg/dL	4 weeks of pretreatment with normal diet (see below) followed by 4 wks of test. Cereal and baked goods containing hulless barley (10% β-glucan) were provided for high fiber, high β-glucan group. Cereal and baked goods containing 75% wheat flour/25% wheat bran (0.5% β-glucan) for low fiber, low β-glucan group. 3-day dietary history recorded last 3 days of study. Pre-treatment diets Groups Wheat / Barley % fat kcals 35 / 42 TDF, g 7.6 / 4.9 Final diets % fat kcals 34 / 35 TDF, g 46.4 / 44.0	The wheat group had a significantly higher total cholesterol and LDL at the end of the study than at the beginning. The barley group showed no significant change from the beginning to the end of the study.	Total fat intake was significantly different between the groups initially. Over the course of the study, there is a large ↓ in the test group's fat intake, and no change in the wheat group.
Shutler et al., 1989 (Ref. 53)	Intervention, randomized, self-controlled, not blinded	13 non-smoking men, 18-26 years old; free living; normal cholesterol (mean of 196 mg/dL)	A 42-day study: 2 weeks test with canned beans added to normal diets, followed by a 3-week wash-out period, then a 14-day control with spaghetti, followed by subjects' regular diets for 20 or more days. Beans: 1 can (450 g) per day (soluble fiber not assessed); Spaghetti: 1 can (440 g) per day. 3-day food diary kept for the pre-trial, bean, and spaghetti periods. Diets Baseline / Beans / Spag. % fat kcals 36 / 31 / 33 P:S 0.4 / 0.4 / 0.4 Chol, mg 290 / 208 / 174 TDF, g 25 / 60 / 24	Test group, while eating beans: TC ↓12% (S); and HDL ↓15% (S) compared to baseline. After a washout period, the same group, substituting spaghetti for beans showed no effect in cholesterol reduction compared to baseline.	Sat. fat and PUFA (polyunsaturated fatty acids) changes in intake during the test periods were similar. No data on soluble and insoluble fibers. Short test period is a limitation of study.
Stewart et al., 1991 (Ref. 55)	Intervention	Test: 175 men and women, mean age 77 years. Treatment group was selected from ambulatory elderly participants attending a health screening and who had been using psyllium as a laxative or stool softener for at least 1 month. The control group consisted of 741, mean age 75, and was selected from program participants not using psyllium.	The test participants had to be taking psyllium (PSY) for at least one month to one year. The intake of PSY varied from less than 9 g (soluble fiber estimated at 7-8 g) per day to over 19 g (SF estimated at 15-17 g) per day. The regular diet of the participants was not assessed.	Those taking greater than 15-17 g of soluble fiber from psyllium per day had a ↓4.1% in TC (significant). Those taking less than 8 g of soluble fiber from psyllium had no significant change in TC. Comparing taking any amount of psyllium to taking none, did not show a significant difference. intake of PSY was significantly correlated with change in serum cholesterol.	Some selection bias may have occurred since the test group included only regular users of bulk laxative and the control group only regular non-users. The quantity of the psyllium test intake was not controlled. Treatment group were older than controls (77 vs 55 years).

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Superko et al., 1988 (Ref. 56)	Intervention, randomized, single blind with crossover	50 men; aged 39-63; free living; mild to moderately hypercholesterolemic (205-282 mg/dL)	An 8 week study with 3 groups: test group consumed medium-viscosity guar gum (liquid or solid form) for 4 weeks on one diet, then crossover to other form of guar for 4 weeks. Second group: high viscosity guar - consumed in solid form for 4 weeks only. Control group consumed placebo for 8 weeks. Diet was self-selected except for fiber supplements and placebo. Guar gum intake: 15 g/day, (estimated soluble fiber of 10.5 g/day). Placebo intake: 15 g/day. 4-day dietary records were obtained at baseline and at end of each test period.	At 4 weeks: Medium viscosity guar group TC ↓10% (S) and LDL ↓14% (S) from baseline. High viscosity guar group TC ↓15% (S) and LDL ↓18% (S) from baseline. Placebo group TC ↓4% from baseline (NS) and ↓7% drop in LDL (NS). At 8 weeks: the guar groups' total cholesterol levels increased during the second half of the study. Net effect over the 8 weeks of the study: a NS difference between guar groups and the placebo.	Study is blinded and fat intake was measured and assessed for differences between groups. Results differed between the first 4 weeks and the second 4 weeks of guar-supplemented diets making it difficult to draw conclusions about the effect of guar gum on serum cholesterol.
Swain et al., 1990 (Ref. 57)	Intervention, randomized, double blind, crossover	4 male, 16 female hospital employees; 23-49 yrs old; free-living; normal cholesterol: mean 185 mg/dL	6-week test period followed by a 2-week washout, then crossover to other diet for 6 weeks. Oat bran and wheat bran were fiber sources added to subjects' regular diets. Dietary intake assessed with food frequency questionnaire; 4-day food records kept during 5th test week of each test period. Oat bran: 15 g soluble fiber (S.F.)/day Wheat bran: 3.7 g S.F./day Base diet Fat: 31% of kcals; high fiber period had 35% kcals as fat, which came from unsaturated fat in oat bran supplements. Authors contend the additional fat does not affect serum cholesterol.	High fiber: total serum cholesterol (TC): ↓7.5%*+; LDL: ↓9.1%*+ Low fiber: TC ↓7.1%*+; LDL: ↓6.4%*+ *significantly lower from baseline +no difference between groups Authors proposes that substitution of either wheat or oat fiber for dietary saturated fat causes the decrease in TC.	No placebo. Study results limited by small number of subjects and short test period.
Taneja et al., 1989 (Ref. 58)	Intervention, controlled crossover	11 Indian girls, 16-18 years old; free living, normal cholesterol (mean 182 mg/dL)	A 6-week study: 3 weeks on low fiber foods; 3 weeks on high fiber foods. Controlled low fiber diet: refined cereals, dehusked pulses, potatoes, milk, curd, eggs, low fiber vegetables. High fiber diet: same diet with added isagbol husks. Isagbol husks - 25 g (estimated 20-22 g SF) per day.	Higher fiber diet: TC significantly lower (↓7%) compared to low fiber diet. LDL and HDL components are not discussed.	The initial TC levels of each group are not reported. In addition, the fat intake is lower in the high fiber group, and soluble and insoluble components of the isabgol husk diet are not reported.

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Tuomilehto et al., 1988 (Ref. 59)	Intervention, placebo-controlled, crossover	23 men and women, 37-67 years, free living; severely hypercholesterolemic (range 309-553 mg/dL); 4 had type II diabetes, 8 had hypertension, five had familial hypercholesterolemia.	A 1-year study: 1 month placebo period at start, followed by 50 weeks of test with guar gum, then 4 weeks of placebo period. Subjects told to mix guar gum granules with water and take before a meal or mix granules with food. Placebo: granulated wheat flour consumed the same as guar. Guar and wheat granules were added to Ss normal diet (not defined). Guar gum: 15-30 g/day (estimated 10.5-21 g soluble fiber) Wheat flour: 15 g/day Dietary intake monitored by food diary for 4 days before test period and at weeks 17 and 33.	Maximum TC ↓18% (S) after 8 weeks; then ↑ to a final TC level (347 mg/dL) significantly lower (10.5%) than baseline. During final placebo month, serum cholesterol ↑ to pretreatment level. Higher intakes of soluble fiber (14-21 g/day) from 20-30 g guar were not well tolerated. At 34 weeks: LDL ↓15% (S).	Subjects had severely high TC and many with other medical problems. There was some weight loss (4.4 lbs) which was not statistically significant, but must be considered when interpreting the results. Diet was not defined, nor was soluble fiber intake defined.
Van Horn et al., 1988 (Ref. 68)	Intervention, randomized, controlled with crossover	236 men and women, ages 30-65, free living; normo-cholesterolemic (163-247 mg/dL)	A 12-week study: 4 weeks on control diet and 8 weeks on test diet. Both test and control groups consumed the Phase II American Heart Association (AHA) diet throughout the study. The test group consumed 56 g oatmeal/day for for 8 weeks. Phase II AHA diet: total fat: ≤ 30% calories; equal distribution among saturated, mono-unsaturated, and poly-unsaturated fatty acids. Dietary cholesterol: 250 mg/day. 56 g per day oatmeal: 8.4 g dietary fiber and 4.2 g of soluble fiber.	Serum cholesterol levels at baseline and after 4 weeks on the AHA diet were similar for both groups. After 4 weeks: test group had significantly lower serum cholesterol than control group. After 8 weeks: no significant difference in total serum cholesterol between groups. Changes in LDL paralleled changes in total cholesterol. Similar and nonsignificant increases occurred in HDL in both groups. Subgroup analysis showed that subjects in test group with highest baseline serum cholesterol had greater reductions in cholesterol. No change in LDL. The low fat diet was effective in lowering serum cholesterol	No beneficial effect of soluble fiber from oatmeal on serum cholesterol after 8 weeks.

TABLE I--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Van Horn et al., 1991 (Ref. 65)	Epidemiological cross sectional survey	5,111 men and women, 18-30 years; normal cholesterol levels	3 diets: a) lower SFA, high PUFA; b) lower SFA and fish; c) lower SFA and cereal	Dietary fiber is inversely and significantly correlated with TC and LDL; and positively and significantly correlated with HDL in 25-30 year-old white women.	Dietary analyses did not assess soluble and insoluble components of dietary fiber. Also, the study did not control confounders such as smoking, alcohol use, exercise, or fat intake differences between groups. Single samples for cholesterol analysis could not correct for intraindividual variability. Statistical significance was not adjusted for multiple comparisons.
Van Horn et al., 1991 (Ref. 69)	Intervention, randomized, controlled	80 men and women, mild to moderate hypercholesterolemia (213-285 mg/dL)	Two groups: control group consumed regular diet; test group consumed regular diet plus instant oats (2 packets/day - 57 g). TDF SF Insol. F Oatmeal 5.6 g 2.2 g 3.4 g	The test group, while supplementing their diet with oatmeal: TC 16% (S); both the LDL and the LDL/HDL ratio 19%. The control group showed no change.	The study was not blinded; the test group reduced their intake of total fat, saturated fat and dietary cholesterol, and may have made other lifestyle changes.

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21 CFR Part 101

[Docket No. 91N-0100]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Folic Acid and Neural Tube Defects

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing not to authorize the use on the label and labeling of foods, including dietary supplements, of health claims relating to an association between folic acid and reduction in risk of neural tube defects. FDA has reviewed the scientific data in conformity with the requirements of the Nutrition Labeling and Education Act (the 1990 amendments) and has tentatively concluded that there is not a sufficient basis to support the use of health claims relating to this topic. FDA also reviewed recently published results of a large intervention trial of effects of supplements containing very high levels of folic acid in women who, because of histories of neural tube defect-complicated pregnancies, were at high risk of recurrences of these specific birth defects in subsequent pregnancies. Currently there is not significant agreement among qualified experts that intakes of folic acid lower than those studied in this intervention trial will have the same effect as that observed with very high intakes.

Additionally, at this time, there is no significant agreement among qualified experts that folic acid supplementation of women at much lower risk of occurrence of neural tube defect-affected pregnancies will reduce the risk of such a complication. However, the results of the recently published intervention trial are causing some qualified experts to reevaluate the preexisting evidence. FDA will consider all developments in this regard and reflect such developments in any final rule that it issues. FDA has tentatively concluded that claims on foods, including dietary supplements, relating to folic acid and reduction in risk of neural tube birth defects are not justified.

DATES: Written comments by (January 27, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jeanne I. Rader, Center for Food Safety and Applied Nutrition (HFF-268), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-6067.

SUPPLEMENTARY INFORMATION:

I. Background

A. The 1990 Amendments

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535), which amended the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorize the Secretary of Health and Human Services (the Secretary), and FDA by delegation, to issue regulations authorizing nutrient content and health claims on the label or labeling of foods. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under the act (21 U.S.C. 343(r)(1)(B)).

Published elsewhere in this issue of the **Federal Register** is a proposed rule to establish general requirements pertaining to the use of health claims on food labels and in labeling that characterize the relationship of nutrients, including vitamins and minerals, herbs, or other nutritional substances (referred to generally as "substances") to a disease or health-related condition. In this document entitled "Food Labeling: General Requirements for Health Claims for Food: Proposed Rule (the companion document), "FDA has tentatively concluded that such claims would only be justified for substances in dietary supplements as well as in conventional foods if the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles) supports a claim; and if there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims about such support.

The 1990 amendments also require (section 3 (b)(1)(A)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x)), that within 12 months of enactment, the Secretary issue proposed regulations to implement section 403(r) of the act, and that such regulations shall determine, among other things, whether claims respecting 10 topic areas, including folic acid and neural tube defects, meet the requirements of the act. In this document, the agency considers whether a claim on food or food products, including conventional foods and dietary supplements, on the relationship between folic acid and neural tube defects would be justified under the standard proposed in the companion document.

FDA has followed the general concepts and criteria proposed in the companion document in considering whether to propose to authorize the use on the labels and labeling of food of health claims for folic acid and neural tube defects. In the companion document, FDA has proposed that, in evaluating whether support exists for a health claim, it will consider the levels and safety of a nutrient within the context of its use in the daily diet. Before a health claim for a particular nutrient will be authorized, it is necessary that the nutrient be safe and lawful for use in food at the level found to have an effect on a disease or health condition.

The topic of folic acid and neural tube defects involves a substance which has recognized uses both as a component of food and of drugs. The agency has looked at all data relevant to this topic whether the data involved tests at dietary levels or at therapeutic levels. The agency thought this necessary to ensure the completeness of its review. However, the agency emphasizes that this proposal is only about whether a claim has been justified for folic acid on food. A component of food must be safe in the context of the daily diet. On the other hand, drugs may be used even if they present questions of safety to the general population, and even to the population being treated, on the basis that there is a benefit from its use that outweighs the potential risk.

B. Folic Acid and Neural Tube Defects: Public Health Aspects

Congenital malformations are structural abnormalities that are present at birth. Several specific malformations of the central nervous system (CNS) are referred to as "neural tube defects" because the brain and spinal cord develop within the neural tube. The neural tube forms early in fetal life, between the 18th and 20th days of pregnancy, and closes between the 24th and 27th days of pregnancy. Neural tube defects include a wide range of abnormalities of the CNS. They may be isolated malformations or may occur in association with other nonneural congenital malformations.

Anencephalus and spina bifida account for about 90 percent of neural tube defects (Ref. 1). Anencephalus is an abnormality in which there is a virtual absence of the forebrain and skull. Most anencephalic infants are stillborn. Live-born anencephalic infants may survive for only a few days. Spina bifida is a general term describing various developmental abnormalities characterized by defective closure of the bony encasement (the vertebrae) of the spinal cord. The spinal cord and nervous system tissues may protrude through openings resulting from failure of the vertebrae to form normally. Infants born with spina bifida may lack normal function below the level of the defect because of damage to specific nerves.

Anencephalus and spina bifida are more common in Caucasian populations than in other racial groups. Reports of prevalence per 1,000 births in Caucasian populations have yielded the following estimates for anencephalus and spina bifida, respectively: Wales, 3.6, 4.1; Scotland (Glasgow), 2.8, 2.8; Northern Ireland, 3.1, 3.3; Hungary (Budapest), 1.1, 1.6 (Ref. 2). In contrast, prevalence of anencephalus and spina bifida in Japan has been reported to be 0.43 and 0.08, respectively, per 1,000 births (Ref. 2). Rates of neural tube defects in hospital series in northern China, however, are among the highest yet reported and range between 5 and 13 per 1,000 births (Ref. 2a).

The incidence rate of neural tube defects at birth has been reported to vary a wide range of factors, including genetics, geography, socioeconomic status, maternal birth cohort, month of conception, race, nutrition, and maternal health including maternal age and reproductive history. Epidemiologic evidence indicates that there is a strong genetic component involved in neural tube defects (Ref. 3). This genetic component is well-recognized, and familial recurrence patterns are the single greatest risk factor for neural tube defects, although studies in humans have not as yet localized the responsible genes. Carriership for inborn (genetic) errors of homocysteine (a metabolic product of methionine; an intermediate in the synthesis of cystine) metabolism has recently been proposed as a risk factor for having an infant with a neural tube defect (Ref. 4).

In the United States, neural tube defects affect approximately 1 in 1,000 infants at birth (Ref. 2) (i.e., the occurrence rate is approximately 0.1 percent). Occurrence rates are about 4 in 10,000 infants at birth (0.04 percent) in low-risk areas. For example, within the United States, the available hospital data and community surveys show that rates are highest in the northeast and lowest in the west, with anencephalus rates of about 0.5 per 1,000 (0.05 percent) in Iowa and Los Angeles (Ref. 2).

The number of first occurrences of neural tube defects exceeds the number of recurrent events. The great majority of families having an anencephalic or spina bifida infant will experience only one such affected pregnancy. A small minority of about 5 percent, however, will have more than one affected infant (i.e., a recurrence) (Ref. 5). Thus, the risk of having an infant with a neural tube defect is much higher among women who have had a previous pregnancy complicated by a neural tube defect than among women who have not had such a complication. Among women with histories of previous neural tube defect-complicated pregnancies, rates for recurrence of such defects have been estimated to be as high as 2 to 10 percent compared to occurrence rates of about 0.1 percent in the general population (Ref. 3). The pattern of recurrence of these defects is that expected of a polygenic (i.e., caused by several genes) trait. Data from the most recent report of the National Birth Defects Monitoring Program of the Centers for Disease Control (CDC) show decreasing trends for anencephalus and spina bifida between 1979 and 1987 in the United States (Ref. 6).

The striking geographical variations in prevalence at birth of anencephalus and spina bifida have not been adequately explained. For example, the range of prevalence rates in the United States and Canada is very large, with the highest prevalence rates found in the eastern portions of both countries. Additionally, the relatively low prevalence rates in western Canada (British Columbia) have been stable over time, in contrast to the higher rates in eastern Canada which have shown large secular variations similar to trends in the British Isles (Ref. 2). These observations suggest the action of fairly stable genetic factors, with higher but less stable rates possibly caused by the interaction of varying environmental factors with stable genetic factors (Ref. 2).

Maternal health, for example, febrile illness (Refs. 1, 7, and 8) and maternal use of certain drugs also have an effect on the development of neural tube defects. There is an increased incidence rate of malformations (including neural tube defects) among infants of diabetic mothers (Ref. 9). Therapeutic use of valproic acid, an anticonvulsant drug, is associated with markedly increased risk of neural tube defects (Ref. 10, 11, 12, and 13).

Epidemiologic studies suggest that factors associated with acute or chronic poverty also play a role in modifying the incidence rates of neural tube defects. Observational studies in humans suggest that poor maternal nutrition, which is among a number of factors associated with poverty, may increase the risk of neural tube defects. For example, in the United Kingdom, mean values for blood levels of a number of vitamins have been reported to be most satisfactory in women in the highest social classes (Ref. 14). Blood concentrations of several vitamins were reported to be lower on average in women who subsequently gave birth to infants with neural tube defects than in women who did not (Ref. 14). Such evidence is relatively nonspecific, however, since dietary deficiency of one nutrient is frequently correlated with deficiencies of other nutrients.

Maternal nutritional status around the time of conception (the "periconceptional period") is of special concern because, as stated above, the neural tube forms and closes very early in embryogenesis (Ref. 3). The periconceptional period, however, has not been precisely defined. The National Academy of Sciences (NAS) suggested in its 1990 report that this period or interval extends from 1 to 3 months before conception to week 6 of gestation (Ref. 3).

The hypothesis that nutritional factors might be involved in causing some human neural tube defects is based on findings from several types of studies. These include: (1) animal studies in which deficiencies of some vitamins during pregnancy (such as vitamin B_{12}, vitamin B_6 and pantothenic acid) produced a variety of fetal abnormalities, including neural tube defects (Ref. 1); (2) epidemiology studies of neural tube defects in humans that suggest a link with nutrition because of variations in prevalence with social class, dietary habits, and season (Ref. 9); and (3) clinical observations of congenital malformations including neural tube defects in offspring of women who were given an antifolate drug (a drug which alters folic acid status by interfering with absorption, metabolism, or functions of the vitamin) to test its efficacy as an abortifacient.

Among the nutrients that may have a role in development of neural tube defects, folic acid has received the greatest amount of attention because of observational studies in humans and because of the well-recognized roles of this vitamin in cell division and growth.

Folic acid is essential for humans. Folate compounds occurring naturally in foods are in a reduced pteroyl form. Folates occurring in plant and animal cells contain two to eight additional glutamic acid molecules which are linked to the glutamate end of the folate molecule. The folylpolyglutamates which occur in foods are broken down to the monoglutamate forms in the intestine. Commercially available folic acid (pteroylglutamate) is in an oxidized state relative to its occurrence in foods.

Insufficient quantities of folate in the diet lead to impaired cell multiplication and alterations in protein synthesis. These effects are most noticeable in rapidly growing tissues. Abnormalities of rapidly dividing cell populations (for example, those of the gastrointestinal tract and bone marrow) are among the most notable results of folate deficiency because of the essentiality of this vitamin for synthesis of deoxyribonucleic acid.

Determinations of folate in serum and in red blood cells are commonly used to assess folate status. Red blood cell folate concentrations are considered to be a better index of long-term folate status than are measurements of serum folate. Folic acid administered orally is effective for the treatment of megaloblastic anemias of nutritional origin, and those that may develop in women during pregnancy, and those that may develop in infants and children. Pregnancy increases the need for folic acid among other nutrients because of the need of the mother to maintain adequate nutrition and to meet the nutritional requirements of the rapidly developing fetus.

The Medical Research Council of the United Kingdom recently reported (Ref. 15) that periconceptional supplementation of women at high risk of recurrence of neural tube defect-complicated pregnancies with 4 milligrams (mg) folic acid per day significantly reduced the rate of such recurrences. In response, CDC issued guidelines (see section II A. below) for physician-directed use of high doses of folic acid by women who, because of histories of neural tube defect-complicated pregnancies, are at high risk of recurrences of these specific birth defects in subsequent pregnancies (Ref. 16). FDA regards the marketing of folic acid at the dosage and for the use recommended in the interim CDC guidelines (Ref. 16) to require an approved new drug application (NDA). No NDA has been approved by FDA for folic acid for prevention of neural tube defects.

C. Folic Acid: Regulatory History

FDA has promulgated regulations describing uses of folic acid as a dietary supplement and as a drug. These designations are dependent on the intended uses of this vitamin. Section 172.345 (21 CFR 172.345) provides for the use of folic acid in dietary supplement preparations. Preparations containing folic acid in excess of the permitted food additive level (see below) are regulated as drugs and are available with a prescription.

FDA evaluated the use of folic acid as a drug in the **Federal Register** of April 9, 1971 (36 FR 6843) in response to reports received from NAS on the therapeutic uses of folic acid. The agency concluded that folic acid administered orally or parenterally is effective for the treatment of megaloblastic anemias of tropical and nontropical sprue, those of nutritional origin, and those which may occur during pregnancy, infancy, and childhood (36 FR 6843). The agency found that administration of folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient (36 FR 6843) because such treatment may mask the symptoms of vitamin B_{12} deficiency. FDA also concluded that there is no evidence that doses of folic acid greater than 1 mg daily have greater efficacy in treatment of megaloblastic anemias than do those of 1 mg (36 FR 6843).

Folic acid is an approved food additive subject to the limitations on use set forth in the food additive regulation § 172.345. Folic acid (folacin) may be safely added to a food for its vitamin properties, provided the maximum intake of the food as may be consumed during a period of 1 day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive in excess of 0.4 mg for foods labeled without reference to age or physiologic state. When age or the conditions of pregnancy or lactation are specified, the regulation provides that the level of ingestion shall not exceed 0.1 mg for infants, 0.3 mg for children under 4 years of age, 0.4 mg for adults and children 4 or more years of age, and 0.8 mg for pregnant or lactating women (21 CFR 172.345).

D. Evidence Considered in Reaching the Decision

The agency has reviewed all relevant scientific evidence on folic acid and neural tube defects. The scientific evidence reviewed by the agency included all human studies considered in "The Surgeon General's Report on Nutrition and Health" (Ref. 21), and the United States Department of Agriculture's and the Department of Health and Human Services' "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 22). The other reviews conducted by widely recognized scientific bodies that FDA considered were NAS' "Diet and Health" (Ref. 23), the National Research Council's "Recommended Dietary Allowances" (Ref. 24), the NAS' "Nutrition During Pregnancy" (Ref. 3), and the Life Sciences Research Office's (LSRO) "Folic Acid and Neural Tube Defects" (Ref. 25). The agency updated the conclusions reached by these documents by reviewing all human studies that appeared in the literature subsequent to these documents and all new review articles. The agency also considered the results of animal studies to the extent that they clarified human studies or suggested possible mechanisms of action.

To assure that its review of relevant evidence was complete, FDA requested, in the **Federal Register** of March 28, 1991 (56 FR 12932), scientific data and information on the 10 specific topic areas identified in section 3(b)(1)(A) of the 1990 amendments. The topic of folic acid and neural tube defects was among the 10 subjects on which the agency requested information.

E. Comments in Response to FDA Request for Scientific Data and Information

In response to the March 28, 1991 notice in the **Federal Register**, FDA received 12 comments to the docket for folic acid and neural tube defects from manufacturers and suppliers of vitamins to the food and dietary supplement industries, trade associations of nutritional supplement manufacturers, national professional organizations of nutritionists and public health nutrition directors, and the government of Canada. The comments dealt with the issue of folic acid and neural tube defects as well as with the goals and requirements of the 1990 amendments in general. FDA reviewed all of the documents, including letters, press releases, scientific articles, review articles, and recommendations included in submissions that it received. The data submitted in scientific articles were included in the agency's review of the scientific literature.

Among the comments received were three from manufacturers and suppliers of vitamins and two from trade associations of nutritional supplement manufacturers. The submissions from these groups stated that there is sufficient evidence to provide claims for

periconceptional multivitamin (including folic acid) supplementation for reduction in risk of neural tube defects and possibly cleft lip/palate. One comment recommended a Recommended Dietary Allowance (RDA) RDA-level multivitamin supplement for all women of child-bearing age.

One comment from a manufacturer of vitamins recommended multivitamin supplementation for 3 months preceding through 3 months following conception. The comment pointed to several reasons for supplementation during this interval including: (a) The available data; (b) almost risk-free nature of such supplementation; (c) low cost of such supplementation; and (d) economic aspects of care and treatment of infants born with severe birth defects. Another comment from a trade association of nutritional supplement manufacturers stated that there is no risk associated with use of a multivitamin supplement with folic acid with or without minerals by women contemplating pregnancy.

The "almost risk-free" or "no risk" rationale does not qualify as a basis for a health claim. The 1990 amendments require that a health claim be based on the totality of all available scientific evidence and significant agreement among experts qualified by training and experience to evaluate such evidence. Thus, the agency rejects the concept of "almost risk-free" or "no risk" as justification for a health claim because it is inconsistent with requirements of the 1990 amendments.

FDA disagrees with statements regarding the "low cost of such supplementation." Practical difficulties of providing folic acid supplements to all women before pregnancy, and particularly to women before their first pregnancies, are formidable and would be of substantial cost. These factors are important in this instance because there are no data demonstrating benefits to be derived from widespread supplementation of all women of child-bearing age.

The comments also included a number of references relating to effects of anticonvulsant drugs on folic acid status. These articles were included to demonstrate that certain subgroups in the population may require supplemental folic acid as a result of medications that they are taking.

Comments were received from two national professional organizations of nutritionists and public health nutrition directors. These comments advised a cautious approach to the use of health claims on foods and supplements with particular attention to avenues by which such claims might be abused or misinterpreted by the general public. The comments recommended that scientific agreement should be the cornerstone for the use of health claims, and that FDA consider data submitted in the context of meeting dietary requirements through intake of food. Some concern was expressed that the 1990 amendments allowed so many potential topics as candidates for possible health claims.

The government of Canada submitted information that it considered helpful in the context of increased harmonization of regulations or standards affecting trade in specific products. The Director General, Food Directorate, Health and Welfare Canada, wrote to the agency that health claims or messages regarding neural tube defects would likely result in a food product being classified as a drug in Canada by virtue of the definition of "drug" embodied in the Canadian Food and Drugs Act.

The official position of Canada on the relationship of diet and nutrients to disease and the metabolic effects of nutrients is stated in the volume *Nutrition Recommendations, the Report of the Scientific Review Committee—1990* (Ref. 17). In sections relating to folic acid, this report noted that there was particular interest in folate intake before conception and in early pregnancy in view of a reported possible relationship between folate and occurrence of neural tube defects. The report noted that intervention trials carried out in the United Kingdom (Refs. 18, 19, and 20) have been criticized, and that a large controlled trial on prepregnancy supplementation was in progress at the time of the report (Ref. 20). The report does not contain a recommendation for periconceptional supplementation with folic acid (Ref. 17).

II. Review of the Scientific Evidence

A. Federal Government Documents and Statements

In 1988, "The Surgeon General's Report on Nutrition and Health" (Ref. 21) considered the role of dietary factors in maternal health. This report reviewed the results of clinical trials in the United Kingdom in which folate and multivitamin supplements were used in attempts to reduce the risk of recurrence of neural tube defects in infants born to women who had previously had a pregnancy complicated by a neural tube defect. The Surgeon General's Report, citing extensive commentaries (Ref. 26), reported that these trials were poorly controlled for maternal diets and were methodologically flawed by poor compliance, questionable exclusion of eligible participants and recruiting bias (Ref. 21). The report did not make a recommendation with respect to folic acid supplementation before or during pregnancy (Ref. 21).

The U.S. Department of Agriculture and the Department of Health and Human Services, in "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 22), did not discuss any scientific evidence on a relationship between folic acid and neural tube defects. The target populations for these guidelines are healthy Americans and not those persons in the population with chronic diseases or those at high risk of specific diseases. In 1988, the CDC reviewed methodological concerns about case-control studies, and stated that the available evidence was insufficient to recommend multivitamin supplementation in the United States to prevent neural tube defects (Ref. 27).

Following the recent publication of the results of the Medical Research Council (United Kingdom) Vitamin Trial (Ref. 15), the CDC published guidelines, reprinted near the end of this preamble, recommending that a woman who has had a fetus or infant with a neural tube defect should consult with her physician at least 4 weeks before becoming pregnant and should take, under a physician's guidance, 4 mg folic acid per day through the first trimester of pregnancy (Ref. 16).

The CDC stated that these guidelines are not intended for women who have never had a neural tube defect-affected pregnancy, for relatives of women who have had an infant or fetus with a neural tube defect, for women who themselves have spina bifida, or for women who take the anticonvulsant drug valproic acid, a known cause of spina bifida (Ref. 16).

The National Institutes of Health's National Institute of Child Health and Human Development does not have a public policy on this issue (Ref. 28).

B. Other Documents and Statements

The NAS' 1989 report "Diet and Health" did not contain any general recommendation for periconceptional supplementation with folic acid (Ref. 23). No recommendations for periconceptional folic acid supplementation to reduce the risk of birth defects were made in the National Research Council's 1989 edition of "Recommended Dietary Allowances" (Ref. 24). In 1990, NAS reviewed the topic of periconceptional vitamin supplementation and neural tube defects in its report "Nutrition During Pregnancy" (Ref. 3). NAS reviewed studies of vitamin supplementation during the periconceptional period, case-

control and cohort studies of periconceptional multivitamin use, results of laboratory assessments of maternal vitamin status, and studies in animal model systems (Ref. 3). NAS found severe limitations in the available evidence including:

(1) Inconsistency of data associating multivitamin or folate use with protection against neural tube defect pregnancies; and

(2) Evidence that in animal model systems, deficiency of nutrients other than folic acid produced lesions similar to human neural tube defects (Ref. 3). NAS concluded that the scientific evidence derived from various types of human studies and from animal studies does not provide a sufficient basis for making broad recommendations concerning the periconceptional use of vitamins and minerals for the prevention of neural tube defects (Ref. 3).

LSRO of the Federation of American Societies for Experimental Biology also reviewed the scientific literature regarding folic acid and neural tube defects (Ref. 25). The LSRO report concluded that there is evidence that women who take folic acid or folic acid-containing vitamin supplements during the periconceptional period have a lower risk of having infants with neural tube defects. In reaching this conclusion, LSRO was frequently inconsistent in its review of the relevant human studies and in the conclusions drawn from the results of the studies. The report also failed to focus on the specific relationship of folic acid to neural tube defects and on the significant differences in risk of occurrence versus recurrence of neural tube defect-complicated pregnancies. LSRO also concluded that women who have given birth to an infant with a neural tube defect will have a lower risk of bearing another child with a similar defect in a subsequent pregnancy if they take a folic acid supplement during the periconceptional period.

Thus, the authors of Federal government documents and other authoritative reports (with the exception of the LSRO report noted above) from panels of experts who conducted indepth reviews of the effects of periconceptional use of vitamins and minerals found that the available evidence did not provide a basis on which to conclude that the periconceptional use of vitamins and minerals will reduce the risk of neural tube defects among women in the general United States population.

Several professional health organizations were also contacted to determine whether they have policies on periconceptional supplementation with folic acid and neural tube defects at this time. The American College of Obstetricians and Gynecologists does not provide any specific recommendations to their fellows on preconceptional folate supplementation (Ref. 29). The Spina Bifida Association of America does not have a policy respecting folic acid supplementation for reduction in risk of neural tube birth defects (Ref. 30). The Teratology Society has not issued a position paper on this topic (Ref. 31).

C. Review of the Scientific Literature

1. Evidence for an Association Between Intake of Folic Acid and Neural Tube Birth Defects

a. *Criteria used in evaluating studies.* Observational studies have suggested that environmental factors such as nutritional deficiencies of vitamins may be associated with the development of neural tube defects (Ref. 32). Such observations stimulated several epidemiological studies and clinical trials. This relationship has also been investigated in some animal studies.

FDA evaluated scientific evidence available from both human and animal studies against general criteria for good experimental design, execution, and analysis. The criteria that FDA used in evaluating human epidemiologic and clinical studies included (as appropriate):

(1) Reliability and accuracy of methods used in dietary assessment;

(2) Potential for misclassification of subjects with regard to dietary intake or supplement intake;

(3) Presence of recall bias and interviewer bias;

(4) Methods of determination of vitamin status;

(5) Methods of assignment of subjects to treatment or control groups for clinical trials;

(6) Choice of control subjects and representativeness of subjects;

(7) Control of confounding factors, such as demographic variables;

(8) Assessment of compliance with treatment regimens and degree of compliance.

The criteria used in evaluating studies in animals included:

(1) Appropriateness of the animal species, diets, and treatment regimens selected for study;

(2) Whether confounding factors were controlled;

(3) Whether the number of animals was large enough to produce reliable data;

(4) Whether duration of exposure and period of observation were appropriate; and

(5) Whether methods used in the measurement of responses were reliable and accurate.

FDA placed particular emphasis on those human studies that specifically addressed the issue of folic acid and neural tube defects. Those human studies that considered effects of combinations of nutrients were given less weight because they did not address the specific question of a relationship between folic acid and neural tube defects which was identified in the 1990 amendments.

Moreover, because the ability to generalize results obtained from studies of small populations to the much larger population of women in the United States is an important consideration, FDA also evaluated human studies with respect to whether the reported results could reasonably be extrapolated to the United States population. Additionally, because health claims will be directed to the general population of healthy adults, FDA did not evaluate studies describing special situations in which use of specific medications led to the development of vitamin deficiencies because these situations require medical supervision.

FDA evaluated the weaknesses and strengths of individual human studies (see "comments" in Tables 1 through 3). It then assessed the strength of the overall evidence (e.g., epidemiologic studies, assessment of maternal vitamin status, intervention trials, animal studies) taking into account the strength of the association, the consistency of findings, specificity of the association, evidence for a biological mechanism, and presence or absence of a dose-response relationship. FDA's conclusions are based upon the strength, consistency, and preponderance of data.

b. *Human studies.* Human studies on the association between folic acid use, multivitamin use, or maternal nutrition and neural tube defects are summarized in Tables 1 through 3. The major features of these studies (type and design of study, number of women studied, location of populations, nature and duration of treatment or supplement use, maternal diet assessments, and blood indices measured and the significant results) are included in these tables.

Human studies reported to date include four supplementation trials undertaken to reduce the recurrence rate of neural tube defects (Refs. 15, 18, 19, 33, and Table 1), and three casecontrol studies (Refs. 34, 35, 36, and Table 2) and one prospective cohort study (Ref. 37 and Table 2) undertaken to identify possible associations between multivitamin use or dietary folic acid intake and incidence of neural tube defects. There have also been a number of studies in which levels of various vitamins were measured in blood samples obtained from women during or following the periconceptional interval (Refs. 14, 38, 39, 40, and Table 3).

TABLE 1.—STUDIES OF EFFECTS OF PERICONCEPTIONAL FOLATE OR MULTIVITAMIN + MINERALS SUPPLEMENTATION ON RECURRENCE OF NEURAL TUBE DEFECTS

Reference study	Type	Location	Design	NTD defined [1, 2]	Subjects	Treatment	Duration begin	End	Recurrences	Comments
Laurence et al., 1981 (Ref. 18).	Recurrence.	South Wales.	Placebo-controlled double-blind clinical trial.	Yes	60 treated ... 51 placebo ...	4 mg folic acid per day or placebo.	Cessation of contraception.	6 weeks into gestation.	3.3 percent among supplemented 7.8 percent among placebo.	Differences were not significant. Twenty-seven percent of treated group did not comply. Protective effect reached level of significance only when apparent noncompliers were removed. All 6 women who had NTD recurrences also had inadequate diets.
Smithells et al., 1983 (Ref. 19).	Recurrence.	United Kingdom (multicenter trial).	Prospective cohort.	Yes	454 supplemented. 519 unsupplement- ed.	Multivitamin + calcium + iron daily (folic acid in multivitamin = 0.36 mg per day) or unsupplemented.	Not less than 28 days before conception.	Approximately 6 weeks into gestation.	0.7 percent among fully supplemented 4.7 percent among unsupplemented.	Some NTD recurrences and some other major malformations occurred in fully supplemented subjects. Questionable exclusion of 4 fully supplemented subjects, 2 of whom subsequently had NTD infants, due to difficulty with precise timing.
Vergel et al., 1990 (Ref. 33).	Recurrence.	Cuba	Prospective cohort.	No	81 treated ... 20 partially supplemented. 114 unsupplemented.	5 mg folic acid per day or unsupplement- ed.	Not less than 1 month before conception for fully supplemented.	10th week of pregnancy.	0 percent among supplemented. 0 percent among partially supplemented. 3.5 percent among unsupplemented.	Differences were not statistically significant. Unsupplemented women were seen later in pregnancy than were supplemented women. Possible bias in recruitment of subjects. Folic acid status was measured in only part of the fully supplemented group and in none of the unsupplemented group.
Wald, 1991 (Ref. 15).	Recurrence.	International multicenter trial in 7 countries.	Randomized double-blind prevention trial.	Yes	1,817 women were recruited of whom 1,195 subsequently had informative pregnancies.	(A) Ca + Fe + 4 mg folic acid per day. (B) Ca + Fe + 4 mg folic acid per day + multivitamins. (C) Ca + Fe ... (D) Ca + Fe + multivitamins.	At randomization (unspecified time before conception).	End of first trimester (12 weeks of pregnancy).	Group (A), 2/298; (B), 4/295; (C), 13/300; (D), 8/302. Recurrence rate among women in groups (A + B) was 1.0 percent. Recurrence rate among women in groups (C + D) was 3.5 percent.	Significant protective effect of folic acid on recurrence of NTDs. There was no evidence that vitamins other than folic acid conferred the protective effect. Six NTDs recurred in women in groups A + B. Lack of compliance was unlikely as an explanation for these failures. There was no excess of non-NTD birth defects reported in any one group.

[1] NTD, neural tube defect, defined as anencephaly, encephalocele, spina bifida cystica (Laurence et al., 1981; Ref. 18) and as anencephaly, encephalocele, cranial meningocele, iniencephaly, myelocele, myelomeningocele and excluding isolated hydrocephalus and spina bifida occulta (Smithells et al., 1983; Ref. 19).

[2] NTD, neural tube defect, defined as anencephaly, spina bifida cystica and encephalocele by Wald, 1991 (Ref. 15). Multivitamin preparations contained vitamins A, D, B_1, B_2, B_6, C, and nicotinamide.

TABLE 2.—STUDIES OF ASSOCIATIONS BETWEEN PERICONCEPTIONAL MULTIVITAMIN USE AND/OR DIETARY FOLATE INTAKE AND OCCURRENCE OF NEURAL TUBE DEFECTS

Reference study	Type	Location	Design	NTD defined [1,2]	Birth years	Subjects	Reported use of supplements	Other	Duration of periconceptional use	Recall interval	Results	Comments
Mills et al., 1989 (Ref. 34).	Occurrence.	CA, IL	Case-control.	Yes	1985 to 1987.	571 NTD 546 other defects-controls. 573 normal controls.	13 to 15 percent in each group.		30 days before 1st day of last menstrual period and continuing for 45 days.	Less than 5 months.	Mothers of infants/fetuses with NTD were no less likely to have taken multivitamins or folate in periconceptional interval than were women in the control groups. Use of multivitamin supplements not associated with reduction in frequency of NTD.	Cases, controls matched for age, race, education, family income, gavidity. Attempts made to minimize recall bias. Information on multivitamin use obtained after abnormal birth was identified. Not all cases could be identified and interviewed.
Bower and Stanley, 1989 (Ref. 35).	Occurrence.	Western Australia.	Case-control.	Yes	1982 to 1984.	77 NTD 77 other defects-controls.	15 to 21 percent in each group.	Food frequency questionnaire covering 12 month interval.	3 months before to 9 months after last menstrual period.	Not stated (possibly at least 1 year).	Increasing intake of folate (assessed by dietary intake and folate supplementation) in 1st 6 weeks of pregnancy was protective against occurrence of isolated neural tube defects.	No evidence for a protective effect of conjugated folate. Protective effect also observed for dietary fiber, calcium, vitamin C, and carotene. Measures of post-partum dietary folate status showed no association with occurrence of NTD births.
Mulinare et al., 1988 (Ref. 36).	Occurrence.	Metropolitan Atlanta.	Case-control (Atlanta Birth Defects Case-control Study).	Yes	1968 to 1980.	349 NTD 2,829 controls.	Case mothers, 7 percent. Control mothers, 15 percent.	Maternal diet not assessed.	3 months prior to pregnancy through 1st trimester.	2 to 16 years.	Estimated risk of having NTD-affected infant was significantly lower for multivitamin users (approximately) 2.5-fold protective effect). Protective effect less pronounced when cases were compared to abnormal controls.	Compositions of multivitamin preparations not known. Users were different from nonusers in some demographic, health-related, lifestyle characteristics. Apparent protective effect was significant for whites but not for other races. Maternal nutrition during periconceptional period not known. No major differences seen for early and late postconceptional use.
Milunsky et al., 1989 (Ref. 37).	Occurrence.	New England (86 percent); other (14 percent).	Prospective cohort-women who underwent screening at about week 16 of pregnancy.	Yes	1984 to 1987.	49 NTD 22,727 controls.	31.9 percent of entire cohort used multivitamins during periconceptional interval.	Maternal diet assessed.	3 months prior to pregnancy through 1st trimester.	Several months.	Prevalence of NTD was significantly lower for women who used multivitamins with folate during periconceptional interval. Among nonusers, prevalence rates were lower for those whose diets provided >100 micrograms (μg) folate per day.	A substantial majority of the preparations contained vitamins A, C, D, and/or E. The possibility cannot be ruled out that vitamins A, C, D, and E alone or in combination(s) with folic acid were protective. Users were defined as taking at least one multivitamin per week but the majority took preparations more frequently.

[1] NTD, neural tube defect, defined as anencephaly, meningocele, encephalocele, rachischisis, iniencephaly, lipomeningocele (Mills et al., 1989; Ref. 34). Isolated hydrocephalus, hydranencephaly, dermal sinus, and spina bifida occulta were excluded from cases, and oral cleft, deformation, cosmetic defects and hydrocephalus were excluded from defect controls by Mills et al. (Ref. 34). NTDs were defined as anencephaly, spina bifida and encephalocele by Bower and Stanley (Ref. 35).

[2] NTD, neural tube defect, defined as anencephaly and spina bifida (Mulinare et al., 1988; Ref. 36) and as any combination of spina bifida, anencephaly, or encephalocele alone or in combination with other defects (Milunsky et al. 1989; Ref. 37).

TABLE 3.—MEASUREMENTS OF MATERNAL VITAMIN STATUS AS RELATED TO CENTRAL NERVOUS SYSTEM DEFECT- OR NEURAL TUBE DEFECT-PREGNANCIES

Reference	Location	Subjects and samples	Major findings
Smithells et al., 1976 (Ref. 14).	Leeds, UK	Approximately 900 women. Blood samples were obtained not more than 13 weeks after the start of the last menstrual period.	Mean values for all vitamin levels determined were most satisfactory for women in the highest social classes. Values for erythrocyte and white blood cell ascorbate were significantly lower in women who subsequently had an infant with a CNS [1] defect than in control women. Mean values for serum folate and saturation index for riboflavin were also poorer among women who had an infant with a CNS defect than mean values for all social classes.
Molloy et al., 1985 (Ref. 48).	Dublin, UK	32 NTD [2] cases, 395 controls. Blood samples obtained from 8 to 32 weeks of gestation.	Maternal serum folate and vitamin B_{12} were not significantly different between cases and controls. An hypothesized association between vitamin B_{12} deficiency and anencephaly was not confirmed in this study.
Yates et al., 1987 (Ref. 49).	Scotland, UK	20 women with history of 2 or more NTDs, 20 matched controls. Blood samples obtained after birth of index case.	Erythrocyte folate was significantly lower in women who had 2 or more NTDs than in controls. No differences in serum folate, vitamin B_{12}, or other serum vitamin measurements (plasma or white blood cell vitamin C, vitamin A, thiamine, riboflavin, pyridoxine, vitamin E) between cases and controls. Distributions of dietary folate intakes were not significantly different among groups.
Mills et al., 1991 (Ref. 50).	Finland	89 NTD cases, 172 controls. Over 85 percent of blood samples obtained within 8 weeks of neural tube closure.	No significant differences between cases and controls in serum levels of folate, vitamin B_{12}, or retinol.

[1] CNS, central nervous system. Specific abnormalities of CNS not defined by Smithells et al. (Ref. 14);
[2] NTD, neural tube defect. Cases of anencephaly, spina bifida, and encephalocele reported by Molloy et al. (Ref. 48); not defined by Yates et al. (Ref. 49) or Mills et al. (Ref. 50).

i. *Recurrence trials.* Of the four intervention trials with women who were at high risk of neural tube defect-affected pregnancies because of a history of such pregnancies (that is, women at high risk of a recurrence) (Refs. 15, 18, 19, 33, and Table 1), three trials involved daily supplementation with 4 or 5 mg of folic acid alone during the periconceptional interval (Refs. 15, 18, and 33). Two of these trials did not find a statistically significant reduction in neural tube defects. In one of these studies (Ref. 18), 27 percent of the folic acid-treated group did not comply with the treatment regimen. A statistically significant difference between treatment and control groups was found only when apparent noncompliers (identified on the basis of arbitrarily determined serum folate values) were discounted (Ref. 18).

A second intervention study involving daily supplementation with 5 mg folic acid alone was a prospective cohort

study carried out in Cuba (Ref. 33 and Table 1). Although this study showed a decreased risk of recurrence of neural tube defect-affected infants in the supplemented women, the reduction was not statistically significant. Furthermore, a bias in recruitment may have occurred because unsupplemented women in this study were seen later in pregnancy than were supplemented women. The characteristics of a "partially supplemented" group with respect to folic acid treatment were not defined (Ref. 33). Folic acid status was measured in only some women in the fully supplemented group and in none of the women in the unsupplemented group.

An intervention trial that did find a statistically significant difference in the recurrence rate of neural tube defects between supplemented and unsupplemented women (Ref. 19) measured the use of a multivitamin preparation containing folic acid, vitamins A and D, thiamine, riboflavin, pyridoxine, nicotinamide, and ascorbic acid plus minerals (ferrous sulfate and calcium phosphate) rather than folic acid alone. Daily folic acid intake from the multivitamin plus minerals preparation was 360 mg (0.36 mg). The design of this study was inadequate to test the hypothesis that folic acid supplementation would reduce the rate of recurrence of neural tube defects in women who had previously given birth to infants with neural tube defects because intakes of other nutrients in addition to folic acid were also increased in the supplemented women.

The results of a major randomized double-blind prevention trial to determine whether supplementation with folic acid alone or in combination with seven other vitamins could reduce the risk of neural tube defects in women at high risk because of a previous affected pregnancy were reported in July 1991 (Ref. 15). This international study involved women in 33 centers in the United Kingdom, Hungary, Israel, Australia, Canada, the USSR, and France. The study began in 1983 under the supervision of the Medical Research Council, United Kingdom, and was stopped in 1991, because of findings of a significant protective effect of folic acid supplementation against recurrences of neural tube defects in infants of women at high risk of this complication.

The major features of this study are included in Table 1. Women with epilepsy were excluded to avoid adverse effects of high folic acid supplementation on their treatment. A total of 1,817 women at high recurrence risk of neural tube defect pregnancies were randomized to the four treatment groups. Women remained in the trial in the same randomization groups until they had a pregnancy in which the fetus could be classified as having or not having a neural tube defect. Such outcomes were defined as "informative" pregnancies. One thousand one hundred ninety-five women of the 1,817 women randomized (66 percent) had such an informative pregnancy. Two hundred eighty-seven of these informative pregnancies (24 percent) were reported from Glasgow, Scotland, and 201 (17 percent) were reported from Budapest, Hungary, both areas of known high prevalence rates of neural tube defects.

All fetuses and infants were examined. Independent corroboration of all reported neural tube defects was obtained with a necropsy report or a description of the lesions for independent review without knowledge of the allocated group. Final results were based upon the results of all informative pregnancies. The characteristics of the 622 women who did not have informative pregnancies (34 percent of the number randomized) have not as yet been reported (Ref. 15).

Information was obtained for all abnormalities other than neural tube defects in all informative pregnancies. This information provided the basis for a determination that supplementation with folic acid specifically affected rates of recurrence of neural tube defects. The variety of other birth defects that occurred were evenly distributed across all randomization groups. The results of this carefully performed study showed that folic acid at 4 mg per day, with or without other vitamins, significantly reduced the risk of recurrences of neural tube defects in women at high risk of this complication. Six neural tube defects recurred in women in the folic acid-supplemented groups, however, showing that factors other than folic acid status are important in the etiology of neural tube birth defects. The trial had sufficient power to demonstrate efficacy of the treatment for women at high risk of recurrence but did not have sufficient power to answer questions of safety for these women.

ii. *Occurrence studies.* Two case-control studies and one prospective cohort study (Refs. 35, 36, 37, and Table 2) found associations between reduced rates of neural tube defects and use of multivitamin supplements in the periconceptional interval. In one case-control study of multivitamin use in women in the Atlanta area (Ref. 36), the compositions of multivitamin preparations used during the periconceptional interval could not be ascertained because of lengthy recall intervals. In this study, supplement use was based upon recall of events occurring 2 to 16 years before the interview (Ref. 36).

A prospective study of women in the Boston area found that use of a multivitamin supplement that contained folic acid during the first 6 weeks of pregnancy was associated with a reduction in the incidence of neural tube defects, and that no effects were observed if use of the folic acid-containing supplement began after the 6th week of pregnancy (Ref. 37). Estimation of when the use of supplements began during pregnancy depended upon self-reported pregnancy duration, which was in practice based on the date of the woman's last menstrual period (Ref. 37). The majority of the preparations reported as used in this study (Ref. 37) contained vitamins A, C, D, or E in addition to folic acid, however. Therefore, the protective agent cannot be identified. In this same study, dietary folic acid intake was calculated by means of the diet portion of the study questionnaire only for those women who were not taking a multivitamin supplement. Nonusers of multivitamin supplements who had dietary folate intakes greater then 100 μg per day had a lower incidence of neural tube defects than did nonusers whose diets provided less than 100 μg of folic acid per day (Ref. 37). Estimated intakes of nutrients other than folic acid were not reported (Ref. 37).

In a case-control study carried out in western Australia (Ref. 35 and Table 2), apparent protective effects were found for folic acid. However, this study found that dietary fiber, calcium, vitamin C, and carotene were also apparently protective against the occurrence of neural tube defects. This study found that free folate appeared to provide a stronger protective effect against occurrence of isolated neural tube defects than did total folate. Such an observation, if confirmed, may imply the existence within subgroups in the Australian population of a defect (possibly genetic) in intestinal conjugase activity (the enzyme activity that breaks down food-derived folylpolyglutamates) that would be expected to reduce the availability of food-derived folate. Alternately, such a result may represent problems in estimating folate contents of diets from food composition tables.

An additional case-control study involving women in California and Illinois did not find a protective effect on the incidence of neural tube defects from the use of folate-containing multivitamin preparations during the

periconceptional interval (Ref. 34 and Table 2). Supplement usage among women who had a neural tube defect-complicated pregnancy was compared to usage of supplements among women who had normal infants as well as to supplement usage among women who had infants born with abnormalities other than neural tube defects. Use of multivitamin supplements was reported to be the same among women in all three groups, and no protective effect was identified (Ref. 34).

Commentaries on the four studies cited above have been numerous (Refs. 38–46) and include considerations of the role of health-conscious behavior in reduction in risk of neural tube defects (Ref. 38), significance of biases in recall (Ref. 39), problems with case-identification methods (Ref. 40), and differences in prevalence rates in the study areas (Ref. 44). Researchers in the United Kingdom observed, in studies with women at high risk for neural tube defect recurrences, that effects of vitamin therapy are more marked in high-prevalence areas than in low-prevalence areas (Ref. 47). It is important to note that among the four epidemiologic studies cited above, the three studies that showed a positive effect of folic acid or multivitamin supplementation involved populations of higher prevalence of neural tube defects (Boston, 3.5 neural tube defects per 1,000 births (Ref. 37); Atlanta, 1.8 per 1,000 (Ref. 36); and Perth, Australia, 1.5 per 1,000 (Ref. 35)) than did the single study that did not reveal such an effect (California and Illinois, 0.91 neural tube defects per 1,000 births (Ref. 34)). The prevalence factor may be highly important when a multifactorial condition is under investigation, and when prevention or reduction in risk is attempted through manipulation of the environmental (for example, nutritional) component (Ref. 41). The environmental contribution to the total etiology is thought to be greater in areas of higher prevalence. Consequently, in low prevalence areas, a higher percent is attributable to genetic factors and less is attributable to environmental factors (Ref. 41).

None of the epidemiologic studies was able to identify any one factor that was specifically related to reduction in risk of neural tube defects. Maternal dietary counseling and maternal dietary improvement appeared to be as effective a measure as supplementation in decreasing the risk of having an infant affected with a neural tube defect (Ref. 60). Furthermore, all of these epidemiologic studies suffered from biases, including problems with differences in length of recall (Ref. 36), differences between cases and controls relative to socioeconomic status and lifestyle characteristics (Ref. 36), nonrepresentativeness of subjects (Ref. 37), inability to identify and interview all cases (Ref. 34), and possible inaccuracies in determining dietary folate content from food composition tables (Ref. 35). In summary, the results of these occurrence studies do not provide a basis on which to find an association between ingestion of folic acid and reduction in risk for neural tube defects.

iii. *Measurements of maternal vitamin status.* Clinical measures of maternal vitamin status (including folate) also provide no evidence for a consistent association between folic acid intake and neural tube defects. One study (Ref. 14, Table 3) showed that mean blood values for all vitamins determined were most satisfactory for women in the highest social classes. Additionally, mean values for several vitamins were poorer among women who had an infant with a CNS defect than mean values for all social classes (Ref. 14).

Another study (Ref. 49 and Table 3) reported that erythrocyte folate values were significantly lower among women who had repeated neural tube defect pregnancies than among controls. However, dietary intakes of folate among the groups of neural tube defect-affected mothers and control mothers were not significantly different and did not correlate with pregnancy outcome. Thus, an association between risk of having offspring with neural tube defects and decreased erythrocyte folate levels could not be attributed to lower dietary folate intake by the mothers of neural tube defect-affected infants (Ref. 49). Another study did not find differences in parameters of folate status between mothers of neural tube defect infants and controls (Ref. 48).

A report of maternal serum vitamin measurements in a population-based study of Finnish women who gave birth to infants with neural tube defects (Ref. 50 and Table 3) found no significant difference in serum folate levels between women who gave birth to a neural tube defect-affected infant and control women (Ref. 50).

c. *Animal studies.* Studies with animal model systems are one of several lines of investigation that are used to establish associations between deficiencies or excesses of various nutrients and birth defects. Such studies have provided some support for the hypothesis that nutrient deficiencies may be one factor in the etiology of neural tube defects (Ref. 51). Deficiencies of nutrients such as vitamin B_{12}, vitamin B_6, pantothenic acid, and vitamin E have been reported to cause neural tube defects in some species (Ref. 1).

In rats, maternal folic acid deficiency alone does not produce neural tube defect-affected embryos in a reproducible manner (Ref. 26). However, rats fed folate-deficient diets in conjunction with antifolates during pregnancy do produce embryos with multiple congenital abnormalities (Ref. 52). A high spontaneous rate of neural tube defects that closely resemble those seen in humans occurs in the curly-tail mouse. These defects appear to be related to a recessive gene whose expression is modified by the rest of the genome (the complete set of hereditary factors contained in the chromosomes) (Ref. 53). Excess vitamin A administered on the 8th day of gestation increased the incidence of neural tube defects in this mouse in a dose-dependent manner. A variety of compounds including folic acid, folinic acid, methotrexate, vitamin B_{12}, and vitamin E did not significantly affect the incidence of the defect in this model system (Ref. 54).

Neural tube defects in the golden hamster model can be induced by maternal hyperthermia or ethanol following exposures early in gestation. Folate supplementation begun before such treatments does not prevent the alcohol or heat-induced neural tube defects (Ref. 55).

Neural tube defects can be induced by administration of the anticonvulsant drug valproic acid to mice on the 8th day of gestation (Ref. 56). The administration of 5-formyltetrahydrofolate, an active metabolite of folic acid, significantly reduces the rates of these defects. The authors of this study suggested that this model system may be appropriate for studies of protective effects of folates on occurrence of neural tube defects (Ref. 56). Results of mechanistic studies directed toward identifying valproic acid-induced disturbances in folate metabolism have been reported (Ref. 57).

The results of animal studies do not provide evidence for a consistent association between folic acid nutriture and neural tube defects but show that disturbed folate metabolism may be one factor in the complex etiology of neural tube defects.

2. Other Relevant Information

a. *Evidence for efficacy of Dericonceptional supplementation of women at high risk of neural tube defect pregnancies with less than 4 mg folic acid per day.* The daily intake of folic

acid that significantly reduced the risk of recurrences of neural tube defects in high-risk women in the United Kingdom trial was 4 mg and was provided as a supplement (Ref. 15). A daily folic acid intake of 4 mg cannot be attained from usual diets, even when such diets are high in folate-rich foods such as dark green leafy vegetables and liver. Additionally, food additive regulations in the United States do not permit addition of folic acid at high levels to foods or supplements (21 CFR 172.345). Therefore, the agency examined the results of all available human studies to determine whether such studies provide data showing that significant reductions in risk of neural tube defects occurred with intakes of folic acid below 4 mg per day and within the range of folic acid intake attainable in usual diets.

The agency examined the results of both intervention and epidemiologic studies. Only one of four human intervention trials involved supplementation with less than 4 or 5 mg folic acid per day (Ref. 19). A nonrandomized intervention trial carried out in the United Kingdom found a significant difference in the recurrence rate of neural tube defects between women given a multivitamin plus minerals supplement and those who were not supplemented. The multivitamin plus minerals supplement given to some of the women provided folic acid at 360 μg per day. No true control group was included in this trial. Supplemented women were recruited well before conception while unsupplemented women were already pregnant before referral to the study. The design of this study was inadequate to test the hypothesis that folic acid supplementation would reduce the risk of recurrence of neural tube defects in women who had previously given birth to infants with such defects because the supplement used contained a number of vitamins and two minerals in addition to folic acid.

In this study (Ref. 19), attempts were made to examine all infants of fully-supplemented mothers to determine whether vitamin supplementation might harm the embryo or fetus. Results of such examinations were reported for only part of the fully-supplemented group but not for partially-supplemented or unsupplemented groups (Ref. 19). Thus, no comparison of effects between supplemented and unsupplemented groups was possible. The proportions of spontaneous abortions examined in fully-supplemented and unsupplemented women were 61 percent in the first cohort and 32 percent in the second cohort reported (Ref. 19). In contrast, results of all informative pregnancies were reported in the recently published Medical Research Council trial (Ref. 15), leading to virtually complete ascertainment of treatment effects. Thus, efficacy of a dose of folic acid of 360 μg cannot be determined from Ref. 19.

Examination of epidemiologic studies for information pertaining to efficacy of lower doses of folic acid did not provide definitive results. For example, in one study that reported that use of multivitamins containing folic acid reduced the risk of having a neural tube defect-affected infant, the compositions of the multivitamin preparations containing folic acid were not known because of long recall intervals (2 to 16 years) (Ref. 36). In another study that reported that the prevalence of neural tube defects was significantly lower for women who used multivitamins during the periconceptional interval than for women who did not, the multivitamin preparations contained folic acid at levels of 100 to 1,000 μg (Ref. 37). A substantial majority of the preparations also contained vitamins A, C, D, or E. In this study, an efficacious dose of folic acid could not be identified and the possibility could not be ruled out that other vitamins alone or in combination with folic acid were protective.

These studies (Refs. 19, 36, and 37) do not provide sufficient evidence that doses of folic acid lower than 4 mg per day provide significant reductions in risk of recurrence of neural tube defect-affected pregnancies. Thus, evidence of efficacy of doses of folic acid lower than 4 mg per day is lacking. The agency tentatively concludes, based on the currently available evidence, that the amount of folic acid supplementation needed for reduction in risk of neural tube defects in women at high risk of this complication is the level used in the Medical Research Council vitamin study (i.e., 4 mg per day) (Ref. 15).

b. *Significance of studies with anticonvulsant drugs.* FDA recognizes that there is a considerable literature on possible roles of drug-induced nutritional deficiencies in causation of birth defects. Anticonvulsant drugs taken during pregnancy are among a number of factors implicated in the increased risk of congenital malformations including neural tube defects reported in children of women with epilepsy. Abnormalities in vitamin status for biotin, folate, 25-hydroxy-vitamin D, and vitamin A have been reported in anticonvulsant-treated epileptic women. FDA believes that serious medical conditions such as epilepsy should be handled under medical supervision, and that nutritional guidance for anticonvulsant-treated pregnant women or anticonvulsant-treated women planning pregnancy should be provided by trained medical personnel.

c. *Safety considerations.* In "Nutrition During Pregnancy," NAS reviewed the safety of folic acid intake during pregnancy (Ref. 3). It found that the safety of large doses of folic acid during pregnancy had not been systematically evaluated, and that the effects of large maternal doses of folate on the developing fetus are not known (Ref. 3). NAS cited studies (Refs. 58 and 59) that suggested that large doses of folic acid may inhibit the absorption of other nutrients by competitive interaction. Large doses of folic acid may also make it more difficult to diagnose the onset of, or a relapse of, pernicious anemia (Ref. 3). This fact is important because pernicious anemia may occur in pregnant women with impaired vitamin B_{12} absorption caused by lack of intrinsic factor, gastrectomy, or small intestinal disorders that affect the ileum.

The National Research Council, in its 1989 edition of the "Recommended Dietary Allowances" (Ref. 24), also reviewed effects of excessive intakes and toxicity of folic acid in humans and animals. The National Research Council (Ref. 24) concluded that without evidence of benefit, and with some potential for toxicity, excessive intakes of supplemental folic acid are not recommended.

The Medical Research Council vitamin study (Ref. 15) examined effects of supplementation with 4 mg folic acid per day in fetuses and mothers. The number of reported congenital abnormalities other than neural tube defects was similar in all four groups. The mean number of women reporting various medical disorders during the study was also similar in all groups. Thus, supplementation of women at high risk of neural tube defect pregnancies with 4 mg folic acid per day during the periconceptional interval was not associated with adverse effects, but the ability of the study to identify such effects was limited by the size of the groups.

The design of the United Kingdom trial was sufficient to demonstrate efficacy of folic acid supplementation in high-risk women (Ref. 15). It did not, however, have sufficient power to evaluate safety for these high-risk women or for broader public health purposes. The study did not examine the benefit or risk of folate supplementation among low-risk women (those who are not at risk of recurrence of a neural tube

defect-affected pregnancy). Unanswered questions of major concern include those of efficacy and safety of similar intervention in the much larger population of women in the United States at considerably lower risk of occurrence of neural tube defect-complicated pregnancies. There are currently no data demonstrating safety of long-term supplementation of women of child-bearing age with folic acid at the dose used in the United Kingdom Medical Research Council vitamin trial.

3. Conclusions

Until the July 1991 publication of the Medical Research Council's report (Ref. 15), the human studies on the hypothesized association between ingestion of folic acid and reduction in risk of neural tube defects were limited in design and were inconsistent in their findings. Human intervention trials using folic acid would be expected to provide the strongest evidence for efficacy of folic acid supplementation if such trials demonstrated significant reductions in the risk of neural tube defects following folic acid supplementation. Two early trials examining periconceptional supplementation with 4 or 5 mg folic acid alone in women at high risk of neural tube defect recurrences produced nonsignificant results (Refs. 18 and 33). A single nonrandomized intervention study that did find a statistically significant reduction in neural tube defects in women at high recurrence risk of this complication measured usage of a multivitamin plus minerals supplement in addition to folic acid rather than folic acid alone (Ref. 19) and thus, could not demonstrate an independent effect of folic acid supplementation.

The Medical Research Council's randomized double-blind multi-center trial (Ref. 15) clearly demonstrated a significant reduction in recurrence rate of neural tube defects in women supplemented kingdom with 4 mg folic acid per day. No protective effects of vitamins other than folic acid were observed (Ref. 15), and no data were provided to demonstrate the efficacy of doses lower than 4 mg per day. This study established a specific role for folic acid in reduction in risk of recurrence for a significant proportion of neural tube birth defects in women at high risk for this complication because of a history of neural tube defect pregnancies and has provided useful information on an important medical question (Ref. 59).

The four human intervention trials reported to date have been recurrence trials carried out in women in the United Kingdom, Hungary, Israel, Australia, Canada, the USSR, France, and Cuba in women with known high risks of neural tube defect-complicated pregnancies (Refs. 15, 18, 19, and 33). The high incidence of neural tube defects among women in Scotland and in Ireland has made these areas a focus of interest for studies of neural tube defects for many years. Studies in such high incidence areas as those mentioned above enhance the ability to examine cause and effect relationships.

Determination of whether the findings of the Medical Research Council trial with respect to supplementation of women at high risk of recurrent neural tube defect-complicated pregnancies can be extrapolated to other populations at much lower risk is problematic. As noted above, the Medical Research Council trial demonstrated efficacy of folic acid supplementation only in women at known high risk of recurrence of neural tube defect-complicated pregnancies because of a prior history of such a pregnancy. It did not examine effects of such supplementation in women at much lower risk of a first occurrence of a neural tube defect. It is important to note that the recurrence rate of neural tube defects in folate-supplemented women in the Medical Research Council trial was 1 percent (Ref. 15). This rate is at least 10 times higher than the rate of occurrence of neural tube birth defects in the general United States population and emphasizes the important distinction that must be made between risk of occurrence and risk of recurrence of neural tube defects.

The ability to project efficacy of folic acid intervention under U.S. dietary and lifestyle conditions is limited by the fact that none of the four intervention trials were carried out in the United States, an area of very low risk relative to the other areas studied. Moreover, the results of these intervention studies, which examined only recurrences of neural tube defects in areas of high prevalence, may not be generalizable to the considerably larger population of women in the United States who are at a much lower risk for a first occurrence of a neural tube defect-affected pregnancy.

The ability to generalize results obtained from studies of high-risk populations to the much larger population of "all women of child-bearing age" who would be targeted by specific health claims is an important concern. There is a question as to whether data obtained from recurrence trials abroad (Refs. 15, 18, 19, and 33) can be extrapolated to women in the United States who have never had a neural tube defect pregnancy.

Considerations of the ability to generalize results also pertain to several epidemiologic studies carried out in the United States. For example, the authors of a large prospective cohort study of the occurrence of neural tube defects recruited women who were receiving prenatal care and had a maternal alphafetoprotein screen or an amniocentesis (Ref. 37). Such women are not representative of pregnant women in the general population. The results of another study found that the apparent protective effects of periconceptional multivitamin use were statistically significant for white women but not for women of other races (Ref. 36). Racial differences in risks for neural tube defects are well-recognized (Ref. 2).

In general, women included in these studies on neural tube defects may not be representative of an entire population of women at lower risk because those who take or are willing to take supplements may have other characteristics that by themselves decrease the risk of having an infant with a neural tube defect. For example women who have had a neural tube defect-complicated pregnancy and who are seeking to avoid a recurrence may be more willing to seek medical advice before conception, or to take a supplement during the periconceptional interval, than women who have never had a birth defect-affected pregnancy. The fact that the sizes of the populations studied and their risks for neural tube defect pregnancies differed widely further complicates a determination as to whether such results can be generalized to a potential target population including all women in the United States of child-bearing age.

To date, a relationship between inadequate dietary intake of folic acid and increased risk of neural tube defects has not been established. The Medical Research Council's multi-center trial did establish that periconceptional supplementation of women at high risk of neural tube defect pregnancies with 4 mg folic acid per day led to significant reductions in recurrences of neural tube defects (Ref. 15). The trial did not, however, demonstrate a total elimination of recurrent neural tube defect complications in the high-risk women. In the Medical Research Council's study, 6 of 27 reported neural tube defects (22 percent) recurred in women in groups receiving folic acid supplementation. Since serum folate levels in these women were not unusually low for supplemented women, lack of compliance with the supplementation or failure to absorb folic acid were unlikely explanations for

these recurrences (Ref. 15). Thus, a significant fraction of neural tube defect recurrences were apparently resistant to folic acid supplementation. The genetic or metabolic factors underlying these defects are not understood. Such observations emphasize the heterogeneous (or multifactorial) etiology of neural tube defects.

The daily intake of folic acid that significantly reduced the risk of recurrences of neural tube defects in high-risk women in the United Kingdom trial was 4 mg and was provided as a supplement (Ref. 15). As stated above, daily folic acid intake of 4 mg cannot be attained from usual diets, even when such diets are high in folate-rich foods such as dark green leafy vegetables and liver. Additionally, the amount of folic acid needed for efficacy in reducing the rates of recurrent neural tube defects in women at high risk exceeds the amount that can safely be added to foods under current food additive regulations (21 CFR 172.345). Therefore, the agency examined the results of all available human studies to determine whether such studies provide data showing that significant reductions in risk of recurrent neural tube defects occurred with intakes of folic acid below 4 mg per day and within the range of folic acid intake attainable in usual diets.

Only one of four human intervention trials involved supplementation with less than 4 or 5 mg folic acid per day (Ref. 19). This nonrandomized intervention trial measured use of a multivitamin plus minerals supplement which provided folic acid at 360 μg per day. No true control group was included in this trial. Thus, the design of the study was inadequate to test the hypothesis that folic acid supplementation would reduce the risk of recurrence of neural tube defects in women who had previously given birth to infants with neural tube defects because nutrients other than folic acid were included in the supplements (Ref. 19). Moreover, examination of epidemiologic studies for information pertaining to efficacy of doses of folic acid lower than 4 mg per day did not provide definitive results because the compositions of multivitamin preparations used could not be determined (Ref. 36) or because folic acid content of preparations varied over a wide range (Ref. 37).

Thus, because scientific evidence of efficacy of doses of folic acid less than 4 mg per day in reducing rates of neural tube defect recurrences is lacking, the agency tentatively concludes that the amount of folic acid supplementation needed for reduction in risk of recurrent neural tube defects in women at high risk of such recurrences is 4 mg per day (i.e., that level which produced significant findings in the United Kingdom trial (Ref. 15)).

The agency also considered whether claims relating intake of multivitamins including folic acid to reduction in risk of neural tube defects would meet the standard set forth in the 1990 amendments. The agency did not broaden the scope of its considerations to include, for example, multivitamins containing folic acid and other combinations of nutrients and folic acid, because the 1990 amendments clearly identified folic acid and neural tube defects as one of 10 specific topic areas for which the validity of health claims was to be determined. Furthermore, the studies that found an association between use of multivitamin supplements and reduction in risk of neural tube defects did not specify the composition of such supplements (i.e., neither the identity of the vitamins present nor their concentrations were known). Most importantly, the United Kingdom Medical Research Council trial (Ref. 15) demonstrated that vitamins other than folic acid provided no protective effect against recurrence risk of neural tube defect pregnancies (Ref. 15).

III. Tentative Decision to Deny a Health Claim Relating Ingestion of Folic Acid to Reduced Risk of Neural Tube Birth Defects

FDA is proposing not to authorize the use on the labels and labeling of foods, including dietary supplements, of health claims relating to the association between ingestion of folic acid and reduction in risk of neural tube birth defects. Health claims on foods are intended to provide consumers in the general population with information relative to relationships between usual intakes of nutrients and reductions in risk of specific diseases (see companion document "Food Labeling: General Requirements for Health Claims for Food: Proposed Rule," published elsewhere in this issue of the **Federal Register**). The amount of folic acid needed for reduction in risk of neural tube birth defects in women at high risk of this condition is significantly in excess of usual intakes and exceeds amounts permitted under current food additive regulations. FDA has determined that products that provide the necessary amount of folic acid are drugs. In addition, there is no scientific evidence that periconceptional supplementation of women of childbearing age with doses of folic acid lower than 4 mg per day will significantly reduce the risk of neural tube birth defects. For all these reasons, FDA has tentatively determined that claims on foods, including dietary supplements, relating to folic acid and reduction in risk of neural tube birth defects are not justified.

The agency recognizes the significance of the recently published Medical Research Council Vitamin trial and the importance of its findings for women at high risk of recurrence of neural tube defect-affected pregnancies. The results of this carefully performed trial demonstrated that significant reductions in risk of recurrent neural tube defects could be achieved by supplementation of women at high risk with supraphysiologic levels of folic acid. Such therapeutic use of folic acid as a drug, however, permits a risk-benefit consideration that is inappropriate for a food. Recent statements by the CDC provide guidelines for use of folic acid by those women who are planning a pregnancy and who are at high risk of such a complication (Ref. 16). Because of the importance of this guidance, FDA is reprinting significant portions of the CDC recommendations:

1. Women who have had a pregnancy resulting in an infant or fetus with a neural tube defect should be counseled about the increased risk in subsequent pregnancies and should be advised that folic acid supplementation may substantially reduce the risk for neural tube defects in subsequent pregnancies.

2. Women who have had a pregnancy resulting in an infant or fetus with a neural tube defect should be advised to consult their physician as soon as they plan a pregnancy. Unless contraindicated, they should be advised to take 4 mg per day of folic acid starting at the time they plan to become pregnant. Women should take the supplement from at least 4 weeks before conception through the first 3 months of pregnancy.

3. The 4 mg daily dose should be taken only under a physician's supervision. Tablets containing 1 mg folic acid are available as a prescription item. The folic acid dose should be obtained from pills containing only folic acid. Multivitamin (over-the-counter and prescription) preparations containing folic acid should not be used to attain the 4 mg dose because harmful levels of vitamins A and D could also be taken. Prescribing physicians should be aware of the potential for high doses of folic acid to complicate the diagnosis of vitamin B_{12} deficiency. Anemia resulting from vitamin B_{12} deficiency may be prevented with high doses of folic acid; however, the neurologic damage that can result from vitamin B_{12} deficiency could continue.

4. These recommendations are provided only for women who previously have given birth to an infant or had a fetus with a neural tube defect; they are not intended for (1) women who have never given birth to an infant or had a fetus with a neural tube

defect, (2) relatives of women who have had an infant or fetus with a neural tube defect, (3) women who themselves have spina bifida, or (4) women who take the anticonvulsant valproic acid—a known cause of spina bifida. (Ref. 16).

The standard proposed in "Food Labeling: General Requirements for Health Claims for Food: Proposed Rule" (published elsewhere in this issue of the **Federal Register**) requires that a health claim be supported by the publicly available scientific evidence, and that there be significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, regarding such support. Clearly, on the issue of use of folic acid supplementation to reduce the risk of neural tube defects, there is no such evidence at levels of folic acid that can be safely added to foods (including dietary supplements), and thus there is no basis for agreement as to the appropriateness of using folic acid-containing dietary supplements to attempt to reduce the risk of neural tube defects among women in the general United States population. Thus, the agency is proposing not to authorize the use on foods and supplements of health claims relating to associations between ingestion of folic acid and reduction in risk of neural tube birth defects.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a) (11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

VI. Comments

Interested persons may, on or before January 27, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. Section 101.71 is amended by adding paragraph (c) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(c) Folic acid and neural tube defects (insert cite and date of publication in the **Federal Register** of the final rule).

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27167 Filed 11-26-91; 8:45 am]

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21 CFR Part 101

[Docket No. 91N-0101]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Antioxidant Vitamins and Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing not to authorize the use on foods, including dietary supplements, of health claims relating to the association between antioxidant vitamins and cancer. FDA has reviewed the authoritative documents and scientific data in conformance with the requirements of the Nutrition Labeling and Education Act (the 1990 amendments) and concluded that there is not significant scientific agreement to support the use of health claims relating to antioxidant vitamins and cancer on labels and labeling. Although scientific evidence is suggestive of an effect of beta-carotene on cancer risk, studies available to date have been based on consumption of fruit and vegetables high in beta-carotene and not beta-carotene itself. Clinical trials are currently underway to clarify

this relationship. Although scientific evidence is suggestive of an effect of vitamin C on cancer risk, data on the relationship are not consistent and have mostly been obtained in studies of consumption of foods containing high levels of vitamin C. Such studies do not permit a conclusion on the specific role of the nutrient. Evidence for an effect of vitamin E on cancer risk are limited and inconclusive.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with the provisions of the Nutrition and Labeling Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John N. Hathcock, Center for Food Safety and Applied Nutrition (HFF-268), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-245-1198.

SUPPLEMENTARY INFORMATION:

I. Background

A. Nutrition Labeling and Education Act of 1990 (the 1990 Amendments)

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535), which amend the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorize the Secretary of Health and Human Services (the Secretary) to issue regulations authorizing nutrient content and health claims on the label or labeling of foods. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under the act (21 U.S.C. 343(r)(1)(B)).

Published elsewhere in this **Federal Register** is a proposed rulemaking to establish general requirements pertaining to the use on food labels and in labeling of health claims that characterize the relationship of nutrients, including vitamins and minerals, herbs or other nutritional substances (referred to generally as "substances") to a disease or health-related condition (proposed in "General Requirements for Health Claims"). In the proposal on general requirements for health claims, FDA following the provisions of the 1990 amendments has tentatively determined that such claims would only be justified for substances in dietary supplements as well as conventional foods if the agency determines based on the totality of the publicly available scientific evidence (including evidence from well designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The 1990 amendments also require (section 3 (b)(1)(A)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x)) that within 12 months of their enactment, the Secretary shall issue proposed regulations to implement section 403(r) of the act, and such regulations shall determine, among other things, whether claims respecting 10 topic areas, including antioxidant vitamins and cancer, meet the requirements of the act. In this document, the agency will consider whether a claim on food or food products, including conventional foods and dietary supplements, on the relationship between antioxidant vitamins and cancer, would be justified under the standard proposed in "Food Labeling: General Requirements for Health Claims for Food: Proposed Rule."

B. Antioxidant Vitamins and Cancer—Public Health Aspects

Section 3(b)(1)(A)(x) of the 1990 amendments requires that FDA determine whether claims for effects of dietary supplements, including the antioxidant vitamins in relation to cancer, meet the standard that FDA adopts under section 403(r)(5)(D) of the act for determining the validity of health claims. Because the standard that FDA is proposing under that section is the same as the standard that is established in section 403(r)(3)(B)(i) of the act for conventional foods, FDA is extending consideration of this topic area to all sources of antioxidant vitamins.

To comply with the provisions of the 1990 amendments, FDA requested, in the **Federal Register** of March 28, 1991 (56 FR 12932), scientific data and information on 10 specific topic areas, including the topic of antioxidant vitamins and cancer. The agency has considered data and information obtained from these submissions in its evaluation of the scientific basis for a health claim for antioxidant vitamins and cancer.

1. Cancer

Cancer is a disease of major public health importance in the United States. All forms of cancer taken together are ranked as the second most common leading cause of death in the United States and account for one in five deaths (Ref. 1). Deaths from cancer numbered more than 475,000 in 1987. The overall economic cost of cancer, including the direct health care costs and losses from morbidity and mortality, was estimated to be $72.5 billion (Ref. 2). The social impact of cancer can be measured in part by the potential years of life lost by death before age 65. Potential years of life lost were 18 million years for cancer compared to 15 million years for heart disease (Ref. 3).

Risk of occurrence differs markedly for various types of cancer. In 1990, the leading types of cancer in men in the United States were lung (35 percent of all cancer deaths), colorectal (11 percent), and prostate cancer (11 percent). For women, the leading types were lung (21 percent), breast (18 percent), and colorectal cancer (13 percent) (Ref. 3).

Factors that may influence the risk of cancer include not only diet but also life style, environment, and genetics. Antioxidant vitamins may have important, possibly protective, influences on the risk of certain cancers, but other dietary factors such as intakes of energy (calories), type and amount of fat, and other food components may also make important contributions to the relationship between diet and cancer (Ref. 4a).

2. Antioxidant Vitamins

The antioxidant substances that FDA has chosen for consideration are vitamin C, vitamin E, and beta-carotene. Vitamins C and E were chosen because they are vitamins that function as antioxidants (Ref. 4). FDA chose beta-carotene because it is an antioxidant, and because it is a provitamin and an important source of dietary vitamin A activity (Ref. 4). FDA did not choose vitamin A (retinol) and retinoic acid because their biological functions are not through an antioxidant role, and because vitamin A cannot function in a fashion similar to that of beta-carotene (carotenoids) and vitamins C and E (Ref. 5b).

a. *Beta-carotene.* Beta-carotene, a yellow-orange plant pigment, is only one of a large family of carotenes, some of which serve as vitamin A precursors and some of which do not (Refs. 6 and 7). Of all of the carotenoids, beta-carotene has the greatest provitamin A activity.

In addition to serving as a source of vitamin A activity, the antioxidant function of beta-carotene is important.

As a common constituent of the human diet, beta-carotene is a component of the body's primary defenses against the harmful substance known as free radicals and reactive oxygen molecules Refs. 8, 9, and 11). Beta-carotene and similar carotenoids trap, deactivate, and destroy these molecules and prevent the damage they can cause. A way in which beta-carotene might possibly alter the risk of cancer is through its effect on the immune system. Beta-carotene and canthaxanthin have been shown to enhance the immune response in rats (Ref. 12). Beta-carotene has been demonstrated to produce changes in immune cellular marker expression in vivo in humans (Ref. 13) in which there was an increase in the percentage of cells expressing natural killer cell characteristics and activities, changes often related to increased resistance to cancer in experimental animals.

All of the carotenoid pigments similar in chemical structure to beta-carotene have antioxidant activity and the capacity for trapping and deactivating free radicals and reactive oxygen molecules. Of the carotenoids that predominate in human plasma (Ref. 131), i.e., lycopene, beta-cryptoxanthin, zeaxanthin, lutein, and alpha- and beta-carotene, all have this activity and capacity. Carotenoids are prevalent in yellow and greenish-yellow foods, such as carrots, squash, broccoli, sweet potatoes, tomatoes, and kale; these foods are some of the best sources of carotenoids. The fact that, collectively, carotenoids contribute significantly to the daily vitamin A intake and function as antioxidants makes these compounds important components of the daily diet.

b. *Vitamin C.* Vitamin C (*L*-ascorbic acid) is a watersoluble antioxidant vitamin that cannot be synthesized by humans. Dehydroascorbic acid, an oxidized form of ascorbic acid, may be present in the diet, and also has vitamin C activity. Dietary deficiency of vitamin C, which is extremely rare in the United States, leads to scurvy.

Vitamin C functions in a variety of enzymatic reactions that require molecular oxygen. For example, vitamin C is involved in enzyme reactions required for formation of proteins in connective tissue. Vitamin C also serves as an effective free-radical scavenger to protect cells from damage by oxidants. It is in this capacity that vitamin C may provide protection against adverse effects of potential carcinogens. Vitamin C plays roles in maintaining the integrity of intracellular matrices, enhances the immune system, and is necessary for several types of biochemical reactions (Ref. 6).

The richest food sources of vitamin C are green peppers, broccoli, citrus fruits, melons, tomatoes, raw cabbage, and green leafy vegetables such as spinach, turnip, and mustard and collard greens. The amount of vitamin C in the United States food supply has increased significantly since the beginning of the century; this has been the result, in part, of the greater availability of citrus fruits and dark green vegetables and to fortification of some foods with vitamin C. About 73 percent of the vitamin C intake in the United States is derived from fruits and vegetables (Nationwide Food Consumption Survey of 1977 and 1978).

The Recommended Dietary Allowance (RDA) for vitamin C for adults is 60 milligrams per day (Ref. 14). The major contributors of vitamin C to the United States diet are orange juice, grapefruit and grapefruit juice, fortified fruit drinks, oranges, tangerines, and potatoes (Ref. 4a).

Estimated average intakes of vitamin C are well above the RDA for men, women, and children (182, 133, and 186 percent, respectively, of the RDA's) (Ref. 4a). Between 35 and 40 percent of the adult U.S. population are estimated to take nutrient supplements, and approximately 90 percent of these take a supplement that includes vitamin C.

A 1986 National Health Interview Survey (Ref. 15) of vitamin and mineral supplement use in the United States found that men and women (about 31 percent of all adults) consumed vitamin C more than any other nutrient, and the median intake of vitamin C was 200 percent of the RDA due to this supplement intake. Current dietary data indicate that mean intake of vitamin C is well in excess of the RDA's for all population groups, and the additional supplement use provides a large segment of the population with intakes several fold the RDA levels (Ref. 2).

c. *Vitamin E.* Vitamin E has received attention as an antioxidant vitamin that may reduce the risk of cancer. The vitamin represents a family of compounds, tocopherols and tocotrienols. These compounds exist in various forms and have different biological activity. The most active form of vitamin E is alpha-tocopherol followed by beta-tocopherol, gamma-tocopherol, and alpha-tocotrienol. The basic biological function of vitamin E in animal tissues is as an antioxidant where it acts as a defense against potentially harmful reactions with oxygen (Ref. 2). Determination of the requirements for vitamin E is complicated by variations in susceptibility of dietary and tissue fatty acids to peroxidation (reaction with an oxygen molecule to form a fatty acid peroxide), and difficulty in demonstrating changes in vitamin E status in the general healthy population (Ref. 16). The richest food sources of vitamin E are wheat germ, vegetable oils (corn, cottonseed, safflower, soybean and sunflower oils), and products made from vegetable oils. Other good sources are nuts, seeds, whole grains, and wheat germ.

The National Research Council (NRC) in the 1989 edition of "Recommended Dietary Allowances" (Ref. 14) stated that an adequate level of vitamin E implies that the ratio of tocopherol to polyunsaturated fatty acid in the tissues protects lipids from peroxidation, permits normal biological functions, and allows for individual variations of lipids in tissues. According to the NRC, these criteria of adequacy appear to be met by amounts of vitamin E and polyunsaturated fatty acids in balanced diets consumed by healthy individuals. Therefore, the RDA's are primarily based on customary intakes from the U.S. food supply.

The RDA's for vitamin E have been set by the NAS (Ref. 14). The RDA is 10 mg of alpha-tocopherol equivalents for males 11 years of age and older and 8 mg of alpha-tocopherol equivalents for females 11 years and older. The allowance of alpha-tocopherol equivalents for infants and children 1 to 10 years of age is 6 to 7 mg and the allowance for infants less than 1 year of age is 3 to 4 mg. One alpha-tocopherol equivalent is defined as 1 mg d-alpha-tocopherol. The adequacy of the RDA's for vitamin E will vary, if the polyunsaturated fatty acid content of the diet increases greatly over intakes in current balanced diets in the United States.

d. *Interactions among antioxidant vitamins.* The antioxidant vitamins are interactive in that they complement each other during situations of biological stress. Vitamin C, most of which is located in the aqueous portion of the cell, spares vitamin E until the vitamin C reserve is depleted (Ref. 17). Vitamin E is located in the lipid portions of all membranes, and it deactivates free radicals. Sparing action has also been observed between beta-carotene, which is also found in the lipid portions of the cell, and vitamin E in that beta-carotene exhibits deactivation of free radicals similar to that of vitamin E. Beta-carotene, vitamin C, and vitamin E all inhibit damage by oxidative chemicals, including carcinogens (Ref. 7). More specifically, beta-carotene traps reactive oxygen molecules, vitamin E and beta-

carotene remove free radicals, and vitamin C inhibits oxidative reactions and also removes free radicals.

The antioxidant vitamins may also interact negatively in that high doses of one can counteract the uptake, transport and storage of another. For example, high intakes of beta-carotene administered to humans for 6 months or more can deplete plasma levels of vitamin E (Ref. 18b). In another report (Ref. 20), high intakes of beta-carotene for over 4 years did not alter vitamin E levels in humans. However, high intakes of vitamin A in rats were shown to deplete plasma levels of vitamin E (Ref. 19).

Because of the complementary and antagonistic interactions among the antioxidant vitamins, high intakes of one without commensurate increases in the others may not support optimum status and functions for these nutrients (Refs. 4a and 21). Foods may, therefore, provide a better balance of these nutrients than do supplements, and foods supply other substances such as fiber, minerals, and many nonnutrients that may be important in reducing the risk of some cancers (Refs. 4a and 17).

3. Basis for Associations Between Antioxidant Vitamins and Cancer

a. *Mechanisms of carcinogenesis and relationship to antioxidants.* The complex process of carcinogenesis is often described as occurring in distinct phases (Refs. 4 and 28) including: (a) Initiation, (b) promotion, (c) progression, and (d) metastasis. Initiation of the carcinogenic process results from chemical or physical damage to cellular genetic material (deoxyribonucleic acid (DNA)). Cell replication then results in fixation of the damage as a mutation. Promotion involves stimulation of the growth of initiated cells. Progression is the malignant transformation of the initiated cell mass into an invasive form that is not subject to the normal limits or controls of cellular replication. Metastasis is the spread or dissemination of cells from the original tumor to new sites in the body.

Most dietary carcinogens occur as procarcinogens, i.e., as substances that require activation to a reactive form that is termed the proximate carcinogen (Refs. 22 and 23). The ultimate carcinogen, an extremely reactive and unstable species, is produced by rearrangement of the proximate carcinogen. The ultimate carcinogen is the form that is directly involved in the reaction with nucleic acids or other substances with similar chemical reactivity (nucleophiles).

This general pattern of carcinogen activation, chemical reaction of the carcinogen molecule with nucleic acids, mutagenesis, and carcinogenesis is firmly established through experiments with animals and with cultures of human and animal cells (Refs. 22 and 24).

A major effect of vitamin C that could be the basis of protection against cancer is its ability to inhibit nitrosamine formation (Ref. 25). Nitrosamines (N-nitroso amines and N-nitroso amides) are types of carcinogens which occur in foods and are produced within the body by reaction of nitrite with other dietary or endogenous amines and amides (Refs. 25 and 26). Some nitrite occurs in food, but more is produced from reduction of nitrate by bacteria in the mouth and small intestine (Ref. 26). Nitrate occurs in food (Ref. 26), and some is produced in the body from L-arginine (Ref. 27). The nitrosation reactions occur rapidly in the acid environment of the stomach and upper duodenum (Ref. 25). Most nitrosamines tested in experimental animals are carcinogenic, and some are very potent carcinogens affecting multiple sites (Ref. 26).

b. *Associations between antioxidant vitamins and risk of cancer Beta-carotene.* Epidemiological studies in the 1970's and early 1980's showed an inverse association between vitamin A intake and lung cancer and cancers at various sites (Ref. 28). A reexamination of the early vitamin A intake data in relation to cancer, however, revealed that the sources of the vitamin A were fruits and vegetables which contain beta-carotene and other carotenoids. As stated above, beta-carotene is a precursor of vitamin A and is not vitamin A itself. Therefore, the focus of research on the relationship between vitamin A and cancer shifted to the carotene content of the foods consumed.

This hypothesis of the relationship between ingestion of beta-carotene and decreased cancer risk has persisted. Results of animal studies indicate that beta-carotene is effective in preventing cancers induced by certain chemical carcinogens. This information however, is helpful only with regard to discerning mechanisms involved in cancer development, because the type and amount of carcinogen used in the animal experiment are not typical for humans. The strongest evidence to support the hypothesis that beta-carotene decreases the risk of cancer is from epidemiological studies involving fruit and vegetable consumption, and not from studies of beta-carotene itself in humans. When completed, clinical trials currently underway should provide more direct evidence on whether beta-carotene alters the risk of cancer in humans.

c. *Vitamin C.* A hypothesized relationship between ingestion of vitamin C and risk of cancer has developed from several types of studies. For example, human studies have shown a protective association between consumption of foods that contain vitamin C and cancers of several sites (Ref. 29). Studies in experimental animals have shown that animals fed both vitamin C and precursors of carcinogenic nitrosamines develop fewer tumors than animals fed the precursors alone (Ref. 30). Vitamin C has been shown to reduce bladder tumors in animals induced by one carcinogen (Ref. 31), but not by another (Ref. 32). Biochemical studies have shown that vitamin C prevents the oxidation of specific chemicals to active carcinogenic forms (Ref. 31), and vitamin C blocks the formation of carcinogenic nitrosamines from nitrates and nitrites in the digestive tract (Refs. 30 and 33b). The combination of evidence from epidemiological studies and evidence from several types of studies with animals which involved administration of carcinogens and carcinogen precursors provides a strong basis on which to postulate that vitamin C reduces the risk of cancer in humans.

d. *Vitamin E.* The hypothesis that vitamin E may reduce the risk of some types of cancer is based on two kinds of scientific findings. Animal studies have demonstrated an inhibitory effect of vitamin E on cancers induced by ultraviolet light and certain chemicals. These studies date back to the earliest days of vitamin E chemistry (Ref. 34). More recently, the implications of reactive oxygen molecules in cancer development provide a theoretical basis for the involvement of vitamin E (a strong antioxidant) in the development of cancer, because carcinogens are activated by oxidative processes and oxidation of cell components may contribute to cancer development (Refs. 4a and 22).

C. Regulatory History of Antioxidant Vitamins

1. Nutrition Labeling

FDA published a proposal to amend the food labeling regulations to codify and clarify the agency's policy on the appropriate use of health claims on food labeling in the **Federal Register** of August 4, 1987 (52 FR 28843). On August 8, 1989, FDA published in the **Federal Register** (54 FR 32610) an advance notice of proposed rulemaking requesting public comments on (among other areas) how to reasonably permit the use of claims on food labels that link food

components to reducing the risk of chronic disease. In the **Federal Register** of February 13, 1990 (55 FR 5176), FDA withdrew the August 4, 1987 proposal (52 FR 28843) and reproposed to amend the food labeling regulations to provide for the use of health claims on food labeling. The purpose of the reproposal was, in part, to establish procedures for permitting valid and reliable consumer information on food labels about the value that ingestion of dietary components may have in either lowering the risk or forestalling the premature onset of particular chronic disease conditions. The topic of antioxidant vitamins and cancer was not specifically mentioned in any of these documents.

Comments from a consumer advocacy group and several industries suggested that topics other than the six specified in the reproposed rule making were worthy of consideration and stated that the role of antioxidant vitamins and beta-carotene in preventing diverse diseases, especially cancer, should be considered. One comment suggested that health claims might be appropriate for the relationship between cancer and fruits and vegetables and the antioxidant vitamins. Another comment argued that a health claim for beta-carotene rich foods would be consistent with the dietary recommendations of organizations such as the National Cancer Institute. Several comments asserted that a substantial body of evidence exists showing an inverse association between foods high in beta-carotene and a reduced risk of certain forms of cancer.

A trade association for the dietary supplement industry commented that, in its opinion, the evidence is "overwhelming" that consumption of fruits and vegetables high in antioxidant vitamins reduces the risk of certain forms of cancer, and that the scientific evidence suggests that vitamins C and E and beta-carotene are responsible for this effect. A pharmaceutical company commented that it felt antioxidant vitamins, particularly vitamin C, are effective in vivo antioxidants and are involved with other diseases such as heart disease, cataracts, rheumatoid arthritis, and Parkinson's disease. A major food manufacturer commented on the relationship of beta-carotene and cancer, citing currently completed epidemiological evidence and ongoing clinical trials.

No comments were received from consumers or from professional organizations of physicians or other health care workers.

These comments were superseded to by section 3(b)(1)(A)(x) of the 1990 amendments, which directed FDA to consider the relationship between dietary supplements of antioxidant vitamins and cancer, among other topics. These topics are considered in this and other documents published in this issue of the **Federal Register**.

2. Regulatory Status

Substances that are added to food may be categorized as generally recognized as safe (GRAS) ingredients, food additives, or subject to a sanction or approval granted by FDA or the U.S. Department of Agriculture (USDA) prior to September 6, 1958. Substances may be GRAS in accord with the general principles stated in 21 CFR 170.30, listed as GRAS in 21 CFR part 182, or affirmed as GRAS in 21 CFR part 184. The status of the most common uses in foods of carotenoids, vitamin C compounds, and tocopherol compounds is summarized below.

The following carotenoid compounds and sources rich in these carotenoid compounds are approved color additives for food use exempt from certification: beta-carotene (21 CFR 73.95), betaapo-8'-carotenal (21 CFR 73.90), and carrot oil (21 CFR 73.300). Beta-carotene is affirmed as GRAS for use as a nutrient supplement (21 CFR 184.1245) and listed for use in dietary supplements § 182.5245. Carrot oil, essential oil or extractive, is listed for use as a flavoring substance § 182.20.

Ascorbic acid (vitamin C) is listed as a GRAS ingredient for use as a chemical preservative (antioxidant) (21 CFR 182.3013), in dietary supplements (21 CFR 182.5013), and as a nutrient (21 CFR 182.8013). Ascorbyl palmitate, ascorbyl stearate, calcium ascorbate, and sodium ascorbate are listed as chemical preservatives (21 CFR 182.3149, 166.110, 182.3189, and 182.3731, respectively). Ferrous ascorbate is affirmed as GRAS for use as a nutrient supplement (21 CFR 184.1307a), although, at usual levels of intake, ferrous ascorbate contributes little vitamin C activity. A nicotinamide-ascorbic acid complex is listed as a special dietary and nutritional food additive in 21 CFR § 172.315.

Tocopherols are listed as GRAS for use as dietary supplements (21 CFR 182.5890), as nutrients (21 CFR 182.8890), and as chemical preservatives (antioxidants, in 21 CFR 182.3890, and inhibitors of nitrosamine formation (21 CFR 184.1890)). Alpha-tocopherol acetate is listed as GRAS for use in dietary supplements (21 CFR 182.5892) and as a nutrient (21 CFR 182.8892).

D. Evidence Considered in Reaching the Decision

The agency reviewed all relevant scientific evidence on associations between ingestion of antioxidant vitamins (vitamins C and E) and beta-carotene and reduced risk of cancer. The scientific evidence and conclusions that the agency reviewed included those in the "Surgeon General's Report on Nutrition and Health" (Surgeon General's Report) (Ref. 4a), "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 35), and the U.S. Department of Health and Human Services (DHHS) "Healthy People 2000: National Health Promotion and Disease Prevention Objectives" (Ref. 3). The agency also reviewed other authoritative documents, NRC's "Diet and Health" (Ref. 2), and "Recommended Dietary Allowances" (Ref. 14), and the Life Sciences Research Office's "Vitamin A and Cancer" (Ref. 36), "Vitamin C and Cancer" (Ref. 37) and "Vitamin E and Cancer (Ref. 38).

The agency updated the evidence reached in these documents by reviewing all human studies in the literature subsequent to these documents and all new review articles. The updated literature search began with 1987. The agency also considered the results of animal studies to the extent that they clarified human studies or suggested possible mechanisms of action.

To assure that its review of relevant evidence was complete, FDA requested, in the **Federal Register** of March 28, 1991 (56 FR 12932), scientific data and information on the 10 specific topic areas identified in section 3(b)(1)(A)(vi) and (b)(1)(A)(x) of the 1990 amendments. The topic of antioxidant vitamins and cancer was among the 10 subjects on which the agency requested scientific data and information. The agency reviewed all of the documents it received, including letters, press releases, scientific articles, review articles, and recommendations. Where appropriate, data submitted in scientific articles were considered in the review of the scientific literature (section II.)

E. Comments Received in Response to FDA's Request for Scientific Data and Information

FDA received 17 comments in response to the March 28, 1991 **Federal Register** notice (56 FR 12932) concerning antioxidant vitamins and cancer health claims. Of the comments received, nine were from industry, three from professional organizations, two from trade associations, one from an individual consumer, one from a state government, and one from the Government of Canada.

Over 435 references were received, including recent review articles on

antioxidant vitamins and cancer. Some of the responses included references only, while others contained references and comments, or just comments. The comments generally cited data or opinions from specific references. The majority of the comments supported a health claim relative to the antioxidant vitamins and cancer. In general, comments from manufacturers and trade associations, as well as from a few research organizations, argued that the evidence for beneficial effects of antioxidant vitamins in relation to cancer is strong, or even compelling, that these substances are safe, and therefore, the only reasonable course of action is to allow health claims in this area.

The regulatory status of health claims for antioxidant vitamins and cancer in Canada was described in comments from the Director General, Food Directorate, Health and Welfare, Canada. The official position of Canada on the relationship of diet and nutrients to disease and the metabolic effects of nutrients is stated in the volume "Nutrition Recommendations, the Report of the Scientific Review Committee–1990." In sections related to Water-Soluble Vitamins and Fat-Soluble Vitamins, this report concluded that, for vitamin C and the fat-soluble vitamins, evidence for protection against cancer lacks specificity and is inconclusive. The Government of Canada pointed out that health claims would be illegal under Canadian law and thus advised against such claims.

All of the nine responses received from industry included literature references on antioxidant vitamins and cancer. One chemical company provided data to demonstrate the efficacy and safety of antioxidant vitamins, especially vitamins C and E, and beta-carotene. A food manufacturer suggested that FDA also consider the interactions between antioxidant vitamins and selenium. The comment also suggested that antioxidants may be depleted by oxidative stress, thereby enhancing risk of a variety of diseases including heart disease, breast and cervical cancer. A diet systems company provided a tabular summary concluding that antioxidant vitamins (but not any one specifically) are protective against cancers of the breast and colon. Another manufacturer argued that animal research and human epidemiologic and blood level studies support a protective effect for vitamin E, vitamin C, and beta-carotene, but that continued research is warranted.

A pharmaceutical manufacturer commented that: (1) Free radical damage is widely accepted as a major theory of carcinogenesis and that the antioxidant vitamins are effective inhibitors of this process; (2) many persons are not consuming RDA levels of the vitamins; (3) epidemiologic evidence is supportive of beneficial effects by the antioxidant vitamins, and the National Cancer Institute and the USDA have recommended increased intakes of certain foods on this basis; (4) there is little or no evidence that consumers will replace conventional medical care with dietary "treatments" for cancer or other disease; and (5) supplementation is beneficial and essentially risk-free. A pharmaceutical and a supplement manufacturer argued that they recommend a benefit/risk approach instead of consideration of only what has been established as an "incontrovertible scientific fact." These two pharmaceutical manufacturers also expressed extreme concern and dissatisfaction with the rulemaking process.

FDA notes in response to these comments that the "benefit/risk" or "essentially risk-free" rationale does not qualify as a basis for a health claim. The 1990 amendments provide that a health claim is justified only if the agency determines, based on the totality of publicly available scientific evidence relating the nutrient and the disease, that there is significant agreement among qualified experts that the claim is supported by such evidence. Therefore, the agency rejects the concepts of "benefit/risk" or "essentially risk-free" as basis for a health claim because of their inconsistency with requirements of the 1990 amendments.

A private research foundation commented that evidence supports the conclusion that increased intakes of micronutrients including the antioxidant vitamins lowers the risk of cancer, especially in the stomach and esophagus. The comments stated, however, that the emphasis should be on avoiding intake of carcinogens, rather than on consumption of anticarcinogens. On the other hand, another professional organization argued that there should be no doubt concerning the antioxidant efficacy of certain vitamins.

A trade association commented that the NRC's book "Diet and Health" (Committee on Diet and Health, 1989) virtually ignored this important topic of antioxidant vitamins and cancer, even though data and conclusions of important benefits have been published by respectable scientists. A trade association for the dietary supplement industry submitted abstracts on selenium and cancer. It also cited evidence that vitamin C is effective, both in animals and in humans, against a wide variety of cancer types/sites, through a variety of mechanisms, and with exposure of animals to a variety of carcinogens.

A state government agency provided only general comments on the nutrient health relationships it believes must be established to justify any health claim. This agency recommended that scientific agreement should be considered the cornerstone of any health claim. This state government agency and a professional organization, however, urged that FDA be extremely cautious in making its decision.

The agency has considered each of these comments in its development of this proposal.

F. Criteria for Evaluation of Scientific Evidence

FDA has evaluated the data from human studies against general criteria for good experimental design, execution, and analysis. The criteria used in evaluating epidemiological studies included:

(1) Reliability and accuracy of the methods used in food intake analysis and measurement of disease endpoints;

(2) Choice of control subjects (e.g., hospital-based versus population-based);

(3) Representativeness of subjects;

(4) Control of confounding factors, particularly fat, which has an inverse correlation with, and fiber intake which has a positive correlation with, fruit and vegetable intake, in data analysis;

(5) Potential for misclassification of individuals with regard to dietary exposure or disease end points;

(6) Presence of recall bias and interviewer bias; and

(7) Degree of compliance and how compliance was assessed.

FDA evaluated the weaknesses and strengths of individual studies (see "Assessment" column of tables following each antioxidant vitamin). The agency then assessed the strength of the overall combined evidence (e.g., epidemiologic studies and animal studies), taking into account the strength of the association, the consistency of findings, specificity of the association, evidence for a biological mechanism, and presence or absence of a dose-response relationship. FDA's conclusions reflect the strength, consistency, and preponderance of data.

II. Review of Scientific Evidence: Beta-Carotene

A. Federal Government Documents and Statements

In 1988, "The Surgeon General's Report on Nutrition and Health (Ref. 4a) considered the role of carotenoids in cancer. The report concluded that some epidemiologic studies provide suggestive evidence that frequent consumption of vegetables and fruits, particularly dark green and deep yellow vegetables which contain carotenoids, including the beta-carotene precursor of vitamin A, may lower risk for cancers of the lung and bladder as well as some cancers of the alimentary tract. The report pointed out, however, that these studies have not ruled out the possibility of protection from some other active component of fruits and vegetables. Until the results of chemoprevention clinical intervention trials examining these relationships become available, the report stated that it could conclude only that an increase in consumption of fruits and vegetables might benefit persons who now consume below average amounts of these foods. No risks from consumption of beta carotene or carotenoids were identified.

USDA and DHHS in "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 35) recommended the consumption of generous portions of vegetables and fruit, but did not make a specific reference to the role of increased consumption of these foods and the lowered risk of cancer.

B. Other Authoritative Documents and Statements

The NAS 1989 report on "Diet and Health" (Ref. 2) found that there is strong evidence that a low intake of carotenoids, which are present in green and yellow vegetables, is related to an increased risk of developing lung cancer. The report stated that the mechanism for the link between frequent consumption of vegetables and fruits, especially green and yellow vegetables and citrus fruits, and decreased susceptibility to cancers of the lung, stomach, and large intestine is not well understood because the responsible agents in these foods and the mechanisms for their protective effect have not been fully determined.

The 10th edition of the "Recommended Dietary Allowances" (Ref. 14) contains a discussion of carotenoids with regard to the recommended allowances for vitamin A. The report stated that most carotenoids, unlike vitamin A, trap free radicals and remove reactive oxygen molecules which can cause changes in cells. The report further stated that because only about 10 percent of carotenoids in nature show provitamin A activity, any anticancer effects that carotenoids possess might be related more to their antioxidant or other properties than to their conversion into vitamin A. The RDA report suggested that, a generous intake of carotenoid-rich foods may be of benefit.

The Life Sciences Research Office (Ref. 36) reviewed the recent scientific literature on "Vitamin A (including beta-carotene) and Cancer" and concluded that: (1) The data relating vitamin A to cancer are inconclusive, (2) the strongest evidence supports a possible protective role of fruits and vegetables in reducing the rates of cancer of various sites, particularly cancers of the lungs, colon/rectum and breast, and (3) the beta-carotene content of these foods may, in part, be exerting some of the effects.

C. Review of the Scientific Literature

The agency reviewed available scientific evidence on beta-carotene and carotenoids and cancer provided by epidemiological studies (prospective and retrospective) and clinical studies published since the publication of "The Surgeon General's Report on Nutrition and Health" (Ref. 4a). The data that FDA reviewed were evaluated according to specific criteria. Studies that involved healthy matched controls (e.g., age, sex, and ethnic origin) that were controlled for confounders, such as smoking, and that used validated dietary assessment instruments, appropriate storage conditions for test samples, and adequate sample size were given the greatest weight by FDA. When the possibility could not be excluded that the observed association was mainly a result of the disease altering indications of beta-carotene, or resulted from an effect of another substance in the foodstuff influencing the disease, the study was given less weight.

1. Primary Human Studies

Epidemiological studies of a retrospective nature that have assessed consumption of fruits and vegetables in relation to cancer mortality are shown in Table 1. Most of these case-control retrospective studies show an inverse association between intakes of fruits and vegetables rich in carotenoids and the risk of lung cancer. However, some studies also show that intakes of these foods are associated with a lowered risk of colorectal and stomach cancers.

LeMarchand and coworkers (Ref. 39) reported that higher intakes of foods containing beta-carotene are associated with lower risk of lung cancer in a multi-ethnic population of men and women in Hawaii. These researchers also reported stronger associations of lower lung cancer risks with consumption of all vegetables, dark green and cruciferous vegetables, and tomatoes than with consumption of beta-carotene.

Bond and coworkers (Ref. 40) reported similar findings of a lower lung cancer risk with higher intakes of foods with a high carotenoid index in a population of chemical company employees in Texas. Recently, upon reevaluation of data relating dietary intake to prostate cancer, these researchers (Ref. 41) reported that beta-carotene intake is not associated with prostate cancer risk. Prostate cancer risk, however, was reported to be inversely related to intake of foods containing beta-carotene in men over 70 years of age in two studies conducted in Japan (Refs. 42 and 43).

Adjusted risk of ovarian cancer was reduced with high intakes of beta-carotene in the study of Slattery et al. (Ref. 44). In a study conducted in England, Coggon et al. (Ref. 45) reported that intakes of fruits and salad vegetables were inversely associated with risk of stomach cancer. Kune et al. (Ref. 46) and LaVecchia et al. (Ref. 47) reported that risks of colorectal cancer were inversely associated with higher intakes of vegetables containing beta-carotene or those with a higher carotenoid index and vitamin C. In both of these studies, however, as with other studies showing a significant inverse relationship of higher intakes of fruits and vegetables and cancer risks, complementary effects of the antioxidants or effects of other components of the foods cannot be ruled out as the cause of the observed association.

In a unique type of case-control retrospective study, Smith and Waller (Ref. 50) included immediate family members of cancer patients and immediate family members of control hospitalized subjects in assessing the association between serum beta-carotene and cancer. Lower serum levels of beta-carotene were observed in patients with cancer of the lung, stomach, esophagus, small intestine, cervix and uterus. Lower serum levels of beta-carotene were also found in relatives of the cancer patients compared to serum levels in control subjects and their relatives. The inclusion of immediate family members as part of the study design corrects for effects from the illness. Additionally, the matching of subjects as to smoking status, age, sex, length of sample storage as well as the use of relatives, make the findings in this study consistent with those of prospective studies.

Prospective studies shown in Table 2 assessed dietary intake of foods rich in carotenoids and the subsequent development of cancer. There was an inverse association between intake of carotenoid-rich fruits and vegetables and risks of breast, lung, and other epithelial cancers in three studies (Refs. 51 through 53). However, Paganini-Hill et al. (Ref. 54) reported no association between intake of beta-carotene-rich foods and cancer at various sites.

In prospective studies (Table 3) in which serum or plasma carotenoid levels were measured in subjects who later developed cancer, Wald et al. (Refs. 55 through 57) and Connett et al. (Ref. 58) reported an inverse association between blood beta-carotene levels and lung and stomach cancers. In a 12-year followup prospective study, overall cancer mortality was inversely associated with plasma carotene adjusted for cholesterol levels, and bronchus and stomach cancers were inversely associated with total plasma carotene (Refs. 59 and 60).

Premalignancy studies, or those in which neoplastic changes in a tissue do not affect appetite and food intake or carotenoid metabolism in blood, offer the advantage of early diagnosis and assessment of dietary associations. An example of premalignancy studies are case-control studies of cervical dysplasia and in situ carcinogenesis in which the stage of cancer development is diagnosed by microscopic examination of cells. Beta-carotene exposure was assessed as intake of deep green and yellow vegetables, dietary beta-carotene, or plasma beta-carotene levels. Beta-carotene exposure from either of the above dietary sources was inversely correlated with the incidence of premalignancy in all but one of the studies reported (Table 4) (Refs. 62 through 66). In a small group of cases and controls, De Vet et al. (Ref. 67) found no association between beta-carotene supplements, consumed at 10 mg per day for 1 month, and changes in cervical dysplasia. The authors suggested that the supplementation period may have been too short to provide conclusive results.

A number of chemoprevention intervention trials are underway that are aimed at preventing or reducing the recurrence of malignancies (Table 5). These trials will be ongoing for some time because of the long latency period for cancer. Subjects are given beta-carotene in capsule or tablet form as a supplement to the beta-carotene and other carotenoids consumed through their diets. The information gathered from these clinical intervention trials should provide important information regarding the efficacy of the carotenoids either alone or in combination with other antioxidants in altering the cancer incidence.

One intervention trial of relatively short duration examined the effects of beta-carotene with and without vitamin A supplementation on oral leukoplakia (a condition of white, rough, sometimes fissured patches on the mucous membranes of the oral cavity that cannot be rubbed off, and which occur most often in smokers) in persons who frequently chewed betel (Ref. 68). After 3 months there was a reduction in symptoms in both beta-carotene groups, and after 6 months the investigators observed a significant regression of this condition.

A trial of longer duration, which examined the role of beta-carotene in preventing new occurrences of nonmelanoma basal cell and squamous cell carcinomas of the skin, has been completed (Ref. 20). Five hundred eighty-two subjects were supplemented with 50 mg beta-carotene per day. Median plasma concentrations after 1 year of supplementation increased 10-fold, with the largest increase occurring in nonsmokers, women and leaner subjects (Ref. 69). No effects on new nonmelanoma basal cell and squamous cell carcinomas of the skin from the supplementation of beta-carotene were observed. It has been hypothesized (Ref. 71) that one reason for the lack of effect observed may be that the amount of beta-carotene administered in the trial (50 mg per day) may be less than that suggested by other studies (e.g., 30 to 300 mg per day) to potentially reduce the risk of the recurrence of this type of cancer. A number of other explanations for the lack of effect are also possible. Other clinical trials employ beta-carotene alone or in combination with vitamins A, C, or E (for summary, see Table 5).

2. Supporting Data From Animal Studies

Experimental cancer in animals occurs by administering a chemical compound, exposure to irradiation or ultraviolet light, or a combination of the two. The efficacy of beta-carotene or other carotenoids reducing the incidence of tumors has been demonstrated at various sites in different animal models. These tumor sites include salivary gland, skin, mammary tissue, colon, and stomach (Ref. 72a). Moreover, feeding a naturally occurring source of beta-carotene, algae *Dunaliella bardawil*, resulted in arked inhibition of spontaneous mammary tumors (Ref. 73).

3. Safety Issues

No risks from consumption of beta-carotene intake per se or carotenoids were identified in any of the above reports. Carotenoids, even when ingested in very large amounts for weeks to years, are not known to be toxic (Ref. 135). An important reason for their lack of toxicity is their relatively limited conversion to vitamin A in the intestine, liver, and other organs. Carotenoids taken in large doses for several weeks are absorbed well enough to color the adipose tissue stores, including the subcutaneous fat. Thus, the skin, especially the palms of the hands and the soles of the feet, appears yellow.

D. Conclusions

Evidence relating beta-carotene intake per se to reduced risk of cancer in humans is, at this time, inconclusive. There is strong evidence that high intakes of fruits and vegetables rich in carotenoids are associated with a reduced risk of developing cancer. However, whether the components of fruits and vegetables responsible for reducing the apparent effect are beta-carotene and other carotenoids or some other compound remains unknown. The positive effects of beta-carotene administration in lowering the frequency and severity of experimental cancer in animals suggest that effects are the result of antioxidant properties. The conclusions cannot be directly applied to humans partly because the type and amount of carcinogen exposure in the experimental conditions was not similar to human exposure.

The most promising prospects of clarifying the possible role for carotenoids in human cancer risk rests with the clinical intervention trials that are currently in progress. In these trials, the administration of purified beta-carotene supplements to individuals at increased risk for developing cancer can provide more information regarding the direct role of beta-carotene. However, based on all of the scientific evidence published since 1987 on the role of carotenoids in human cancer risk, the agency finds only that the conclusion of the Surgeon General's Report (Ref. 4a) remains valid; the Surgeon General's report concluded that some epidemiologic studies provide suggestive evidence that frequent consumption of vegetables and fruits, particularly dark green and deep yellow vegetables which contain carotenoids, including beta-carotene, may lower risk for cancers of the lung and bladder, as well as some cancers of the alimentary tract.

Moreover, the recommendation in the "U.S. Dietary Guidelines" to consume generous portions of fruits and vegetables remains appropriate advice.

E. Tentative Decision To Deny a Health Claim Relating to Ingestion of Carotenoids to Risk of Cancer

Evidence of a direct relationship between beta-carotene intake and lowered risk of developing cancer at various sites in humans is inconclusive. The primary source of beta-carotene in the U.S. diet is green and yellow fruits and vegetables. From epidemiological data, there is strong evidence that consumption of fruits and vegetables has an associative relationship to lowered risk of cancer at various sites in humans. However, whether the protective effects of fruits and vegetables against cancer risk is the result of beta-carotene content or some other component remains unknown. Experimentally induced cancer at various sites in animals has been shown to be delayed and decreased in frequency with beta-carotene administration. This effect in animals is through the antioxidant potential of the beta-carotene. Clinical intervention trials for cancer that are in progress may, in a few years, provide additional information of effect of beta-carotene per se, rather than foods containing this substance, on cancer.

FDA has tentatively determined, based on all of the publicly available scientific evidence regarding an association between beta-carotene and cancer, that there is not significant scientific agreement, among experts qualified by scientific training and expertise to evaluate such claims, that a claim associating beta-carotene to the risk of cancer is supported by such evidence.

The agency recognizes that the evidence is strong that consumption of fruits and vegetables, good sources of beta-carotene, is associated with lowered risk of cancer at a number of sites. However, the agency believes that the data are not sufficiently convincing that beta-carotene per se is responsible for this association. Further, even if the evidence for a cause-and-effect relationship of beta-carotene intake with lowered risk of cancer was assumed to be adequate, the agency finds the data to be insufficient to determine the quantity of beta-carotene needed to produce the effect. If such data were available, it would be necessary for the agency to determine whether the food supply already provides enough beta-carotene to produce that effect.

In summary, the agency requests submission of data which directly bear on: (1) Whether beta-carotene per se, rather than some other component of food, decreases the risk of cancer in humans, and (2) the range of beta-carotene intake which produces this effect.

III. Review of the Scientific Evidence: Vitamin C

A. Federal Government Documents

"The Surgeon General's Report on Nutrition and Health" (Ref. 4a) reviewed human studies relating to associations between vitamin C and cancers of specific sites. These included studies of foods that contain vitamin C and cancers of the esophagus, stomach, and cervix. The report also reviewed: (1) Studies that showed that colonic polyps regressed or decreased in area with vitamin C therapy; and (2) studies that reported variable effects (positive and negative) of supplements of vitamin C and vitamin E on formation of fecal mutagens (Ref. 4a). The report also noted that most studies demonstrating beneficial effects of vitamin C did not quantify its actual intake (Ref. 4a). The report concluded that no wholly consistent picture of the role of vitamin C in human cancer has been defined.

The Surgeon General's report also observed that, despite limitations in the data, the American Cancer Society guidelines recommend consuming foods rich in vitamins A and C, and that the National Cancer Institute suggests eating a variety of fruits and vegetables to ensure an adequate supply of vitamin C (Ref. 4a). There is no adequate evidence that larger intakes of vitamin C provide any additional benefits (Ref. 4a).

The 1990 "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 35) recommends consumption of diets with "plenty" of vegetables and fruits. Such diets contain generous levels of the antioxidant vitamins, which were recommended because fruits, vegetables and whole grain cereals are likely to reduce the fat content of the diet, a change associated with decreased risk of cancer. Any possible direct association of antioxidant vitamins with lowered risk of cancer was not discussed.

The DHHS "Healthy People 2000" (Ref. 3) recommends increased consumption of complex carbohydrates and fiber-containing foods to 5 of more daily servings of vegetables (including legumes) and fruits and 6 or more daily servings of grain products. Vegetables, fruits, and grains are good sources of complex carbohydrates and fiber as well as of several vitamins and minerals. The report noted that dietary patterns with higher intakes of vegetables, fruits, and grains are associated with a variety of health benefits including a decreased risk for some types of cancer (Refs. 2 and 4a).

B. Other Authoritative Documents

The NAS in its 1989 Report "Diet and Health" (Ref. 2) reviewed and summarized the role of dietary factors as related to risk of various types of cancer. The NAS reviewed epidemiologic data and evidence from animal studies and studies on mechanisms of carcinogenesis.

The report reviewed associations among dietary factors and stomach cancer. It described major dietary associations between gastric cancer and consumption of dried, salted, or smoked fish or pickled vegetables (foods high in salt and nitrates). It also indicated that a second major dietary association observed with stomach cancer is the protective effect of fresh fruits, vegetables, and vitamins, particularly vitamin C. The report noted in summary that stomach cancer is associated with diets containing large amounts of salt-preserved foods and low levels of fresh fruits and vegetables. The report found, however, that evidence was inconclusive concerning the significant decline in stomach cancer mortality in the United States over the last half-century relating to dietary shifts away from consumption of high salt-preserved foods and toward increased consumption of fruits and vegetables (Ref. 2).

In summary, the report stated that although the contribution of diet to total incidence and mortality from cancer in the United States cannot be determined with certainty, it is reasonable that approximately one-third of all cancer mortality may be related to diet. Data on the carcinogenicity of most components of human diets are quite limited, however, and the exact mechanism of carcinogenesis in humans have not yet been established for any diet-related cancer (Ref. 2).

The NAS in its "Recommended Dietary Allowances" (Ref. 14) noted that vitamin C may prevent the formation of carcinogenic nitrosamines by reducing nitrites. The NAS concluded that ingestion of fruits and vegetables rich in vitamin C has been associated with reduced incidence of some cancers, but that there is no evidence that vitamin C is responsible for such effects.

The Life Sciences Research Office of the Federation of American Societies for Experimental Biology, reviewed the

relationship between ingestion of vitamin C or foods rich in vitamin C and cancer (Ref. 37). The report concluded that epidemiologic studies have provided evidence for a role of nutrients in the reduction of the risk of specific cancers. The report found that one of the most consistent epidemiologic findings has been an association between high intakes of vitamin C-rich foods and a reduction in risk of stomach cancer (Ref. 29). The report noted that intake of citrus fruits has been associated with a significantly reduced risk of oral cancer, and that risk of esophageal cancer was reduced with increased intakes of vitamin C-rich fruits and juices. Intake of vitamin C-rich foods, the report concluded, appears to have no relationship to cancers of the colon, prostate, or ovary. The report found that results with respect to pancreatic cancer are equivocal, and results with respect to vitamin C and breast cancer are inconsistent (Refs. 2 and 29).

C. Review of the Scientific Literature

The agency reviewed the publicly available scientific evidence on vitamin C and cancer provided by epidemiologic and clinical studies in accord with the standard described in the general document on health claims on foods (published elsewhere in this **Federal Register**). Studies that included healthy matched (e.g., age, sex, and race) controls, that controlled for confounders such as smoking, and that used validated dietary assessment instruments and adequate study size were given the highest weight. When the possibility could not be excluded that the observed association was mainly a result of the disease altering indicators of vitamin C status, or resulted from the effect of another substance in the food, the study was given less weight.

1. Evidence for an Association Between Ingestion of Vitamin C or Foods High in Vitamin C and Reduced Risk of Cancer

Research studies published since 1987 include more than 30 case-control studies, 1 prospective study, and 2 randomized clinical intervention trials. Because associations between dietary patterns and cancer appear to be site-related, the recent studies are grouped by site and summarized as follows: Table 6, lung; Table 7, colon and rectum; Table 8, breast; Table 9, prostate; Table 10, pancreas; Table 11, stomach; Table 12, head and neck; Table 13, cervix or ovary. Table 14 summarizes results of a study of patients with bladder cancer and a second study of cancer at various sites. Details of the studies including type and location, description of subjects, methods, and results are presented in these Tables.

a. *Human studies*—(i) *Lung cancer (Table 6).* Adjusted risk analysis (for age and smoking) showed no difference in vitamin C intakes between 450 patients with lung cancer and 902 control subjects (Ref. 74). Dietary information in this study was obtained from a food frequency questionnaire.

In contrast, an inverse association between vitamin C intake and specific types of lung cancer was reported by Fontham et al., (Ref. 75) in a case-control study involving 1,253 patients with lung cancer and 1,274 controls matched for race, sex, and age. Dietary information was obtained from a food frequency questionnaire. No descriptive data were reported for nutrient intakes, and no comparisons were made with standards (e.g., RDA's).

A protective effect of high consumption of leafy green vegetables, carrots, tofu, fresh fruit, and fresh fish against specific types of lung cancer (adenocarcinoma and large cell cancer) was reported by Koo et al., (Ref. 76). Dietary data was obtained from a food frequency questionnaire. Consumption of fresh fruits was found to offer protection against squamous cell tumors of the lung. The data obtained in this study were analyzed by foods without specific analysis for single nutrients.

(ii) *Cancers of the colon and rectum (Table 7).* Food frequency questionnaires were used to obtain information on dietary patterns and risk of colorectal cancer. Freudenheim et al. (Ref. 77) reported that decreased risk of rectal cancer was associated with increased intake of carotenoids, vitamin C, and dietary fiber from vegetables. Graham et al. (Ref. 78) reported that there was a significantly reduced risk of colon cancer associated with high intakes of tomatoes, peppers, carrots, onions, and celery. LaVecchia et al. (Ref. 47) reported that the risk of both colon cancer and rectal cancer was inversely related to intake of green vegetables, tomatoes, melon, and coffee. There were also inverse relationships between risk and indices of carotenoid and vitamin C intake. Tuyns et al. (Ref. 79) found no association between risk for either colon cancer or rectal cancer and vitamin C intake (determined from food frequency questionnaires) in a case-control study in Belgium. West et al. (Ref. 80) also reported no association between risk of colon cancer and intake of vitamin C (determined from a food frequency questionnaire) in a case-control study of colon cancer patients and matched controls in Utah.

Several of these studies identified other dietary risk factors for colon and rectal cancers including increased risk with increasing intakes of calories and fat (Refs. 77 and 78) and consumption of rice and pasta.

A recent randomized clinical trial has been reported that describes a test of the effect of a vitamin C supplement on recurrence of polyps in the colon or rectum (Ref. 81). Subjects in this trial were randomized to receive 400 mg of vitamin E and C (96 subjects) or lactose (placebo; 89 subjects) for a 2-year period. Examination of subjects after 2 years revealed polyps in 41.4 percent of the vitamin-treated group and in 50.7 percent of the placebo group. The relative risk of polyps in the treatment group was not significantly different from that in the placebo group.

In a second intervention trial, De Cosse et al. (Ref. 82) studied the effects on rectal polyps of vitamin C plus vitamin E with and without grain fiber supplements. Fifty-eight patients with familial adenomatous polyposis who had total colectomy and ileorectal anastomosis 1 year before the study were randomized into groups receiving 2.2 grams (g) of fiber and placebo (low fiber), 2.2 g fiber plus 4 g vitamin C and 400 mg vitamin E per day (low fiber plus vitamins C and E), or 22.5 g fiber plus both vitamins per day (high fiber plus vitamins C and E). All groups also received a supplement containing vitamins C and A and several other vitamins and minerals. The results did not show any protective effect of the vitamin C and vitamin E supplement on the occurrence of rectal polyps.

(iii) *Breast cancer (Table 8).* The authors of a case-control study of women with breast cancer and hospital controls in Athens, Greece reported that there were no differences between cases and controls in intakes of vitamin C (determined from food frequency questionnaires) (Ref. 83). This study found no association between intake of vitamin C and risk of breast cancer.

In a case-control study in Italy, Toniolo et al. reported that there was no difference in vitamin C intake in 250 women with breast cancer and 499 women from the general population. Vitamin C intakes were determined from a modified food frequency questionnaire (Ref. 84).

Howe et al. performed a meta-analysis that included all case control studies relating diet and breast cancer that were completed by 1986. Dietary data were available from 9 of 12 studies. Estimates of intakes were made for the other three studies based upon responses to food frequency

questionnaires. A statistically significant inverse association between vitamin C and breast cancer was reported (Ref. 85). Beta-carotene, fiber, and carotenoids (other markers for consumption of fruits and vegetables) also showed an inverse relationship with risk of breast cancer (Ref. 85).

(iv) *Prostate cancer (Table 9).* Kolonel et al. (Ref. 86) found no associations between risk of prostate cancer and total of food sources of vitamin C in a case-control study involving 452 cases of prostatic cancer and 899 age-matched controls. Dietary information was obtained from a food frequency questionnaire. Increased risk was found to be associated with intake of saturated fat and zinc (Ref. 86).

In two case control studies, Ohno (Ref. 43) and Oishi (Ref. 42) reported that intake of vitamin C from foods was not significantly associated with risk of prostate cancer.

(v) *Pancreatic cancer (Table 10).* LaVecchia et al. (Ref. 48) reported a statistically significant decreased risk of pancreatic cancer with increased intake of fresh fruits. A similar inverse relationship between intake of fish and oil and risk of pancreatic cancer was also reported in this study. This case-control study, carried out in Italy, involved 247 patients with pancreatic cancer and 1,089 age and sex-matched hospital-based controls with acute nondigestive, nonneoplastic disease. Subjects were interviewed to obtain data on socioeconomic status, tobacco and alcohol use, coffee consumption, medical history, and dietary intake of 14 "indicator" foods. No assessment of intake of individual nutrients was made in this study.

Mills et al. (Ref. 87) investigated dietary habits and risk of pancreatic cancer in about 34,000 non-Hispanic Seventh Day Adventists in California. All subjects completed a life-style questionnaire. A significant protective relationship between consumption of vegetable protein products, beans, lentils, or peas, and dried fruits and fatal pancreatic cancer was reported (Ref. 87). No relationship was found between risk and intake of other fresh fruit, canned or frozen fruit, fresh citrus fruit, green salads, or cooked green vegetables (Ref. 87). No data on individual nutrients were provided in this study.

Falk et al. (Ref. 88) reported a significant inverse relationship between consumption of fresh fruit and fruit juice and pancreatic cancer. The case-control study involved 363 cases of pancreatic cancer and 1,234 hospital-based controls matched on hospital of admittance, race, sex, and age. A food frequency questionnaire was used to obtain dietary information. No descriptive nutrient data was reported, and there were no comparisons of dietary intakes to reference standards (e.g., RDA's).

(vi) *Stomach cancer (Table 11).* You et al. (Ref. 89) reported the results of a case-control study in China involving 564 subjects with gastric cancer and 1,131 population-based control subjects. An undefined number of years had elapsed between the "reference period" and the interviews which served to collect data about demographics, medical histories, occupations, smoking histories, and diet. There was a decline in risk of gastric cancer with increased consumption of beta-carotene, vitamin C, and calcium which was associated with high intakes of fresh fruits and vegetables (Ref. 89).

Kono et al. (Ref. 90) reported an inverse relationship between intake of fruits and risk of gastric cancer in a case-control study involving 139 cases of newly diagnosed gastric cancer, 2,574 hospital-based control subjects, and 278 randomly-selected community control subjects in Japan. Gastric cancer patients and hospital-based control subjects were interviewed before diagnosis. A questionnaire was used to obtain information on dietary habits and on consumption of specific food items. The data showed a protective effect against stomach cancer associated with increased frequency of consumption of fruits, mandarin oranges, and green tea (Ref. 90). Attribution of effects to vitamin C could not be made because of the design of this study. Dietary components other than vitamin C, or in addition to vitamin C, could have been responsible for the protective effects.

Buiatti et al. (Ref. 91) studied 1,016 cases of gastric cancer and 1,159 control subjects matched for age and sex. Data regarding demographics, socio-economic status, occupational histories, smoking, medical histories, and diet were obtained from an interview. Intakes of specific nutrients were calculated from responses to a food frequency questionnaire. Buiatti et al. (Ref. 91) reported that decreased risk of gastric cancer was associated with increased consumption of citrus fruits, other fresh fruits, and raw vegetables. Results of further evaluation of the data (Ref. 92) suggested that the protective effects of fresh fruits, fresh vegetables, and olive oil may be associated with vitamins C and E present in these foods. Estimates of the intakes of nitrates and nitrites were calculated for several geographic areas studied, and results indicated an increasing risk of stomach cancer with increasing consumption of nitrates and nitrites. Risk decreased with increasing intakes of vitamin C and vitamin E (Ref. 92).

Chyou et al. (Ref. 93) initiated a case-cohort study of about 8,000 Hawaiian men of Japanese ancestry during 1965 to 1968. Stomach cancer was diagnosed in 111 men during the following 18 years. Dietary data obtained from these subjects and from 361 cancer-free men revealed that consumption of all types of vegetables was protective against stomach cancer (Ref. 93). Increased intake of fruits was also protective against stomach cancer, but this trend was weakened when cigarette smoking was taken into account (Ref. 93).

Burr et al. (Ref. 94) carried out a cross-sectional study in two towns in England and Wales that had differing death rates from stomach cancer. Burr et al. (Ref. 94) reported that plasma ascorbate levels and fruit intakes were significantly higher in individuals in the low-risk town than in individuals in the high-risk town. No direct relationship between plasma ascorbate levels and the presence of severe atrophic gastritis was found. No dietary data were presented in this study, and the nature of a food frequency questionnaire was not described. There were significant socio-economic differences between the towns, and subjects were not matched for smoking, health histories, or demographics. There were also significant differences in incidence of gastric surgery and severe atrophic gastritis between towns.

Stahelin et al. (1989) (Ref. 61) reported on a prospective cohort study of 2,975 men, 17 of whom subsequently developed stomach cancer. The authors reported that after adjusting for smoking, plasma vitamin C was significantly lower in cases of stomach cancer than in control men. This study relied on a point sample analysis and provided no dietary intake data.

(vii) *Cancers of the head and neck (Table 12).* Franco et al. (Ref. 95) investigated risk factors for oral cancer in a case-control study in Brazil. Dietary information and health and demographic characteristics were obtained from interviews with 232 patients with oral cancer and 464 hospitalized non-cancer subjects. The strongest risk factors identified in this study were use of tobacco and alcohol. A decrease in risk was observed with more frequent consumption of citrus fruits. It was not possible to calculate intakes of vitamin C in this study.

Results of a population-based case-control study on association of dietary factors with oral cancers were reported by McLaughlin et al. (Ref. 96). Frequency of consumption of food items was

obtained by questionnaire from 871 patients with oral cancer and 979 control subjects. Protective effects were reported with increased consumption of citrus fruits. The study was not designed to specifically address a possible role of vitamin C in reduction in risk of oral cancer.

(viii) *Cancers of the cervix and ovary (Table 13).* Brock, et al. (Ref. 62) reported that when considered together, vitamin C, fruit juices, and plasma beta-carotene showed a significant protective effect against cervical cancer. Dietary information was obtained from a food frequency questionnaire. Cases in this study were not matched on sexual habits, smoking, or use of oral contraceptives. Plasma levels of ascorbic acid were not determined.

Shu et al. (Ref. 97), Slattery et al. (Ref. 44), and Ziegler et al. (Ref. 98) reported no effects of dietary vitamin C on risk of ovarian cancer or cervical cancer. Dietary information in these studies was obtained from a food frequency questionnaire. Significantly increased risk of ovarian cancer was associated with intake of total and saturated fat (Ref. 97). Verreault et al. (Ref. 63) found a decreased risk of cervical cancer associated with high intakes of vitamin C. After adjustment of data for other known risk factors, increased intakes of dark green or yellow vegetables and fruit juices were associated with significantly reduced risk (Ref. 63).

(ix) *Other studies (Table 14).* Results of a case-control study of bladder cancer patients and hospital controls in Italy showed that risk of bladder cancer was not related to intake of vitamin C (Ref. 49).

b. *Studies on vitamin C in relation to carcinogen-forming reactions.* Ascorbic acid is an effective antioxidant in human plasma (Ref. 99). It is also secreted into gastric juice in concentrations that often exceed those in plasma (Ref. 100).

Patients with chronic gastritis have lower concentrations of vitamin C in gastric juice than do those without chronic gastritis, and those with lower gastric juice vitamin C levels are more likely to develop stomach cancer (Ref. 101). Concentrations of vitamin C in both gastric juice and in plasma are lower in patients with chronic atropic gastritis who also have intestinal metaplasia than in chronic atropic gastritis patients without intestinal metaplasia (Ref. 101). The patients with intestinal metaplasia also had higher plasma nitrite levels than those without the disorder.

Biochemical and experimental animal evidence is compelling that vitamin C can inhibit nitrosation reactions, and thereby act as an effective anticarcinogen under experimental conditions (Ref. 25). Most nitrosamines, including diethylnitrosamine, are animal carcinogens that are mutagenic through reactions with DNA (Ref. 102). Carcinogenic nitrosamines can be formed in vivo (Ref. 103). In vivo synthesis of nitroso compounds may be the greatest source of exposure for the general population (Ref. 2). Ascorbic acid in gastric juice may be an effective inhibitor of gastric nitrosation reactions.

N-nitrosoproline is one of the few apparently noncarcinogenic N-nitrosamines. As such, it is considered a good model compound for studying nitrosation reactions in humans. A method to quantify in vivo nitrosation in humans using sequential oral doses of nitrate and proline and measuring excretion of N-nitrosoproline has been reported (Ref. 104). This technique has been used to show that large doses of ascorbic acid can inhibit formation of nitrosoproline (Refs. 132 and 133). Recent studies in humans by Leaf et al. (Ref. 27) showed that in vivo nitrosation is very complex and may involve many factors in addition to nitrate exposure. These findings indicate that ascorbic acid is capable of inhibiting in vivo synthesis of putative human carcinogens. It is not clear from these studies what dosage of vitamin C is necessary to achieve biologically significant inhibition of nitrosamine synthesis at various intakes of nitrite and nitrate, or whether the food supply already supplies that amount of vitamin C. It also is not clear what degree of such inhibition would be necessary to generate a meaningful decrease in cancer risk.

The relevance of ascorbic acid inhibition of nitrosation and possibly other reactions to human cancer risk may be more directly addressed by studies of dietary relationships to fecal genotoxicity (Ref. 105). The basic assumption is that at least a large fraction of total cancer is produced by genotoxic (i.e., mutagenic) mechanisms, an assumption that is well documented (Refs. 4a, 22, 24). Consumption of supplements containing ascorbic acid decreases fecal mutagenicity (Ref. 106), but this effect may not be completely attributable to inhibition of nitrosation reactions. Ascorbic acid inhibits nitrosation reactions but also decreases stool concentrations of mutagenic products, fecapentenes, which are derived from lipids (Ref. 105).

c. *Animal studies.* Data from research links vitamin C to lowered risk of cancer in animals under a variety of experimental conditions (Refs. 107 and 108). In animals and in in vitro systems, both vitamin C and vitamin E can inhibit the formation of carcinogenic nitrosamines. Most nitrosamines are carcinogenic in one or more assay systems, but they are most accurately described as procarcinogens, because biological activation is required to convert them to the reactive ultimate carcinogen.

Because of the antioxidant nature of vitamin C, it is reasonable to hypothesize that this vitamin may prevent activation of procarcinogens to the ultimate carcinogen, or, if activation occurs, vitamin C may react with and deactivate the ultimate carcinogen. Animal studies that examined the effect of vitamin C on nitrosamine synthesis and subsequent carcinogenesis as a result of exposure to the nitrosamine precursors, nitrite and a monoamine, provide strong evidence that vitamin C can lower risk of cancer through this mechanism (Refs. 25 and 134). Other studies with animals that examined the effect of vitamin C on other types of chemically-induced cancers have not produced consistent results (Ref. 108).

2. Safety Issues

The Surgeon General's report stated that amounts of vitamin C in excess of the RDA's may cause rare adverse effects including gastrointestinal disturbances, iron overload in susceptible individuals, altered metabolism of certain drugs, precipitation of calcium oxalate kidney stones, altered absorption (both positive and negative) of several minerals, and interference with clinical laboratory tests (Ref. 4a).

3. Conclusions

The majority of the studies summarized above on the association between vitamin C and cancer are epidemiologic studies. These studies depended on dietary data gathered with the use of food frequency questionnaires. In some studies, retrospective dietary information was collected to provide insight into associations between nutrient intakes and cancer at specific sites. However, in most studies, collection of direct data on actual intakes of specific nutrients was not possible.

In a number of the studies, protective effects against cancer at specific sites were observed with increased frequency of consumption of such foods as vegetables, green leafy vegetables, fresh fruits, citrus fruits, and fruit juices. In most studies, it was not possible to determine whether a protective effect was due to the presence of vitamin C, beta-carotene, other nutrients, or

combined effects of both vitamins and other dietary factors such as fiber. In addition, levels of ascorbic acid were rarely measured in the studies reviewed.

The evidence for associations between consumption of foods high in vitamin C and reduced risk of cancer appears to differ markedly by site. Consumption of vitamin C-rich foods appears to be most frequently associated with lower risk of cancer of different parts of the gastrointestinal tract. Intake of vitamin C-rich foods does not appear to be associated with risk of breast cancer. Recent data provide mixed or negative results with regard to vitamin C-rich foods and cancer of the colon/rectum, pancreas, lung, prostate, and cervix/ovary.

Overall, the recent human studies provide evidence that consumption of certain foods notably many fruits and vegetables (which contain higher levels of vitamin C and other nutrients) may reduce the risk of certain cancers, notably those of the stomach and other parts of the gastrointestinal tract. These studies do not clearly demonstrate that the effects are the result of the vitamin C per se.

D. Tentative Decision To Deny Health Claims Relating Ingestion of Vitamin C to Reduced Risk of Cancer

The agency is proposing not to authorize the use on foods, including conventional foods and dietary supplements, of claims relating to associations between ingestion of vitamin C and reduced risk of cancer.

There is strong epidemiologic evidence that consumption of certain foods, notably many fruits and vegetables (which tend to contain higher levels of vitamin C), reduce the risk of cancers at some sites, notably the stomach and other parts of the gastrointestinal tract. It is not possible to determine from the currently available data whether the reduced risks of cancers at specific sites are caused by the vitamin C content of foods or by other components that are also present.

The agency's tentative conclusion is consistent with information and conclusions found in Federal Government and other authoritative documents. The Surgeon General's report on "Nutrition and Health" (Ref. 4a) concluded in 1988 that no wholly consistent picture of the role of vitamin C in human cancer had been defined. The NAS "Diet and Health" report (Ref. 2) concluded that diets high in plant foods (fruits, vegetables, legumes, and whole-grain cereals) are associated with a lower incidence of coronary heart disease and cancers of the lung, colon, and stomach. The NAS report observed that such diets are low in total fat and rich in complex carbohydrates and certain vitamins and minerals. The NAS report concluded that epidemiologic studies suggest that vitamin C-containing foods such as citrus fruits and vegetables may offer protection against stomach cancer, and that animal studies indicate that vitamin C itself can protect against nitrosamine-induced stomach cancer. Evidence linking vitamin C, or foods containing vitamin C, to cancer at other sites is more limited and less consistent.

The scientific data that have become publicly available since the publication of authoritative documents of the Federal Government and others provide no substantive evidence that would alter the conclusions found in these reports.

FDA has tentatively determined, based on the totality of publicly available scientific evidence regarding an association between vitamin C and cancer, that there is not significant scientific agreement, among experts qualified by scientific training and expertise to evaluate such claims, that the claim associating vitamin C to the risk of cancer is supported by such evidence. Therefore, the agency is proposing to deny the use on foods of claims relating to associations between ingestion of vitamin C and reduction in risk of cancer.

The agency recognizes that the evidence is strong that consumption of fruits and vegetables, good sources of vitamin C, is associated with lowered risk of cancer at a number of sites, especially of the stomach. However, the agency believes that the data are not sufficiently convincing that vitamin C itself is responsible for this epidemiological association, even though the inhibition of nitrosation reactions in human subjects by vitamin C is established. Further, even if the evidence for a cause-and-effect relationship of vitamin C intake with lowered risk of stomach cancer was assumed to be adequate, the agency finds the data to be insufficient to determine the quantity of vitamin C needed to produce the effect. If such data were available, it would be necessary for the agency to determine whether the food supply already provides enough vitamin C to produce that effect.

In summary, the agency requests submission of data which directly bear on: (1) Whether vitamin C itself, rather than some other component of food, decreases the risk of cancer in humans, and (2) the range of intake in which vitamin C produces this effect.

IV. Review of Scientific Evidence: Vitamin E

A. Federal Government Documents

In 1988, the "Surgeon General's Report on Nutrition and Health" (Ref. 4a) summarized the evidence on the role of vitamin E and cancer. The Surgeon General's Report stated that in human studies, no relationship had been found between vitamin E levels and the risk of cancer when the incidence rates of all cancer sites were combined. In addition, the report proposed that because vitamin E is an antioxidant, the protective role tentatively assigned to both the carotenoids and vitamin C may be hypothesized to apply, but that present data are too limited to draw conclusions.

B. Other Authoritative Documents

The 1989 NAS report on "Diet and Health" (Ref. 2) concluded that some investigators have postulated that vitamin E may block the initiation or promotion of cancer, but the committee judged the evidence to be too limited to draw conclusions.

The Life Sciences Research Office (Ref. 38) in a detailed review of recent observational and intervention studies on vitamin E and cancer concluded that available information still is not sufficient to support definite conclusions concerning vitamin E intake and the risk of human cancer. The report stated that more studies, especially well designed intervention trials and observational studies, are needed.

C. Review of Scientific Literature

1. Introduction

The agency reviewed the available scientific evidence on vitamin E and cancer provided by epidemiological studies (prospective and retrospective) and clinical studies. The data reviewed were evaluated according to specific criteria. Studies that involved healthy matched controls (e.g., age and sex), that were controlled for confounders, such as smoking, used validated dietary assessment instruments, appropriate storage conditions for test samples, and adequate sample size were given the most weight. When the possibility could not be excluded that the observed association was mainly a result of the disease altering indicators of vitamin E status, or resulted from an effect of another substance in the food, the study was given less weight.

2. Primary Studies in Humans

Prospective studies are considered first in this section, followed by retrospective studies and clinical trials.

The prospective studies were generally conducted in case-control designs (Table 15). In most of the prospective studies, plasma/serum vitamin E and subsequent cancer development was studied.

The prospective studies generally concentrated on all sites of cancer, hormone-related cancers, and cancers of the lung and gastrointestinal tract (Table 15). Studies that concentrated on all cancer sites generally observed an inverse association between serum vitamin E and subsequent cancer, (Refs. 109 through 113). In a 12-year cancer mortality followup of one of the studies, no significant association was found between low plasma vitamin E levels and all cancer sites combined (Ref. 61). Comstock et al. (Ref. 114) reported a significant dose response trend between serum vitamin E and lung cancer. However, other workers, reported no significant association of serum vitamin E and the subsequent development of lung cancer (Ref. 57 and 109).

Two studies using two different population groups observed an association between vitamin E and gastrointestinal cancers (Refs. 109 and 113). A 12-year followup study (Refs. 60 and 61) conducted using one of the same population groups did not confirm the association between vitamin E and gastrointestinal cancer. In another prospective study (Ref. 115) reported an apparent association between low serum levels of vitamin E and reduced risk of pancreatic cancer. However, the difference was not statistically significant. The number of cases was small, and the storage time for the serum was very long prior to analysis, making the reliability of these data doubtful. Schober et al. (Ref. 116) studied the same population group and found no association between vitamin E and colon cancer.

No relationship was found between vitamin E levels and the subsequent development of breast cancer (Refs. 110, 113, 114, and 117). In an earlier study, Wald et al. (Ref. 55) reported a significant inverse association between vitamin E and breast cancer. The number of breast cancer cases in these studies was generally very small.

The maximum followup time in these prospective studies generally ranged from 7 to 8 years (Refs. 109 and 117) to 9 to 13 years (Refs. 60, 61, and 114). In all the studies that FDA examined, except the Basel study (Refs. 60, 61, and 109), vitamin E determinations were based on stored frozen serum/plasma samples collected in baseline examination and thawed for analyses at the end of the followup. It has been reported that the length and storage conditions of the test samples may decrease the levels of vitamin E in serum/plasma, and therefore make the data unreliable (Ref. 57).

Retrospective studies on vitamin E and cancer are shown in (Table 16). Breast cancer has been the subject of several case-control studies (Refs. 84, 118, and 119). With one exception (Ref. 119), the studies generally found no significant association between breast cancer and vitamin E levels in the serum or vitamin E intake. Gerber (Ref. 119) found that plasma vitamin E was significantly higher in breast cancer cases than hospital controls. However, the vitamin E intake data did not support this observation.

Another study observed lower serum vitamin E levels in lung cancer patients (Ref. 120). Adjustment of the vitamin E levels for serum cholesterol reduced the difference between lung cancer cases and controls. The experimental groups used in this study were not matched for smoking history.

Two studies conducted in other countries reported a significant inverse association of vitamin E with either gastric or digestive cancers (Refs. 92 and 121). One author (Ref. 92) suggested that the observed decrease in serum vitamin E in digestive cancer cases may be a consequence of nutritional inadequacies. Verreault (Ref. 63) examined the association of vitamin E using invasive cervical cancer cases and population controls. High intakes of vitamin E were associated with lower cancer risk. Another study reported (Ref. 122) a significant trend of lower mean serum vitamin E levels in association with cervical intraepithelial neoplasia. The sample size was small and the authors pointed out the need to examine interactive factors such as sexual behavior and smoking.

Two studies (Refs. 123 and 124) observed no significant association between vitamin E and specific cancer sites (rectal and larynx). Stryker (Ref. 125) observed that vitamin E intake, but not serum vitamin E, displayed a significant trend of decreasing risk of malignant melanoma. The vitamin E intake in the studies cited were based on retrospective dietary data, and the accuracy of the data is therefore difficult to assess. In addition, the evidence based on dietary intake data is often confounded by other nutrients that may also be associated with the risk of cancer.

Intervention trials (clinical) involving vitamin E and cancer are limited. One recent clinical trial examined the effect of vitamins C and E in the reduction of the risk of recurrence of colorectal polyps (Ref. 81). Another study (Ref. 82) reported a chemoprevention trial on large bowel neoplasia using either supplements of ascorbic acid plus vitamin E alone or with a grain fiber supplement. The combined use of vitamins prevented an analysis of the independent effect of vitamin E or interactions with vitamin C.

3. Supporting Data From Animal Studies

Animal studies on the effect of vitamin E (usually alpha-tocopherol) on carcinogenesis have yielded conflicting results. Several recent reports (Refs. 5b, 34, and 126) have reviewed the experimental evidence on the effects of vitamin E in cancer prevention. Most studies have dealt mainly with chemically induced cancers. Birt (Ref. 126) summarized the results of 14 animal studies involving the use of 3 different species of animals and 4 preformed carcinogens. Some of the studies observed inhibition of two-stage skin, oral and forestomach tumorigenesis. Other studies showed enhancement, no effect, or inhibition of rat mammary gland and rat and mouse carcinogenesis.

Mergens and Bhagavan (Ref. 34) and Merrill et al. (Ref. 5b) summarized animal studies on the inhibition of carcinogenesis by alpha-tocopherol. These reviews show that results from animal studies were frequently positive, however, many studies show no effect or are negative. Animal studies have shown that, under certain conditions, vitamin E has been shown to inhibit the formation of carcinogenic nitrosamines (Refs. 5b and 34).

4. Safety Issues

The NRC, in "Diet and Health" (Ref. 2), summarized two studies (Refs. 127 and 129) and a review article on the safety of oral intake of vitamin E. The studies suggested that large doses of vitamin E are relatively nontoxic. The review article (Ref. 130) cited by the Council extensively reviewed overall safety issues of vitamin E. The authors reported that in human studies conducted with double blind protocols and in large population studies, oral vitamin E supplementation resulted in few side effects even at doses as high as 3,200 mg per day. They concluded that most of the reported side effects: breast soreness, altered creatinine excretion, emotional disorders, fatigue, gastrointestinal stress, thrombophlebitis, and decreased thyroid levels, have come from uncontrolled studies or case reports (Ref. 130). However, in persons with vitamin K deficiency produced either by malabsorption or anticoagulant therapy, vitamin E

supplementation can exacerbate the coagulation defect.

In the 1989 edition of "Recommended Dietary Allowances," the NRC (Ref. 14) stated that compared with other fat-soluble vitamins, vitamin E is relatively nontoxic when taken by mouth.

D. Conclusions

Some recent prospective studies provide suggestive evidence of an association of lower plasma/serum vitamin E levels with increased risk of cancer (Ref. 113). However, the different population groups studied were limited and results from some followup studies were inconsistent. Clarification of the role of vitamin E in the reduction of cancer risk would be greatly enhanced by studies that also examine the quantitative dietary intake of vitamin E. Many of the studies were based on relatively small numbers of cancer cases, used test samples that had been stored for long periods of time prior to analysis, or relied on retrospective food frequency interviews. These factors may contribute to unreliable interpretations of the results.

While some of the recent retrospective studies have provided suggestive evidence that low vitamin E intake or low plasma/serum levels of vitamin E may be associated with the increased risk of some cancer, other studies have not. Many of the studies have study design flaws (e.g., inappropriate controls, small sample size). Too few clinical trials have been conducted on the association of vitamin E status and the risk of cancer to clearly implicate vitamin E.

E. Tentative Decision To Deny a Health Claim Relating to Ingestion of Vitamin E to the Risk of Cancer

FDA considered conclusions reached by Federal Government documents, and other authoritative documents, a review of the topic by Life Sciences Research Office of the Federation of American Societies for Experimental Biology, and all comments received in response to a **Federal Register** notice of a request for scientific data and information. The agency also reviewed recent publicly available scientific data on the association between vitamin E and cancer.

In 1988, the *Surgeon Generals' Report on Nutrition and Health* (Ref. 4a) documented and reviewed available literature on the possible relationship of vitamin E and cancer. The Surgeon General did not find the evidence strong enough to justify a recommendation to the general public on vitamin E and cancer. However, the report proposed that the protective role tentatively assigned to both carotenoids and vitamin C may apply to vitamin E. The NRC Committee on Diet and Health (Ref. 2) also reviewed current literature on the topic. The committee's report concluded that the scientific evidence was insufficient to draw conclusions about the relationship between vitamin E and cancer.

Several followup studies and new studies have appeared in the literature since the above reports (see Tables 1 and 2). Recent epidemiological studies exploring the association of blood levels of vitamin E as well as dietary vitamin E intake with the risk of cancer are contradictory. Some studies support an inverse association of blood levels of vitamin E/vitamin E intakes with the risk of certain cancers, while others do not.

FDA has tentatively determined, based on the totality of publicly available scientific evidence regarding an association between vitamin E and cancer, that there is not significant scientific agreement among experts qualified by scientific training and expertise to evaluate such claims that the claim associating vitamin E to the risk of cancer is supported by such evidence.

The agency recognizes that consumption of food sources of vitamin E is frequently, but not consistently, associated with lowered risk of cancer at a number of sites. However, the agency believes that the data do not sufficiently demonstrate that vitamin E itself is responsible for this association, or permit identification of what other factors may produce or prevent the effect. Further, even if the evidence for a cause-and-effect relationship of vitamin E intake with lowered risk of cancer was assumed to be adequate, the agency finds the data to be insufficient to determine the quantity of vitamin E needed to produce the effect. If such data were available, the agency would have to determine whether the food supply already provides that amount of vitamin E.

In summary, the agency requests submission of data which directly bear on: (1) Whether vitamin E itself, rather than some other component of food, decreases the risk of cancer in humans, (2) the range of intake in which vitamin E produces this effect, and (3) factors which may limit any vitamin E effect.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

VII. Comments

Interested persons may, on or before February 25, 1992 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. Received comments may be seen in the office between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food Labeling, Reporting and recordkeeping requirements.

PART 101—FOOD LABELING

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. Section 101.71 is amended by adding new paragraph (d) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(d) Antioxidant vitamins and cancer (insert cite and date of publication in the **Federal Register** of the final rule).

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

TABLE 1.—ANTIOXIDANT VITAMINS AND CANCER: RETROSPECTIVE STUDIES OF DIETARY AND SERUM CAROTENOIDS AND CANCER

Authors and year	Source exposure	Study population	Cancer site	Cases/controls	Results	Assessment of study
LeMerchand, et al., 1991 (Ref. 41).	Beta-carotene, reevaluation of dietary data.	Oahu, Hawaii, multiethnic men.	Prostate	452/899	Reexamined data eliminating papaya and found no association of beta-carotene with prostate cancer risk in men 70 years.	Positive association between papaya and prostate cancer was observed in men >70.
LeMerchand, et al., 1989 (Ref. 39).	Beta-carotene, other provitamin A carotenes, vegetables and fruits.	Oahu, Hawaii, multiethnic men and women.	Lung	230/597	Higher intakes of foods containing beta-carotene associated with lower lung cancer risks.	Stronger inverse association occurred with all vegetables, dark green and cruciferous vegetables, and tomatoes than with beta-carotene.
Bond, et al., 1987 (Ref. 40).	Dietary carotenoids	Chemical company employees, Texas, men.	Lung	308/616	Higher intakes of foods with high carotenoid index were associated with lower lung cancer risks.	The reported reliance on surrogate sources of dietary information and the relatively long retrospective period are flaws which detract from the results.
Kune, et al., 1987 (Ref. 46).	Vegetables	Case-control in Melbourne, Australia, men and women.	Colon, rectum	715	Higher intakes of beta-carotene, total vegetables, fiber and vitamin C were related to lowered risks.	Also some protection occurred with supplement usage. Retrospective period of long duration.
Coggon, et al., 1989 (Ref. 45).	Fruits and vegetables	Case-control, England.	Stomach	95/190	Intakes of fruit and salad vegetables inversely associated with risk.	Did not report on supplement alcohol, smoking or health history. Difficult to draw conclusions on effects due to beta-carotene.
LaVecchia, et al., 1988 (Ref. 47).	Fruits and vegetables	Case-control, Italy	Colon, rectum	339, 236, 778, controls.	Risk of both cancers inversely related to carotenoid and vitamin C indices.	Reported no information on supplement usage or community-based controls.
Smith and Waller, 1991 (Ref. 50).	Beta-carotene	Wellington, New Zealand cases, controls and their families.	Lung, stomach, esophagus, small bowel, cervix, uterus.	618/675	Plasma beta-carotene was lower in cancer patients and their relatives compared with control patients and their relatives.	A unique study of cancer and control patients and their families.
Ohno, et al., 1988 (Ref. 43).	Beta-carotene and vitamin A.	Japan case-control	Prostate benign prostatic hyperplasia	100/100	Intakes of beta-carotene and vitamin A inversely related to prostate cancer.	Report did not provide data on smoking or supplement usage. The time between the disease reported and dietary intake data is of long duration.

TABLE 2.—ANTIOXIDANT VITAMINS AND CANCER: PROSPECTIVE STUDIES OF DIETARY CAROTENOIDS AND CANCER

Authors and year	Source or exposure	Study population	Cancer site	Cases/controls	Results	Assessment of study
Paganini-Hill, et al., 1987 (2) (Ref. 54).	Carotenoids	5-yr cohort study, California retirement community, men and women.	All cancer, breast, bladder, lung, colon.	638, 123, 58, 55, 110.	No association found between beta-carotene consumption and subsequent development of cancer.	Study conducted in a retirement community where intakes of all nutrients are already very high. No specifics on supplement use was reported. The agreement between the questionnaire used in the first and second followup was reported to be only 50% reducing reliability of study.
Lee, et al., 1991 (Ref. 52).	Beta-carotene, soya, products and PUFA [1].	Chinese women of Singapore.	Breast	200/420	Inverse association with higher intakes of beta-carotene and other foods. Cannot separate effects due to beta-carotene versus those due to soya foods and poly-unsaturated fatty acids.	Authors suggested that soya products which are rich in phytoestrogens and beta-carotene may have influenced results in premenopausal women.
Harris, et al., 1991 (Ref. 51).	Beta-carotene	Men with cancer	Lung, other epithelia cancer controls.	96, 75, 97	Stronger inverse association with beta-carotene intake and cancers than with carotene-rich vegetables. Serum carotene correlated with dietary carotenes.	Age-matched controls were inpatients with nonmalignancy. Relatively small sample population.
Rohan, et al., 1988 (Ref. 53).	Beta-carotene foods	Australia. Case-control women.	Breast	451/451 (community-based controls).	Risk in premenopausal women decreased with increased intake of beta-carotene foods. In postmenopausal women risk was highest in the second lowest quintile of consumption.	Reported no data on supplement use. The standardized questionnaire used in collecting food intake data did not make use of food models or photographs in estimating portion sizes.

[1] Polyunsaturated fatty acids.

TABLE 3.—ANTIOXIDANT VITAMINS AND CANCER: PROSPECTIVE STUDIES OF SERUM OR PLASMA CAROTENOIDS AND CANCER

Authors/year (#)	Source/exposure	Study population	Cancer site	Cases/controls	Results	Assessment of study
Wald, et al., 1988 (Ref. 56).	Beta-carotene	BUPA [1] Medical Center, London, United Kingdom, men.	All cancer, lung, colorectal, CNS, bladder, stomach.	271/533, 50/99, 30/59, 17/34, 15/29, 13/26.	Reduced serum beta-carotene levels in all, lung, and stomach cancers and nonsignificant reduced levels in colorectal, CNS,[2] and bladder cancers.	No information reported on median storage times between sample collection and cancer diagnosis or death.
Connett, et al., 1989 (Ref. 58).	Total carotenes and beta-carotene.	22 MRFIT [3] centers, men.	All cancer, lung, gastro-intestinal, colon.	156/311, 66/131, 28/56, 41/28.	Higher serum levels were related to lower rates of lung cancer and trends towards relationship to reduced rates of gastrointestinal cancer.	One limitation is that this study used a single 24-hour dietary recall for collecting dietary information, therefore, the trend toward lower intake of beta-carotene in lung cancer cases may have assumed greater significance had more extensive dietary data been collected.
Stahelin, et al., 1991 (Ref. 60).	Beta-carotene	Chemical Company employees, Basel, Switzerland, men.	Bronchus, stomach, colo-rectal.	68, 20, 17	Overall cancer mortality was associated with low plasma carotene, but specifically that from bronchus and stomach cancer.	Well-designed study with good controls. However, no dietary data or supplement usage reported.

TABLE 3.—ANTIOXIDANT VITAMINS AND CANCER: PROSPECTIVE STUDIES OF SERUM OR PLASMA CAROTENOIDS AND CANCER—Continued

Authors/year (#)	Source/exposure	Study population	Cancer site	Cases/controls	Results	Assessment of study
Burney, et al., 1989 (Ref. 115).	Beta-carotene, lycopene.	Washington County, Maryland men and women.	Pancreas	22/44	Lower serum lycopene, not beta-carotene was associated with higher mortality from pancreatic cancer.	Storage of serum samples was of long duration and there was no report of dietary intake or supplement usage.
Knekt, et al., 1990 (Ref. 142).	Beta-carotene	Finland, cohort	All cancer sites	766/1419	Inverse relationship between mean serum beta-carotene levels and smoking and cancer risk after adjustment for smoking.	Blood storage time was of long duration. No dietary intake or supplement usage data were reported.

[1] British United Provident Association.
[2] Central nervous system.
[3] Multiple risk factor intervention trial.

TABLE 4.—ANTIOXIDANT VITAMINS AND CANCER: PREMALIGNANCY AND BETA-CAROTENE

Authors and year	Source/exposure	Study population	Cancer site	Cases/controls	Results	Assessment of study
VanEenwyk, et al., 1991 (Ref. 65).	Dietary and Serum Beta-carotene.	Women	Cervical Intra-epithelial, neoplasia (CIN).	102/102	Higher intakes and serum levels of lycopene were associated with lower frequency of CIN.	Combined dietary and serum data with biopsy data plus the control of confounding variables makes this a convincing study.
De Vet, et al., 1991 (Ref. 67).	Supplemental beta-carotene 10 mg per day.	Women	Cervical dysplasia	137/141	Inconclusive	Duration of supplementation too short and sample size was too small to allow conclusions to be drawn.
Palan, et al., 1991 (Ref. 66).	Plasma beta-carotene.	Cross-sectional study, women.	Uterine cervic dysplasia.	116	Reduced plasma beta-carotene and vitamin E associated with increased cervix dysplasia and cancer.	Cross-sectional study without proper control groups. However, study considered for smoking behavior as a confounding variable.
Brock, et al., 1988 (Ref. 62).	Dietary and plasma beta-carotene.	Patients and community-based matched controls.	Cervical cancer *in situ*.	117/196	Higher dietary and plasma beta-carotene were inversely associated with cancer.	Matched cases with controls for smoking and other confounding variables. Good overall design.
Verreault, et al., 1989 (Ref. 63).	Beta-carotene and dark green and yellow vegetables.	Case-control, Washington.	Cervical cancer	189/227	Higher intakes of carotenes related to lower risks of squamous cell cancers.	Limitations are the long duration between interview and reference period and long retrospective period.
Basu, et al., 1991 (Ref. 64).	Plasma beta-carotene.	Women patients with diagnosed cervix abnormality.	Cervical dysplasia	75	Reduced levels of beta-carotene in smokers and nonsmokers with cervix dysplasia.	No report as to whether or not reduced plasma beta-carotene is due to the disease state.

TABLE 5.—ANTIOXIDANT VITAMINS AND CANCER: CHEMOPREVENTION INTERVENTION TRIALS WITH BETA-CAROTENE

Study site/investigator	Target site/organ	Target/risk group	Supplementary agent	Results	Assessment of study
Greenberg, et al., 1990, Dartmouth, UCLA,[1] U Minn,[2] UC-San Francisco [3]. (Ref. 20).	Skin	Biopsy proved nonmelanoma basal-cell or squamous-cell carcinoma.	Beta-carotene, 50 mg per day.	No difference between cases and control groups in new cases of nonmelanoma skin cancer.	Well-designed double-blind intervention trial of 5-year duration.
Buring and Hennekens, 1990, Harvard School of Public Health (Ref. 140).	All cancer sites	American Physicians	Beta-carotene, aspirin	Continuing	N/A.
Stich, et al., 1988 (Ref. 68).	Oral leuplakias and micronucleated cells.	Betel nut/tobacco chewers.	Beta-carotene, 180 mg/week; Vitamin A, 100,000 IU [4]/week.	Inhibition of micronucleated cells after 3 months. Regression of leukoplakias after 6 months..	Authors suggested considerable variation in tissue levels of beta-carotene may affect study outcome.

[1] University of California, Los Angeles.
[2] University of Minnesota.
[3] University of California at Los Angeles.
[4] International units.

TABLE 6.—ANTIOXIDANT VITAMINS AND CANCER: VITAMIN C AND LUNG CANCER

Study	Type and location	Subjects	Methods	Results	Comments
Fontham, et al., 1988 (Ref. 75).	Case-control, Los Angeles, California.	1,253 cases, 1,274 hospital controls matched for race, sex, age.	All subjects interviewed via questionnaire regarding tobacco use, diet, etc. Food frequency questionnaire used with reference period before appearance of symptoms.	An inverse association was found between intake of vitamin C and specific types of lung cancer. A similar but less strong association was found for carotene.	Control group had 31.6% nonsmokers versus 4.3% in the case group. No biochemical indices measured. No population-based control group. No comparisons were made to nutrient intake standards.
Koo, et al., 1988 (Ref. 76).	Case-control, Hong Kong.	88 cases, 137 district-matched controls. All subjects were women with no known history of smoking.	All subjects interviewed regarding demographics, etc. Diet information obtained from food frequency questionnaire.	Reduced risk of adenocarcinoma and large cell cancer associated with consumption of leafy green vegetables, carrots, tofu, fresh fruit, fresh fish. Reduced risk of squamous cell tumors associated with consumption of fresh fruits.	No biochemical measurements. No analysis of diet information for specific nutrients.
Le Marchand, et al., 1989 (Ref. 39).	Case-control, Hawaii	432 cases, males and females, 865 community controls matched for age and sex.	Structured interview provided data on smoking, alcohol use, diet, etc. Food frequency questionnaire given to all subjects.	Inverse association found between vitamin C from foods and supplements and risk of lung cancer. A dose-dependent negative association was found between dietary beta-carotene and risk of lung cancer.	No biochemical measurements. No controls for ethnic differences in intake.
Le Gardeur, et al., 1990 (Ref. 120).	Case-control, Los Angeles, California.	59 cases, 59 hospital controls, 31 community controls.	Cases and hospital controls interviewed regarding smoking, history, diet, etc. Community controls not interviewed. Blood samples collected from all.	Mean serum levels of carot-enoids, vitamin E were lower for lung cancer cases than for hospital controls. Hospital controls had lower levels of vitamins C and E than community controls.	No diet results reported. No diet data collected for community controls. Hospital control group not appropriate because of nature of illnesses.

TABLE 7.—ANTIOXIDANT VITAMINS AND CANCER: VITAMIN C AND CANCERS OF THE COLON AND RECTUM

Study	Type and location	Subjects	Methods	Results	Comments
Graham, et al., 1988 (Ref. 78).	Case-control, New York, N.Y.	428 cases of colon cancer, 428 controls matched for sex, age, neighborhood.	Interview consisted of food frequency questionnaire, smoking and alcohol use, health history, etc.	Increasing intake of tomatoes, peppers, carrots, onions, celery associated with decreased risk of colon cancer. Risk was positively associated with increasing intake of total fat and total calories.	No biochemical measurements. No reference period for food frequency questionnaire.
La Vecchia, et al., 1988 (Ref. 47).	Case-control, Italy	339 cases of colon cancer, 236 cases of rectal cancer, 778 hospital controls (acute nonneoplastic, nondigestive disorders).	Dietary information obtained from food frequency questionnaire.. Data also collected on demographics, smoking, alcohol use, etc.	Intake of green vegetables, tomatoes, melon, coffee inversely related to risk of colon and rectal cancers. Inverse relationship between indices of carotenoid and vitamin C intake and risk.	Variability in reference period among groups. No biochemical measurements. No population-based controls.
Neugut, et al., 1988 (Ref. 136).	Cross-sectional, New York, N.Y.	105 cases of polyps, 56 cases of colon cancer, 83 controls without neoplastic disease. All subjects were women who had undergone colonoscopy.	Questionnaire used to obtain information on demographics, health history. Subjects asked about use of vitamin supplements.	Significant differences in socio-economic factors among the groups.	No dietary information. No information on duration of supplement use. No biochemical measurements.

TABLE 7.—ANTIOXIDANT VITAMINS AND CANCER: VITAMIN C AND CANCERS OF THE COLON AND RECTUM—Continued

Study	Type and location	Subjects	Methods	Results	Comments
West, et al., 1989 (Ref. 80).	Case-control, Utah	231 cases of colon cancer, 391 controls matched by age, sex, county of residence.	Interviews provided information on demographics, health history. Food frequency questionnaire used to obtain dietary information.	Protective effects of beta-carotene and cruciferous vegetables in males and of fiber in females. No effects of vitamin C	No biochemical measurements. Relationship of reference period for dietary data and time of diagnosis not identified.
Freudenheim, et al., 1990 (Ref. 77).	Case-control, New York, N.Y.	422 cases of rectal cancer, 422 controls matched for sex, race, age.	Interview used to obtain information on food frequency, smoking, alcohol use, health history, etc.	Increasing intake of carotenoids, vitamin C, and dietary fiber from vegetables associated with decreased risk of rectal cancer.	No biochemical measurements. Reliance on retrospective food frequency information.
McKeown-Eyssen, et al., 1988 (Ref. 81).	Randomized double-blind intervention trial, Toronto, Canada.	185 cases with at least one colon or rectal polyp.	96 subjects received vitamins E plus C, and 89 received placebo over a 2 year period.. Food frequency questionnaire used to obtain dietary data.	137 participants completed the trial. There was no significant difference in the number of polyps found in vitamin-treated or placebo groups.	No biochemical measurements Small sample size Study design did not allow differences in effect of individual vitamins to be distinguished
De Cosse, et al., 1989 (Ref. 82).	Randomized double-blind intervention trial study. Participants from several states, United States.	58 patients with familial adenomatous polyposis who had total colectomy and ileorectal anastomosis 1 year prior to study.	Vitamin group received 2.2 g fiber and 4 g vitamin C and 400 mg vitamin E daily. Fiber group received both vitamins plus 22.5 g fiber daily. Control group received placebo and 2.2 g fiber daily. All groups received supplement of vitamins C and A, and several other vitamins and minerals daily.	There were no significant effects of the vitamins.	No biochemical measurements. Analysis of independent effects of vitamins was not possible because of design of the study.

TABLE 8.—ANTIOXIDANT VITAMINS AND CANCER: VITAMIN C AND BREAST CANCER

Study	Type and location	Subjects	Methods	Results	Comments
Katsouyanni, et al., 1988 (Ref. 83).	Case-control, Athens, Greece.	120 cases, 120 hospital controls.	Dietary histories collected with a 120 item food frequency questionnaire. Nutrient intakes adjusted for calories.	No association between intake of vitamin C and risk of breast cancer. No differences in intakes of vitamin C between cases and controls.	No biochemical measurements. Supplement use not documented. 25% of controls had osteoarthritis, which affects vitamin C metabolism.
Toniolo, et al., 1989 (Ref. 84).	Case-control, Italy	250 cases, 499 controls from general population stratified by age, geographical area.	Dietary information collected by use of a modified food frequency questionnaire.	No differences in vitamin C intake between groups. Reduced risk of breast cancer was associated with decreased intakes of saturated fat and animal fat.	No biochemical measurements. Retrospective diet data not necessarily indicative of diets prior to diagnosis.
Howe, et al., 1990 (Ref. 85).	Case-control, meta-analysis of all studies of diet and breast cancer completed by 1986.	4,437 cases, 4,341 population-based controls, 1,754 hospital controls.	Data on vitamin C intake available from 9 to 12 studies. Estimates of intake were made for other three studies using food frequency answers.	Vitamin C intake had a statistically significant inverse association with risk of breast cancer. Consumption of B-carotene, fiber [markers of fruit and vegetable consumption] were also inversely related to risk.	Lack of control of independent variables that could be related to outcome. Reliability of dietary data questioned for some of studies used.

TABLE 9.—ANTIOXIDANT VITAMINS AND CANCER: VITAMIN C AND CANCER OF THE PROSTATE

Study	Type and location	Subjects	Methods	Results	Comments
Kolonel, et al., 1988 (Ref. 86).	Case-control, Hawaii	452 cases, 899 age-matched controls.	Home interview used to collect data on dietary, medical, occupational history, etc.. Food frequency questionnaire used to determine dietary intakes.	No associations were found between intake of vitamin C from food sources and risk of prostate cancer.	Total vitamin C intake ranged from 2,500 to 3,000 mg/week in all groups.
Ohno, et al., 1988, and Oishi, et al., 1988 (Ref. 43).	Case-control, Japan	100 cases of prostatic cancer, 100 controls with benign prostatic hyperplasia, 100 hospital controls without neoplasia or hyperplasia.. All subjects matched for hospital, age, date of admission.	Interviews used to collect data on occupation, medical history, etc. Dietary information obtained from food frequency questionnaire.	Intake of vitamin C from foods was not associated with risk of prostate cancer	No biochemical measurements. No community-based control group.

TABLE 10.—ANTIOXIDANT VITAMINS AND CANCER: VITAMIN C AND CANCER OF THE PANCREAS

Study	Type and location	Subjects	Methods	Results	Comments
Falk, et al., 1988 (Ref. 88).	Case-control, Los Angeles.	363 cases, 1,234 hospital controls matched on hospital. Race, sex, age	Interview used to obtain data on smoking, medical history, etc. Food frequency questionnaire used to obtain dietary information.	Significant inverse relationship between consumption of fruit (fresh or juice) and risk of pancreatic cancer.	No biochemical measures. Use of surrogates for more than 50% of cases. 13% of controls were not available.
Farrow, et al., 1990 (Ref. 137).	Case-control, Washington.	148 cases, 188 randomly selected controls.	Data for all subjects collected from surrogates. Food intake was determined from food frequency questionnaire.	No association between intakes of vitamin C and risk of pancreatic cancer.	Questionable validity/reliability of data acquisition.
La Vecchia, et al., 1990 (Ref. 48).	Case-control, Italy	247 cases, 1,089 hospital-based controls.	Interview used to obtain data on tobacco, alcohol, coffee intake, etc. Dietary intake of 14 "reference foods" determined.	Statistically significant decrease in risk of pancreatic cancer with increased intake of fresh fruits.	No biochemical measurements. No community based control. No matching for confounding variables.

TABLE 11.—ANTIOXIDANT VITAMINS AND CANCER: VITAMIN C AND STOMACH CANCER

Study	Type and location	Subjects	Methods	Results	Comments
Burr, et al., 1987 (Ref. 94).	Cross-sectional, England, Wales.	267 and 246 subjects selected randomly from pools of men aged 65 to 74 years in two towns with differing death rates from stomach cancer.	Standardized questionnaire. Blood samples for ascorbate and pepsinogen.	Intake of fruit and plasma ascorbate levels were significantly higher in men from town with lower rates of stomach cancer.	No information on nature of food frequency questionnaire. No diet data provided. No matching of subjects by health history, smoking, demographics, etc.
You, et al., 1988 (Ref. 89).	Case-control, China	564 cases of stomach cancer, 1,131 population-based controls.	Dietary data obtained from a food frequency questionnaire. Reference periods were about 1980 and about 1965.	Increased consumption of vitamin C, carotene, and calcium (associated with high intakes of fruits, vegetables) associated with decreased risk of stomach cancer.	Data represented 1980 interviews. No biochemical measurements. No information on mean intakes of nutrients.
Buiatti, et al., 1989, 1990 (Refs. 91 and 92).	Case-control, Italy	1,016 cases of gastric cancer, 1,159 community controls matched for age, sex.	Interview used to obtain information about demographics, medical history, diet, etc.	Significantly reduced risk associated with increased intake of raw vegetables, fresh fruit, citrus fruit. Risk decreased in proportion to intake of vitamin C, beta-carotene, alpha-tocopherol and vegetable fat.	No biochemical data. Reliance on retrospective data. No comparison with known standards of intake.

TABLE 11.—ANTIOXIDANT VITAMINS AND CANCER: VITAMIN C AND STOMACH CANCER—Continued

Study	Type and location	Subjects	Methods	Results	Comments
Chyou, et al., 1990 (Ref. 93).	Case-control, Hawaii	111 cases of gastric cancer, 361 controls. All subjects were American men of Japanese ancestry interviewed from 1965 to 1968.	Food frequency questionnaire provided information on food items consumed.	Statistically significant inverse relationship between risk of gastric cancer and intake of all vegetables.	No biochemical measurements. No assessments of individual nutrients.
Kono, et al., 1988 (Ref. 90).	Case-control, Japan	139 cases of stomach cancer, 2,574 hospital controls, 278 randomly selected community controls.	Data collected on dietary histories, occupation, smoking, etc.	Inverse relationship between risk of stomach cancer and consumption of fruits. Decreased risk also associated with increased consumption of green tea.	No biochemical measurements. No evaluation of individual nutrients. No information on health problems of hospital-based controls.

TABLE 12.—ANTIOXIDANT VITAMINS AND CANCER: VITAMIN C AND CANCERS OF THE HEAD AND NECK

Study	Type and location	Subjects	Methods	Results	Comments
Brown, et al., 1988 (Ref. 139).	Case-control, South Carolina.	207 males with esophageal cancer and 74 hospitalized cases and 133 deaths, 157 hospitalized noncancer controls and 265 noncancer deaths.	Patients interviewed about alcohol, tobacco use and diet. Next of kin of cancer and control subjects interviewed at home.	Leading risk factors for esophageal cancer after adjusting for smoking and tobacco use were low intakes of citrus fruits and juices and high intakes of liver.	No biochemical measurements. Reliance on retrospective dietary data and use of proxy data for mortality phase of study.
McLaughlin, et al., 1988 (Ref. 96).	Case-control, four regions of United States.	871 cases of oral and pharyngeal cancer, 979 population-based controls matched for age, sex, and race.	All subjects or next of kin provided data on alcohol and tobacco use and normal diet during adulthood.	Vitamin C was associated with decreased odds ratios and risk of oral cancer in men and women. There was a significant protective effect of vitamin C, vitamin A, and fiber derived from fruit.	No biochemical measurements. Reliance on retrospective diet data.
Franco, et al., 1989 (Ref. 95).	Case-control, Brazil	232 cases of oral cancer, 464 hospital, noncancer controls matched for sex, age, trimester of hospital admission.	All subjects interviewed regarding history of alcohol and tobacco use, general health, etc. Dietary information obtained from a food frequency questionnaire.	Strongest risk factors were alcohol and tobacco use. Without adjustments, significantly reduced risk associated with increased consumption of carrots, pumpkins, papaya, citrus fruits.	No biochemical measurements. No data on vitamin C specifically. Lack of population-based control group.
Li, et al., 1989 (Ref. 138).	Case-control, Linxian, China.	1,244 cases of cancer of esophagus or gastric cardia. 1,314 sex and age-matched controls from same area.	Data collected on smoking, diet history, personal health history. Questions were referenced to 2 time periods (late 1950's and late 1970's).	All subjects consumed diets low in fruits and vegetables. No association with risk of cancer at the sites examined.	Insufficient variability in intake to assess relationship to risk of cancer at sites examined.

TABLE 13.—ANTIOXIDANT VITAMINS AND CANCER: VITAMIN C AND CANCER OF THE OVARY OR CERVIX

Study	Type and location	Subjects	Methods	Results	Comments
Brock, et al., 1988 (Ref. 62).	Case-control, Australia	117 cases of cervical cancer, 196 controls matched for socio-economic status, age.	Interview and food frequency questionnaire used to obtain information on demographics, reproductive history, dietary data, etc.	Cases not matched for sexual habits, smoking, use of oral contraceptives. Adjusted risk estimate showed protective effect for vitamin C.	No biochemical measures of vitamin C status. No comparisons made with regard to dietary intake and blood levels.
Shu, et al., 1989 (Ref. 97).	Case-control, Shanghai	172 cases of epithelial ovarian cancer, 172 controls (age-matched).	Interview used to obtain information on demographics, reproductive history, dietary intake, etc.	No effect of intake of vitamin C on risk of ovarian cancer.	No biochemical measurements. No descriptive statistics. No comparisons to known standards of intake.

TABLE 13.—ANTIOXIDANT VITAMINS AND CANCER: VITAMIN C AND CANCER OF THE OVARY OR CERVIX—Continued

Study	Type and location	Subjects	Methods	Results	Comments
Slattery, et al., 1989 (Ref. 44).	Case-control, Utah	85 cases of ovarian cancer, 492 population-based controls matched for age.	Interview provided data on demographics, health history, dietary intakes, etc.	No effect of intake of vitamin C on risk of primary ovarian cancer.	No reference period given for dietary data. No biochemical measurements.
Verrault, et al., 1989 (Ref. 63).	Case-control, Washington.	189 cases of cervical cancer, 227 randomly selected age-matched controls.	Demographic, dietary, etc. data collected by interview.	Decreased risk of cervical cancer associated with high intakes of vitamin C.	No biochemical measurements. Retrospective period was 2.7 to 2.8 years. Food portion sizes estimated from food composition tables.
Ziegler, et al., 1990 (Ref. 98).	Case-control, cross-sectional multi-multi-center study.	271 cases of cervical cancer, 502 controls matched by age, race, telephone exchange.	Data collected by interview. Medical history, family health, food intake data collected.	No effect of vitamin C or vitamin C-rich foods on risk of cervical cancer.	Cases confirmed during 1982 and 1983. No reference period relative to onset or symptoms of diagnosis in cases.

TABLE 14.—ANTIOXIDANT VITAMINS AND CANCER: OTHER STUDIES

Study	Type and location	Subjects	Methods	Results	Comments
La Vecchia, et al., 1989 (Ref. 49).	Case-control, Northern Italy.	163 cases of confirmed bladder cancer; 181 hospital controls.	All subjects interviewed for information about health history, alcohol, tobacco use, coffee consumption, etc. Dietary data obtained from food frequency questionnaire.	Bladder cancer cases had lower frequency of consumption of green vegetables, carrots. No reduced risk related to intake of vitamin C.	No biochemical measurements. Food frequency questionnaire had only 10 items.
Stahelin, et al., 1989 (Ref. 61).	Prospective cohort, Basel, Switzerland.	2,975 men, 102 cancer deaths (lung, 37; stomach, 17; colorectal, 9; others 39).	Samples were collected in 1971 to 1973 and analyzed immediately.	Vitamin C was significantly lower in cases of stomach cancer than in controls.	Reliance on point sample analysis. No dietary data.

TABLE 15.—ANTIOXIDANT VITAMINS AND CANCER: PROSPECTIVE STUDIES ON VITAMIN E AND CANCER

Authors/year	Source/exposure	Study population	Cancer site	Cases/controls	Results	Assessment of the study
Wald, et al., 1987 (Ref. 57).	Serum vitamin E	22,000 men, 35 to 64 years, London, England.	Lung, colorectal, stomach, bladder, CNS, skin, other sites, all sites.	9/17, 6/12, 3/6, 8/15, 5/10, 31/57, 28/55, 90/172.	Mean vitamin E level of the cases was not significantly different from the controls in cancer subjects diagnosed >1 year after blood collection. Vitamin E levels of cancer cases diagnosed <1 year after blood collection was significantly lower than controls.	No dietary use data or data on the health history of the controls. Cases per cancer site were small. The difference reported for cases diagnosed at <1 year may have been the consequence of cancer rather than the precursor.
Russell, et al., 1988 (Ref. 117).	Serum vitamin E	5,086 women, 26 to 88 years, Guernsey, England.	Breast	30/288	No significant difference between the serum vitamin E levels of cases with breast cancer and the controls.	No matching for smoking, long storage time of the samples and no dietary use data.
Gey, et al., 1987 (Ref. 109).	Plasma vitamin E	3,000 men, Basel, Switzerland.	All sites, lung, gastrointestinal survivors.	102, 37, 17, 2,707	Significantly lower plasma vitamin E levels were associated with overall cancer and combined gastrointestinal cancer mortality.	No dietary use data. Small size was very small per site.
Stahelin, et al., 1989, 1991 (Refs. 60 and 61).	Plasma vitamin E	2,974 men Basel, Switzerland.	Bronchial, stomach, gastrointestinal, colon, survivors.	68, 20, 37, 17, 2,421.	No significant association of plasma vitamin E and the risk of cancer.	No dietary data. Results did not confirm findings reported in an earlier study using the same population group.

TABLE 15.—ANTIOXIDANT VITAMINS AND CANCER: PROSPECTIVE STUDIES ON VITAMIN E AND CANCER—Continued

Authors/year	Source/exposure	Study population	Cancer site	Cases/controls	Results	Assessment of the study
Schober, et al., 1987 (Ref. 116).	Serum vitamin E	25,802 adults, Washington County, Maryland.	Colon	72/143	No significant association of serum vitamin E and colon cancer.	No dietary data and long storage time of the sera samples.
Burney, et al., 1989 (Ref. 115).	Serum vitamin E	25,620 adults, Washington County, Maryland.	Pancreas	22/44	Low levels of serum vitamin E appear to have a protective effect on pancreatic cancer.	A chance association between vitamin E and pancreatic cancer could not be excluded. Samples were stored for a long time period and there was no information on diet history or intake. The number of cases was also very small.
Comstock, et al., 1991 (Ref. 114).	Serum vitamin E	25,800 adults, Washington County, Maryland.	Colon; rectum; pancreas; lung; melanoma, skin; basal cell, skin; Breast; Prostate; Bladder.	72/143, 34/68, 22/44, 99/196, 20/40, 21/42, 30/59, 103/103, 35/70.	The association of vitamin E with lung cancer showed a dose-response trend in a protective direction. There were no other significant associations.	Storage time of samples was very long, sample size at some cancer sites was small and no diet history or usage reported.
Knekt, et al., 1988 (Ref. 112).	Serum vitamin E	36,265 men and women, 15 to 99 years, Finland.	Gastrointestinal	150/276	Upper gastrointestinal tract cancers were associated with lower serum vitamin E. The risk differed significantly between tertiles among men.	Samples collected and stored a long time before analysis of vitamin E and no diet usage data were reported.
Knekt, et al., 1988 (Ref. 111).	Serum vitamin E	21,172 men, Finland	All sites, Stomach, Pancreas, Colon and rectum, Other sites.	453/841, 48/90, 17/28, 21/39, 367/723.	Significant increase in the risk for all cancers unrelated to smoking and some gastrointestinal cancers with low serum vitamin E.	The number of cases at certain sites was small, samples were stored for a long period of time and no dietary data were reported.
Knekt, et al., 1988 (Ref. 110).	Serum vitamin E	15,093 women, Finland.	All sites, Epithelial, Breast, Cervix, Endometrium, Ovary.	313/578, 184/339, 67/123, 23/44, 12/21, 16/29.	Significant inverse association between serum vitamin E for all cancer sites combined and epithelial cancer.	The number of cases at some sites was small, samples were collected and stored a long time before analysis of vitamin E and no dietary data reported.
Knekt, et al., 1991 (Ref. 113).	Serum vitamin E	36,265 men and women, Finland.	All sites, Gastrointestinal.	557 sets, 160 sets.	The association of serum vitamin E with cancer was strongest for all cancer sites and gastrointestinal cancer.	Same as above.

TABLE 16.—ANTIOXIDANT VITAMINS AND CANCER: RETROSPECTIVE STUDIES ON VITAMIN E AND CANCER

Authors/year	Source/exposure	Location	Cancer site	Cases/controls, type of control	Results	Assessment of the study
Basu, et al., 1989 (Ref. 118).	Serum vitamin E	Canada	Breast	30/30, Population	No significant association between breast cancer and serum vitamin E.	All cases were in the advanced stage of breast cancer. No dietary or clinical data were reported. Sample size was small.
Gerber, et al., 1989 (Ref. 119).	Vitamin E intake Plasma Vitamin E	France	Breast	120/109, Hospital	Plasma vitamin E was significantly higher in cases than controls. No significant association of vitamin E intake and breast cancer.	The control group was made of hospital patients and no information was given on medication use. Dietary data were retrospective.

TABLE 16.—ANTIOXIDANT VITAMINS AND CANCER: RETROSPECTIVE STUDIES ON VITAMIN E AND CANCER—Continued

Authors/year	Source/exposure	Location	Cancer site	Cases/controls, type of control	Results	Assessment of the study
Toniolo, et al., 1989 (Ref. 84).	Vitamin E intake		Breast	250/499, Population.	No significant association of vitamin E intake and breast cancer.	No biochemical data were reported. Dietary data were retrospective and obtained on the average of 7.8 months after diagnosis.
LeGardeur, et al., 1990 (Ref. 120).	Serum vitamin E	New Orleans, Louisiana.	Lung	59/59, Hospital	Lower serum vitamin E of cases when compared with controls.. Adjustment for serum cholesterol reduced the differences.	No dietary data were reported. Hospital patients who may have been predisposed to changes in serum vitamin E were used as controls. Groups were not matched for smoking history.
Charpiot, et al., 1989 (Ref. 121).	Serum vitamin E	France	Digestive	50/50, Hospital	Serum vitamin E of cases were significantly lower than controls.	Dietary intake information was not reported. No information was provided on whether the hospitalized controls were on any medication. Data were not provided on the stage or type of digestive cancer.
Buiatti, et al., 1990 (Ref. 92).	Vitamin E intake	Italy	Gastric	1,016/1,159, Population.	Risk decreased with increased intakes of vitamin E and C.	No biochemical data were reported. Retrospective dietary data on vitamin E were calculated using English tables.
Verrault, et al., 1989 (Ref. 63).	Vitamin E intake	Seattle, Washington	Cervical carcinoma	189/227, Population.	High vitamin E intake was associated with lower cancer risk.	No biochemical data were reported. Retrospective dietary data focused on the recall of foods use several years prior to the interview.
Cuzick, et al., 1990 (Ref. 122).	Serum vitamin E	London	Cervical intraepithelial neoplasia I, Cervical intraepithelial neoplasia II.	30/40, 40/45. Patients of general practitioners and clinics.	Significant decreasing trend of mean levels of serum vitamin E in cases.	No dietary data reported. Sample size was small. No medical history of controls was reported.
Freudenheim, et al., 1990 (Ref. 77).	Vitamin E intake	Western New York	Rectal	277/277 (men), 145/145 (women), Neighborhood.	No significant association between rectal cancer and vitamin E intake.	No biochemical data reported and retrospective food frequency interviews were used.
Stryker, et al., 1990 (Ref. 125).	Plasma vitamin E, Vitamin E intake.	Boston	Malignant melanoma.	204/248, Skin clinic.	Intake alone displayed a significant trend of decreasing risk with increasing intake.	Clinic patients were used as controls and no information was reported on medication or supplement use.
Drozdz, et al., 1989 (Ref. 124).	Serum vitamin E	Poland	Larynx	22/16, Hospital	No significant association of serum vitamin E and cancer of the larynx.	Hospital controls were used who may have been predisposed to changes in serum vitamin E. No diet or supplement information were reported. Sample size was very small.

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21 CFR Part 101

[Docket No. 91N-0102]

RIN 0905-AD08

Food Labeling: Health Claims; Zinc and Immune Function in the Elderly

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing not to authorize the use on foods, including dietary supplements, of health claims relating to the association between zinc and immune function in the elderly. FDA has reviewed the scientific data in conformity with the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and has tentatively concluded that there is not a sufficient basis to support the use of health claims relating to this topic. The agency's examination of publicly available evidence revealed that a specific protective role of zinc supplementation of the elderly population has not been demonstrated. Although some small clinical studies suggested such a relationship, these results were not substantiated in subsequent research using better study designs and larger samples.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, Center for Food Safety and Applied Nutrition (HFF-268), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5104.

SUPPLEMENTARY INFORMATION:

I. Background

A. Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535), which amend the Federal Food, Drug, and Cosmetic Act (the act). Section 403(r) of the act (21 U.S.C. 343(r)) authorizes the Secretary of Health and Human Services and FDA by delegation to issue regulations authorizing nutrient content and health claims on the label or labeling of foods. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under the act (21 U.S.C. 343(r)(1)(B)).

Published elsewhere in this **Federal Register** is a proposed rule to establish general requirements for health claims that characterize the relationship of nutrients, including vitamins and minerals, herbs, or other nutritional substances (referred to generally as "substances") to a disease or health-related condition on food labels and in labeling for conventional foods and dietary supplements. In this companion document, FDA has tentatively determined that such claims would only be justified for substances in dietary supplements as well as in conventional foods if it determines, based on its review of all the publicly available scientific evidence (including evidence from well designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The 1990 amendments also require (sections 3(b)(1)(A)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x)) that within 12 months of enactment, the Secretary of Health and Human Services shall issue proposed regulations to implement section 403(r) of the act and that such regulations shall determine, among other things, whether claims respecting 10 topic areas, including zinc and immune function in the elderly, meet the requirements of the act.

In this document, the agency will consider whether a label or labeling claim on a food, including conventional foods and dietary supplements, on the relationship between zinc and immune function in the elderly would be justified under the standard proposed in the companion document entitled "Food Labeling: General Requirements for Health Claims for Food.

B. Zinc and Immune Function in the Elderly: Public Health Aspects

1. Zinc and Immune Function

Immune function refers to the body's defense processes to prevent and contain infection. The immune system is composed of lymphoid, thymus, and bone marrow cells. Poor nutrition (for example, malnutrition consisting of inadequate protein and calorie intake and multiple nutrient deficiencies) increases susceptibility to infectious disease (Refs. 1 through 4). In addition, diminished immune function is recognized as an adverse consequence of deficiencies of several specific nutrients including iron, zinc, copper, magnesium, selenium, vitamin E, vitamin C, vitamin B_6, vitamin B_{12}, and folic acid. The effect that a deficiency in a particular nutrient has on immune function in human populations is not well understood. Zinc deficiency and immune function have been investigated extensively because studies in humans and animals have shown that zinc deficiency causes a selective suppression of lymphoid organ weight and abnormalities in immune responses.

Experiments in zinc-deficient animals and humans have shown that zinc is essential for specific immune function (Refs. 5 through 8). Immunological disorders of some disease conditions characterized by secondary zinc deficiencies can be corrected by zinc supplementation (Refs. 5 and 7). Such disease states and conditions include acrodermatitis enteropathica, alcoholism, diabetes, gastrointestinal disorders, sickle cell anemia, some cancers, protein-calorie malnutrition, parenteral nutrition with inadequate zinc, and hypoglobulinemia. There is no evidence, however, that immune function in healthy persons can be enhanced by zinc supplementation.

Zinc is considered to be relatively nontoxic, particularly if taken orally. However, adverse effects, which include impaired immune function, are known to occur with zinc intake in excess of the Recommended Dietary Allowance (RDA) (Ref. 9).

2. Mechanisms and Measures of Immune Function

The immunologic defense mechanisms mediated by T lymphocytes are collectively known as "cell-mediated immunity." T. lymphocytes, a specific type of white blood cell, attack and kill cells infected with viruses, bacteria, and protozoa. Thymic hormone stimulates maturation and differentiation of immature lymphocytes into several specific types of functional T lymphocytes. Thymic hormone requires zinc for activation. Various subsets of differentiated T lymphocytes (e.g., "helper", "suppressor", and "killer" T cells) can attach to infected cells and kill them directly or can function indirectly by releasing substances that influence the actions of other immune cells.

Several common tests are used to measure the level of cell-mediated

immune function. In the delayed cutaneous hypersensitivity (DCH) test, a small amount of foreign substance (an antigen) is injected under the skin. With normal functioning cell-mediated immunity, a localized inflammatory reaction develops at the site of the injection within 48 hours. The immune response to the antigen is measured by the diameter of the welt and inflammation appearing at the site. "Anergy" is a term used to describe the condition in which no cell-mediated allergic reaction occurs in response to such antigen injection.

Another type of test of cell-mediated immunity uses lymphocytes separated from blood samples and cultured in test tubes. Addition of a small amount of mitogen (a substance such as bacterial fragments) to the isolated lymphocytes stimulates functional, immunocompetent T lymphocytes to divide and proliferate. Impaired cell-mediated immunity is indicated by a failure of the mitogen to stimulate T lymphocyte proliferation. The lymphocyte proliferative response (LPR) is a measure of the rate of lymphocyte division in response to a mitogen challenge.

Zinc deficiency has been associated with decreased thymic hormone levels and with a corresponding decrease of both functional T lymphocytes and cell-mediated immunity in experimental animals and humans, as shown by anergy in DCH and decreased LPR (Refs. 8 and 10).

3. Immune Function in Aging

One of the physiologic changes that characterizes aging is a gradual senescence of some components of the immune system, particularly cell-mediated immune function (Refs. 5, 11, and 12). The primary age related changes in immune systems of both human and experimental animals result from gradual thymic atrophy and changes in the T lymphocyte population. There are age related decreases in the number of blood T lymphocytes as well as in the proportion of helper/inducer T lymphocytes and increases in the proportion of immature T lymphocytes. Accompanying the change in T cell population is a functional decline in cell-mediated immunity as indicated by reduced lymphocyte proliferation in response to mitogens.

Progressive impairment of cellular immunity observed in generalized malnutrition, including zinc deficient states, is similar in some respects to the age related decline of cell-mediated immune function. When insufficient protein calorie nutrition is responsible for depressed immune function, improved diet may restore such function and improve disease resistance. There is evidence that a balanced, complete nutritional supplementation can improve impaired cell-mediated immunity in protein-calorie malnourished elderly (Ref. 13).

4. Zinc Nutritional Status of the Elderly in the United States

Several reports have suggested that the elderly U.S. population may be at risk of zinc deficiency. A review of reports by 17 different groups concerning zinc intake in the elderly has recently been published (Ref. 14). The results of dietary surveys have been fairly consistent in suggesting that elderly persons consume zinc at less than RDA levels. Diets representative of those consumed by elderly women generally contain less dietary zinc than do those for elderly men (Ref. 15), and institutionalized subjects generally consume less zinc than do persons living at home (Refs. 16 and 17).

Intake of zinc appears to diminish as elderly persons advance in age (Refs. 14 and 18). Small studies of selected populations have also identified pockets of zinc insufficiency in some populations (Ref. 14). Additionally, the elderly frequently alter their dietary habits and may also lose their appetites and reduce their food intake (i.e., become anoretic).

For these reasons, the elderly population has been proposed as one of the groups which may have a high incidence of inadequate zinc nutriture (Refs. 19 through 21). The question of adequacy of zinc nutriture in the elderly is one of the issues that FDA examined in this review.

C. Zinc: Regulatory History

One zinc salt, zinc methionine sulfate, is regulated as a direct food additive for use as a special dietary and nutrient food additive in 21 CFR 172.399.

Five other zinc salts are listed in part 182 (21 CFR part 182) as generally recognized as safe (GRAS) for use in dietary supplements or as nutrients: Zinc chloride (§§ 182.5985 and 182.8985), zinc gluconate (§§ 182.5988 and 182.8988), zinc oxide (§§ 182.5991 and 182.8991), zinc stearate (§§ 182.5994 and 182.8994), and zinc sulfate (§§ 182.5997 and 182.8997). No zinc compounds are affirmed as GRAS in part 184—Direct Food Substances Affirmed as Generally Recognized as Safe (21 CFR part 184) nor under part 186—Indirect Food Substances Affirmed as Generally Recognized as Safe (21 CFR part 186). FDA proposed to affirm the GRAS status of the use of zinc salts in a document published on October 26, 1982 (47 FR 47441). FDA proposed to affirm as GRAS the use of zinc oxide and zinc sulfate as direct food ingredients, to affirm as GRAS the use of zinc chloride as an indirect food ingredient, and to remove zinc chloride and zinc stearate from the listing in part 182 (§§ 182.8985 and 182.8994). For technical reasons not related to the safety of the compounds,

FDA proposed on August 28, 1991 (56 FR 42668) to withdraw pre-1986 GRAS proposals, one of which is the use of zinc salts.

FDA has issued a health fraud bulletin pertaining to drug products, including vitamins and minerals, that bear claims that they enhance, strengthen, or otherwise benefit the immune system for the purpose of preventing or treating any disease condition. The bulletin stated that such products are drugs under section 201(g)(1)(B) of the act (21 U.S.C. 321(g)(1)(B) (FDA Health Fraud Bulletin No. 11. *Immune System Products*, August 17, 1987).

D. Evidence Considered in Reaching the Decision

FDA has reviewed all relevant scientific evidence on zinc and immune function in the elderly. The scientific evidence reviewed by FDA included all relevant studies considered in two U.S. Government documents: "The Surgeon General's Report on Nutrition and Health," U.S. Department of Health and Human Services, 1988 (Ref. 22) (the Surgeon General's report) and the U.S. Department of Agriculture (USDA) and DHHS pamphlet "Nutrition and Your Health, Dietary Guidelines for Americans" (Ref. 23). FDA reviewed relevant studies considered in three nongovernment documents: the National Research Council's report "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy of Sciences (Ref. 24), the Tenth Edition of "Recommended Dietary Allowances" (Ref. 25) and the Life Sciences Research Office of the Federation of American Societies of Experimental Biology report "Zinc and Immune Function in the Elderly" (Ref. 26) (the Life Science Research Office report). FDA updated the conclusions reached in these documents by reviewing all human studies and all review articles relevant to the topics that were published in the literature since the publication of these documents.

To assure that its review of relevant evidence was complete, FDA requested, in the **Federal Register** of March 28, 1991, (56 FR 12932) scientific data and information on the 10 specific topic areas identified in section 3(b)(1)(A) of the 1990 amendments. The topic of zinc and immune function in the elderly was

among the 10 subjects on which the agency requested information.

E. Comments Received in Response to FDA Request for Scientific Data and Information

In response to the March 28, 1991 notice in the **Federal Register**, FDA received six comments from food manufacturers or processors, trade associations of dietary supplement manufacturers, national associations of public health and nutrition officials, and the Government of Canada. The comments dealt with the issue of zinc and immune function in the elderly as well as with the goals and requirements of the 1990 amendments. One comment was from a private citizen, who submitted a computer search of medical literature. FDA reviewed all of the documents, including letters, press releases, scientific articles, review articles, and recommendations included in submissions that it received. The data submitted in scientific articles were included in FDA's review of the scientific literature.

Comments from a food manufacturer and from a trade association of nutrient supplement manufacturers included a recommendation that FDA include additional population groups and additional nutrients in its evaluation of nutrition/immune function relationships for label health claims. Another comment noted that dietary intake data from several sources indicate that the zinc intake of several age groups is less than the RDA. One comment noted that although there is not sufficient data at this time to support disease related claims for the population, including the elderly, it is important to encourage adequate consumption of zinc.

Comments were received from two national professional organizations of nutritionists and public health nutrition directors. These comments advised a cautious approach to the use of health claims on foods and supplements with awareness of the potential for abuse and misinterpretation of health claims. The comments recommended that the cornerstone for approval of a health claim be significant scientific agreement that the claim is supported by publicly available evidence, and that health claims be evaluated in the context of the total diet rather than on the basis of individual foods, supplementation, or fortification practices.

The Government of Canada submitted information that it considers helpful in the context of increased harmonization of regulations or standards affecting trade in specific products. The Canadian Food and Drugs Act prohibits advertising and labeling of a food as a treatment, preventative, or cure for specific diseases and disorders listed in the act. The Director General, Food Directorate, Health and Welfare Canada, stated that although immune function is not included in the act, health claims regarding zinc and immune function in the elderly would likely result in a food product being classified as a drug by virtue of the definition of "drug" embodied in the Canadian Food and Drugs Act.

The official position of Canada on the relationship of diet and nutrients to disease and the metabolic effects of nutrients is stated in "Nutrition Recommendations, the Report of the Scientific Review Committee—1990" (Ref. 27) (the Canadian Report). In sections relating to zinc and disease prevention, this report noted that abnormal zinc intakes have been associated with impaired immune function. Zinc supplementation of zinc-deficient persons improves many aspects of immune function. The report did not specifically address the issue of zinc and immune function in the elderly.

The Canadian report noted that excessive intakes of zinc have been shown to impair immune function and to cause adverse effects on copper metabolism (Ref. 27). In view of potential detrimental effects of high intakes of zinc on the immune system and on copper metabolism, the Canadian report suggested that large supplementary amounts of the element be avoided. There is no scientific evidence, the Canadian report continued, to support ingestion of megadoses of zinc except in the treatment of specific diseases such as Wilson's disease, in which excess copper is absorbed and stored in the body. The recommended zinc intakes for Canadian adult males and females (over 13 years of age) are 12 and 9 milligrams (mg) zinc per day, respectively (Ref. 27).

II. Review of the Scientific Evidence

A: Federal Government Documents

The Joint Nutrition Monitoring Evaluation Committee (JNMEC) DHHS/USDA, was established in 1983 by the USDA and DHHS to coordinate survey methods used by the two departments to obtain information on nutritional status of the U.S. population. The first report (Ref. 28), issued in 1986, provided food intakes data from the 1977 to 1978 Nationwide Food Consumption Survey (NFCS) and information on nutritional status based upon biochemical analyses from the National Health and Nutrition Examination Survey (NHANES II, 1976 to 1980). JNMEC judged that zinc was among a number of nutrients and dietary components that required further investigation because data regarding intake and nutritional status were inadequate (Ref. 28).

The "Surgeon General's Report on Nutrition and Health" (Ref. 22) did not consider the specific topic of zinc and immune function in the elderly. In sections dealing with infection and immunity and with aging, however, the Surgeon General's Report (Ref. 22) noted that deficiencies of a number of nutrients have been associated with reduced function of specific components of the immune system, and that during aging there is a gradual senescence of some components of the immune system. The Surgeon General's report pointed out, however, that distinguishing age related physiologic changes from those changes caused by poor nutrition in older persons has not yet been possible (Ref. 22). The Surgeon General's report observed that research has not yet resolved whether progressive impairment of cellular immunity with age might cause older populations to have more infections than young people of equivalent nutritional and health status. The relationships among malnutrition, infections, and changes in immune system function in elderly persons have yet to be clarified (Ref. 22).

The Surgeon General's Report (Ref. 22) further noted that nutritional status evaluation of older people is complicated, and that clinical and dietary standards for younger adults may not be appropriate for older persons. Few data are available on nutritional requirements of older adults. A very serious problem in nutritional status assessment of older adults is the lack of correlation between dietary intake data and clinical and laboratory assessment methods (Ref. 22).

B. Other Documents

The Food and Nutrition Board of the National Academy of Sciences did not specifically address the topic of zinc and immune function in the elderly in the Tenth Edition of "Recommended Dietary Allowances," (Ref. 25). The Food and Nutrition Board concluded that marginal states of zinc nutriture may exist in segments of the U.S. population, but that the data are fragmentary.

The Life Sciences Research Office report reviewed the literature on the relationship between zinc and immune function in the elderly (Ref. 26). This report concluded that:

(1) Zinc is of profound importance for proper immune system function. Too much or too little zinc can induce immunological dysfunctions. Steps to

return zinc nutriture to normal serve to correct such dysfunction;

(2) Elderly persons who are poor, who live alone or in institutions, who are female, who have acute or chronic illnesses or disabilities, or who reach very advanced ages are at risk for developing zinc malnutrition;

(3) Immunological dysfunctions in the elderly have been improved by nutritional means, but the role of zinc in this remains unclear. Reported immune system improvements induced by supplemental zinc generally occurred in subjects with preexisting evidence of zinc deficiency;

(4) RDA intakes of zinc may not correct preexisting zinc deficiencies in the elderly. Even large supplements may not improve plasma zinc values if disease induced zinc sequestering mechanisms are involved; and

(5) There is no definitive evidence to suggest that the current RDA for zinc is inadequate for healthy elderly individuals. Elderly persons who are truly zinc deficient may benefit immunologically from medically supervised nutritional rehabilitation.

C. Review of Scientific Literature

1. Evidence for an Association Between Zinc Intake and Immune Function in the Elderly

a. *Introduction.* FDA reviewed all the publicly available evidence on zinc and immune function in the elderly provided by intervention studies. The agency evaluated these human intervention studies to determine whether there is an association between zinc supplementation and improvements in immune function in this age group. Pertinent information regarding these studies, such as study design, number of subjects studied, nature and duration of supplement use, and significant results are included in Table 1. The evaluation focused on studies in which supplemental zinc was administered to healthy elderly persons to determine whether zinc had specific effects on the immune system function of the general population for which health claims are targeted.

TABLE 1.—ZINC AND IMMUNE FUNCTION IN THE ELDERLY: SUPPLEMENTATION STUDIES

Reference	Study design and duration	Description of subjects	Test material and intake level	Diet	Additional treatments	Other factors affecting interpretation	Results	Assessment of study
Duchateau et al., 1981 (Ref. 29).	Prospective intervention study with controls; 1 month.	30 healthy institutional patients, age >70 years; test group (n=15), control group (n=15); Belgium.	Zinc (Zn) sulfate; 100 mg Zn/day orally.	Not reported	Tetanus vaccination.	Institutionalized subjects only. No measure of Zn status. No blinding.	20% increase of T lymphocytes (p<.05), improved DCH response (p<.01), and greater post vaccine tetanus titre (p<.001) in treated group. No change of in vitro LPR.	Results not applicable to free-living elderly. Immunological improvement small, no assessment of initial Zn status.
Wagner et al., 1983 (Ref. 30).	Prospective intervention study, not controlled; 1 month.	5 anergic, low income elderly, age 64 to 76 years; Alachua Co., FL.	Zinc sulfate; 55 mg Zn/day orally.	Self-selected	None	Incomplete serum data from 1 subject. Low income subjects only. All subjects initially anergic.	All 5 subjects had at least 1 positive DCH response from 5 test antigens: Serum Zn increase.	Small, uncontrolled, unblinded study.
Bogden et al., 1988 (Ref. 34).	Prospective double-blind intervention study; 3 months.	103 healthy free living elderly, age 60 to 89 years, 3 groups: placebo (n=36), 15 mg Zn (n=36), 100 mg Zn (n=31); Bergen Co., NJ.	Zinc acetate, 15 mg Zn/day, 100 mg Zn/day, 0 mg Zn/day (lactose placebo) orally.	Self-selected 8 to 9 mg Zn/day.	Multiple vitamin-mineral (-Zn) oral supplement.	Free living healthy subjects. Compliance monitored by pill counts.	Plasma Zn increase (p<.05) in 100 mg Zn group. Increase DCH response in all groups. Decrease anergy same in all groups. No change of in vitro LPR.	Large, well conducted study, no differences were found in immune functions between placebo and Zn supplemented groups. No effect of supplemental Zn on immune function.
Bracker et al., 1988 (Ref. 35).	Prospective double-blind intervention study; 2 months.	41 healthy elderly, age 64 to 90 years, Zn supplemented group (n=23), placebo group (n=18); California.	Zinc gluconate; 0 mg Zn/day (placebo) 50 mg Zn/day orally.	Not reported	Trivalent influenza vaccine at 1 month.	41 of 60 subjects (68%) completed study. Dietary assessment not included.	45% increase in serum Zn in supplemented group (p<.001). Post vaccination antibody titre increase not different between supplement and placebo groups.	Limited to healthy subjects, results can be generalized to U.S. population. Previous influenza vaccination may have influenced results.
Soltesz et al., 1988 (Ref. 31).	Prospective intervention study; 4 weeks.	6 nursing home residents, age not specified. Ohio.	Zinc gluconate; 15 mg Zn/day orally.	Institutional food; 6.8 to 13 mg Zn/day calculated intake.	One subject received liquid nutritional supplements.	Nursing home patients, screened for confounding problems. Age not specified. Data from 5 subjects.	Small increase in number of positive DCH responses p<05, n=5).	Small, uncontrolled, unblinded study; immunological improvement small.
Cossack, 1989 (Ref. 32).	Prospective intervention study; 4.5 months.	8 Zn deficient, low income elderly men, age 65 to 78 years Denmark.	Zinc acetate; 60 mg Zn/day orally.	Not reported	None	Comparison values from 13 age matched men. Subjects selected from group of low socioeconomic men on basis of low Zn status and anergy.	Plasma and cellular Zn levels increase to normal DCH response and RBC[1] nucleoside phosphorylase activity increase to near normal.	Small, uncontrolled, unblinded study. Results applicable only to individuals diagnosed as Zn deficient.

Bogden et al., 1990 (Ref. 34).	Prospective double-blind intervention study; 16 months overall, last 4 months all groups received placebo.	63 healthy free living elderly, age 60 to 389 years; 3 groups: placebo (n=24), 15 mg Zn (n=20), 100 mg Zn (n=19); Bergen Co., NJ.	Zinc acetate 15 mg Zn/day, 100 mg Zn/day, 0 mg Zn/day, (placebo) orally.	Self-selected; Zn intake less than 2/3 RDA for 67% of men and 81% of women.	Multiple vitamin-mineral (-Zn) oral supplement continued for 16 months.	Free living healthy subjects. 63 of 158 subjects (40%) completed 16 months. Zn supplementation for 12 months, all groups received placebo final 4 months. Compliance monitored by pill counts.	Plasma Zn increase ($p<.05$) in 100 mg Zn group, returned to baseline at 16 months. No change in cellular Zn except for transient increase of PMN[2] Zn at 3 months in 15 mg Zn group. DCH response increased in all groups, doubled in placebo group, increased least in Zn supplement groups DCH suppression in Zn groups persisted after Zn supplementation discontinued. Transient increase NK cell activity at 3 month in 100 mg Zn group.	Large, well conducted study. Improvements in immune function likely due to multivitamin-miner supplement, and suppressed by supplemental Zn.
Soltesz et al., 1988 (Ref. 31).	Prospective intervention study; 4 weeks.	6 nursing home residents, age not specified. Ohio.	Zinc gluconate; 15 mg Zn/day orally.	Institutional food; 6.8 to 13 mg Zn/day calculated intake.	One subject received liquid nutritional supplements.	Nursing home patients, screened for confounding problems. Age not specified. Data from 5 subjects.	Small increase in number of positive DCH responses ($p<.05$, $n=5$).	Small, uncontrolled, unblinded study; immunological improvement small.
Cossack, 1989 (Ref. 32).	Prospective intervention study; 4.5 months.	8 Zn deficient, low income elderly men, age 65 to 78 years Denmark.	Zinc acetate; 60 mg Zn/day orally.	Not reported	None	Comparison values from 13 age matched men. Subjects selected from group of low socioeconomic men on basis of low Zn status and anergy.	Plasma and cellular Zn levels increase to normal DCH response and RBC nucleoside phosphorylase activity increased to near normal.	Small, uncontrolled, un blinded study. Results applicable only to individuals diagnosed as Zn deficient.

[1] Red blood cells.
[2] Polymorphonuclear cells.

FDA did not review studies of: (1) Influence of zinc on immune function in disease states; (2) effects of in vitro addition of zinc to lymphocytes; or (3) animal studies. The results of studies of immune function in malnourished populations and in specific disease states are widely reported in the scientific literature (Refs. 1 through 8, and 10). Such studies, however, do not contribute specific information helpful in evaluating the relationship of zinc to immune function in the elderly because it is difficult to identify the role of zinc versus other nutrient insufficiencies or to extrapolate from sick persons to the general population of healthy elderly in the United States. To the extent that zinc is used to cure, treat, or mitigate a disease, it is a drug (21 U.S.C. 321(g)(1)(B)).

The relevance of findings of effects of addition of zinc to lymphocytes in vitro to function of the immune system in vivo is simply not clear. Studies with animals have repeatedly demonstrated the effects of zinc deficiency on immune function. Thus, the existence of a role for zinc in immune function is not at issue. However, animal studies in general, while providing invaluable insights into the role of nutrition in immune function, do not contribute directly to an understanding of zinc and immune function in the elderly human population in the United States, the subject that the statute directs FDA to consider.

b. *Criteria used in evaluating evidence.* The criteria used in evaluating evidence included: (1) Reliability and accuracy of the methods used in food intake analysis and measurement of endpoints; (2) choice of control subjects (e.g., hospital-based versus population-based); (3) representativeness of subjects; (4) control of confounding factors in data analysis; and (5) degree of compliance and how compliance was assessed.

FDA evaluated the weaknesses and strengths of individual studies (see "Assessment" column of Table 1). The agency then assessed the strength of the overall combined evidence taking into account the strength of the association, the consistency of findings, and specificity of the association. FDA's conclusions reflect the strength, consistency, and preponderance of data.

c. *Review of evidence.* In 1981 Duchateau et al. (Ref. 29), published the first report of an effect of zinc supplementation on immunocompetence in healthy elderly persons. Two age and sex matched groups of institutionalized healthy persons over 70 years old were studied. One group (n=15, mean age=81) received 100 mg zinc per day orally for 1 month; the second group (n=15, mean age=80) received no supplement and served as a nonblinded control group. No measures of zinc status nor of dietary zinc intake were reported in the study. Several measures of cell-mediated immunity (proportion of T cell lymphocytes, DCH response, and antibody response to tetanus toxoid vaccination) increased in the zinc supplemented group but not in the control group. No differences between groups were noted for other indicators of immunocompetence, i.e., in vitro LPR to mitogens and numbers of circulating leukocytes or total lymphocytes. Side effects, including transient nausea and mild diarrhea, were noted in 5 of 15 zinc supplemented subjects (Ref. 29).

Another report associating zinc supplementation and improved immunocompetence in the elderly, as measured by DCH response, was reported in 1983 by Wagner et al. (Ref. 30). Five low income elderly (age 64 to 76 years) individuals in Alachua County, FL, who showed no DCH responses on two occasions before zinc supplementation, were supplemented with 55 mg zinc per day orally. Following one month of supplementation, all five subjects developed a positive DCH response to at least one of five test antigens. Serum zinc concentration increased in the four subjects for whom both initial and final serum samples were obtained. A control group was not included in this study, and only a single indicator of immunocompetence was measured (Ref. 30).

A study of six elderly nursing home patients (ages not stated) reported improved DCH following oral zinc supplementation (Ref. 31). Dietary zinc intake of the six subjects ranged from 6.8 to 13 mg per day. Subjects received oral zinc supplements of 15 mg zinc per day, as zinc gluconate, for 28 days. Plasma zinc and DCH responses were evaluated before and after the supplementation period. Serum zinc levels increased significantly with zinc supplementation (paired t-test, $p<.05$, $n=5$). Mean serum zinc, initially 98 micrograms per deciliter (μg per dL), increased to 102 μg per dL following zinc supplementation. Five of the subjects were tested for DCH responses to four test antigens. The number of positive responses increased significantly from a mean of 1.8 positive reactions per subject before zinc supplementation to 2.8 positive reactions per subject after zinc supplementation (paired t-test, $p<.05$, $n=5$). Nonsupplemented control subjects were not included. Of the six test subjects, one subject received liquid nutritional supplementation for weight gain, and one subject did not participate in DCH testing (Ref. 31).

In a study of immune function in zinc-deficient elderly subjects, Cossack (Ref. 32) selected eight zinc-deficient subjects from among 50 relatively healthy, low-socioeconomic status men age 65 to 78 years. Zinc deficiency was determined on the basis of "low status of zinc," subnormal DCH reactions, and low red blood cell (RBC) activity of a zinc-dependent enzyme (nucleoside phosphorylase) relative to normal values for healthy men of the same age. The zinc-deficient subjects received 60 mg zinc per day for 4.5 months, after which zinc concentration of plasma, RBC's, and white blood cells increased to normal values. The number of positive DCH responses to 4 test antigens increased from a mean of 2.1 positive responses per subject before supplementation to 3.1 positive responses per subject after supplementation. Zinc status and DCH reactions in the zinc-deficient subjects after zinc supplementation were comparable to the normal values determined for 13 healthy men of the same age (Ref. 32).

FDA believes that little weight can be given to these studies. The numbers of subjects in these four studies were quite small (eight or fewer subjects in three studies), providing little confidence in the results. Initial nutritional status of the institutionalized subjects, and reason for institutionalization, were not reported by Duchateau et al. (Ref. 29). Two of these studies (Refs. 30 and 32) were uncontrolled case reports on the effects of zinc supplementation of initially anergic or low zinc status elderly individuals selected from elderly populations surveyed for nutritional status and immunological indices. Similarly, the study of Soltesz et al. (Ref. 31) was uncontrolled and not blinded. Many potentially confounding factors in these studies were not considered or were not reported. Such factors include lack of dietary assessment, use of institutionalized elderly, and lack of monitoring for compliance with supplementation. Most importantly, the health significance, if any, of the findings of these studies with respect to enhanced resistance to disease is unknown.

Bracker et al. (Ref. 33) reported no effect of zinc supplementation on the antibody response to influenza vaccination. In this study, 41 healthy persons, age 64 to 90 years, were randomly assigned to supplemented (n=23; 50 mg oral zinc per day) or placebo (n=18) groups in a double-blind

2 month study. Subjects with diabetes, cancer, chronic renal disease, malabsorption, or senile dementia were excluded from the trial. Initial serum zinc was 80 ± 10 μg per dL, increasing to 116 μg per dL (mean value) in the supplemented group and 84 μg per dL (mean value) in the placebo group. Following the first month of supplementation, initial influenza antibody titres were measured, and trivalent influenza vaccine was administered. Influenza antibody titres were measured again following the second month of supplementation. No influence of zinc supplementation on post-vaccination increase of antibody titre was observed (Ref. 33).

Two recent well-controlled clinical studies by Bogden et al. (Refs. 34 and 35) failed to support the hypothesis that zinc supplementation can improve immunocompetence in the elderly. The first of these (Ref. 34) reports the findings of a double-blind, 3 month oral supplementation study of 103 apparently healthy, free-living persons, aged 60 to 89 years recruited from senior citizen centers in Bergen County, NJ. Subjects with a history of cancer, recent infectious disease, those on corticosteroid or estrogen therapy, or those using zinc supplements were excluded from the study. The subjects were randomly assigned to 3 groups: placebo (n=36), 15 mg zinc per day (n=36), and 100 mg zinc per day (n=31). All subjects received a daily multiple vitamin-mineral supplement without zinc in addition to oral zinc (or placebo) supplements. Compliance to supplementation was determined by a pill count at 3 months. A dietary questionnaire consisting of a food frequency checklist and a 24 hour dietary recall of the prior day's meals was also administered. The subjects consumed self-selected diets, providing an estimated average intake of 8 to 9 mg zinc per day. Plasma zinc increased from initial levels (84 to 86 μg per dL) in the group supplemented with 100 mg zinc per day but not in the placebo or 15 mg zinc per day groups. There were no changes from mean baseline zinc levels in RBC's, mononuclear cells, polymorphonuclear (PMN) cells, or platelets at 3 months in any group. There was a tendency for increased DCH responses after 3 months in all groups, and the increase was not different among groups.

Thirty study subjects, spread among the study groups, were initially anergic for DCH responses. The proportion of initially anergic subjects who developed positive DCH responses at 3 months was not different between placebo and zinc groups. In addition, there was no effect of zinc supplementation on in vitro LPR. In this study neither the cellular immunity nor zinc status, as indicated by cellular zinc content, of healthy elderly individuals with usual dietary zinc intakes of approximately 66 percent of the RDA, was enhanced by zinc supplementation (Ref. 34).

The second study (Ref. 35) followed the same double-blinded three group study design, with supplements provided for 12 months, after which all groups were switched to the placebo for an additional 4 months. Of 158 individuals initially enrolled, 63 subjects completed the entire 16-month study period, giving a response rate of 40 percent. The placebo group consisted of 24 persons. Twenty persons were included in the 15 mg zinc per day-supplemented group, and 19 persons were included in the 100 mg zinc per day-supplemented group. Dietary zinc intake (mean of 8.6 mg per day for males and 7.8 mg per day for females) from self-selected diets was similar among the three treatment groups and consistent over the course of the trial. Plasma zinc (initially about 85 μg per dL) increased only in the group taking 100 mg zinc per day and returned to baseline after zinc supplementation was discontinued. Monocyte, polymorphonuclear, erythrocyte, and platelet zinc levels were not altered, except for a transient increase of polymorphonuclear zinc in the 15 mg zinc per day group which returned to baseline at 12 months. DCH responses in all groups increased continuously over the study to about twice the initial values. The increase in DCH response was significantly greater in the placebo group than in either zinc-supplemented group. Furthermore, the suppression of the increased DCH response in the zinc-supplemented groups persisted 4 months after zinc supplementation was discontinued. The in vitro LPR increased during the study, particularly in the placebo group. There was a transient increase of T lymphocyte killer cell activity in the 100 mg zinc per day group, which did not persist beyond 3 months.

The authors speculate that the progressive increase of DCH response may be the result of a booster effect of repeated skin tests or a response to the multiple vitamin/mineral supplement administered to all subjects or to other unknown factors (Ref. 35). Except for a transient increase of natural killer cell function, this study did not show that zinc supplementation improved cellular immunity in the elderly. In fact, zinc at both doses appeared to have retarded improvement of cellular immunity. Lack of increased cellular (monocyte, polymorphonucleocyte, erythrocyte, and platelet) zinc levels with zinc supplementation suggests that the population was not zinc deficient, even though average dietary zinc intake was apparently well below the RDA (Ref. 35).

2. Other Relevant Information

a. *Physiological changes in aging.* Physiological changes of aging have effects on normal zinc metabolism and homeostasis, particularly the efficiency of intestinal absorption of zinc (Ref. 36). Average zinc absorption in six men aged 65 to 74 years and in six men aged 22 to 33 years was 17 percent and 31 percent, respectively (Ref. 36). This difference in zinc absorption between elderly and young men was significant. However, endogenous zinc losses in the elderly men were proportionally less than those in the younger men. There was no difference between young and elderly men in zinc balance. Lower zinc absorption in elderly men may reflect a lower requirement for zinc in the elderly. Homeostatic mechanisms also strongly influence zinc absorption. With decreasing zinc intake, the efficiency of intestinal zinc absorption increases, and excretion of endogenous zinc decreases. Thus the body is capable of adapting to variations in dietary zinc intake through increasing absorption and reducing endogenous loss (Ref. 36).

b. *Zinc status in the elderly.* The adult RDA (Ref. 25) for zinc is 15 mg per day for men and 12 mg per day for women. Differences in values for men and women reflect sex-related differences in body weight. The RDA is not a requirement below which deficiency diseases are apt to develop. Rather, for many nutrients, they are set at sufficiently high levels to cover the needs of practically all healthy individuals. Because individuals differ in their requirements for specific nutrients, it is impossible to know from a dietary survey which person requires at least the RDA and which one requires less or, in rare cases, possibly more. The intent of the RDA is to provide the basis for recommendations for healthy diets and for planning for the national food supply to improve the nutritional status of the population. It is not an appropriate use of the RDA to assert that adherence to the RDA will ensure protection against disease, or that intakes less than the RDA are necessarily inadequate or deficient (Ref. 25).

Dietary intake data are available from large national surveys such as the NFCS

conducted by the USDA and the NHANES II conducted by the National Center for Health Statistics (NCHS) (Ref. 37). NHANES III, which is currently in progress (1988 to 1994), will be the first NHANES to include sampling of the population older than 74 years of age. Other current data on nutritional status of older Americans comes from cross-sectional studies on relatively small selected samples.

Using the 1977 to 1978 NFCS and 1976 to 1980 NHANES II food consumption data bases, FDA's Total Diet Study designed diets to be representative of food intakes of men and women aged 60 to 65 years. Chemical analysis of the zinc content of these representative diets provided estimated average zinc intakes of 73 percent and 86 percent of the RDA for women and men, respectively, aged 60 to 65 years (Ref. 38). In smaller studies, dietary zinc intakes of institutionalized or house bound elderly people tended to be lower than those of free-living elderly persons (Refs. 16 and 17).

A recent review of studies of zinc intake by elderly individuals (Ref. 14) showed consistent average intake of 7 to 11 mg zinc per day. Two prospective zinc intervention studies of elderly subjects (Refs. 35 and 39) reported average dietary zinc intake of 8 to 9 mg per day which is consistent with other reports (Refs. 14 and 38).

It seems likely, from such studies, that some of the elderly in the United States consume less than the RDA for zinc. However, this finding does not necessarily imply that these elderly persons are consuming inadequate amounts of zinc. There is increasing evidence that these types of food intake estimates may underestimate food and nutrient intakes by significant amounts (Ref. 40). A more complete evaluation of problems of sensitivity and specificity of nutrient intake based on dietary recall data and the difficulty in predicting nutritional status from dietary data alone were described in a National Academy of Science report (Ref. 41).

Dietary data frequently estimate nutrients from foods alone. Contributions of dietary supplements are rarely considered but can provide significant quantities of zinc to total daily intake. The 1986 National Health Interview Survey showed that 38 percent of elderly Americans consumed over-the-counter vitamin and mineral products at least once during a 2-week period, with a median zinc intake of 100 percent of the RDA (Ref. 42). Another survey of elderly persons in the Boston area, found regular multivitamin-mineral use in 31 percent of males and 43 percent of females which supplied an average of 10 mg of zinc per day (males) and 9 mg zinc per day (females) (Ref. 43).

The best measures for determining nutritional status of human subjects are clinical and biochemical measures. Data on the nutritional status of the U.S. population have been collected in the NHANES. Results from NHANES II (1976 to 1980) were used to evaluate the prevalence of low serum zinc levels (defined as serum zinc less than 70 μg per dL for morning fasting blood samples) in the U.S. population (Ref. 44). The prevalence of low serum zinc levels was 3 percent in both males and females among the elderly (age 65 to 74 years). The prevalence across all ages was 1.3 percent for males, and an overall adjusted prevalence (excluding oral contraceptive users, pregnant, recently pregnant, and lactating women) of 2.1 percent was observed for females. Serum zinc reached peak levels in young adulthood (93 μg per dL in males; 85 μg per dL in females) and declined with age. Mean serum zinc levels for the elderly age group (65 to 74 years) were well within normal range (86 and 84 μg per dL for males and females, respectively). Poverty status was not associated with serum zinc levels in the elderly age group. Overall, blacks tended to have lower serum zinc values than did whites; however, there was no racial difference in serum zinc levels within the elderly age group (Ref. 44). Two prospective zinc intervention studies of elderly subjects (Refs. 35 and 39) also found mean serum zinc levels (about 86 μg per dL) to be within the normal range and consistent with NHANES data (Ref. 44).

An expert panel was convened to evaluate the usefulness of the serum zinc values from the NHANES II in determining the zinc nutritional status of the U.S. population (Ref. 44). This panel concluded that serum zinc values by themselves are not definitive for the assessment of zinc nutritional status because many factors besides zinc deficiency can depress serum zinc levels, e.g., stress/inflammatory response, albumin levels, diurnal variations, and meal consumption/fasting effects. In these cases, increasing zinc intake would not likely be effective in improving zinc status.

A recent report of the ad hoc Expert Panel on National Nutrition Monitoring, which reviewed data available through the National Nutrition Monitoring System of the USDA and DHHS, concluded that zinc is not a current public health issue to be assigned high priority, but that it does constitute a potential public health issue for which further study is needed (Ref. 45). The report also noted the discrepancy between apparently high percentages of people with moderate to low dietary intake and very small percentages of persons with low serum values. The Expert Panel on National Nutrition Monitoring recommendation for further research was made in recognition of the fact that the significance of the observed low dietary intakes of zinc cannot be evaluated without additional research to determine zinc requirements and to develop better measures of zinc status.

Zinc nutritional status is difficult to assess because of the lack of reliable noninvasive and specific methods and of the confounding of available measures of zinc status by factors unrelated to zinc insufficiencies. Thus the prevalence of poor zinc nutrition in the U.S. elderly is unknown. While zinc levels of blood cellular components has been proposed as a criterion for diagnosing mild zinc deficiency (Ref. 46), values for the general healthy elderly population in the United States are not currently available (Ref. 47). The high percentage (97 percent) of serum zinc values in the normal range for 65 to 74 year age group in the NHANES II do not provide compelling evidence of inadequate zinc nutriture in this population.

c. *Safety considerations.* The National Academy of Sciences in "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 24) and "Recommended Dietary Allowances" (Ref. 25) discussed potential health risks associated with oral zinc supplements. Considering the potential risks, these reports recommended against chronic ingestion of zinc supplements exceeding 15 mg per day (Refs. 24 and 25). Oral zinc supplementation at higher levels (e.g., 100 mg of zinc per day) is reported to suppress immune function (Ref. 48). Oral supplementation of 300 mg zinc per day was administered to 11 healthy males for 6 weeks. Subjects consumed self-selected diets providing an average of 11 mg per day. At 4 and 6 weeks several measures of immunocompetence were decreased (e.g., LPR and polymorphonuclear chemotaxis and phagocytosis). Other measures of immunocompetence (e.g., total number of lymphocytes, T cells, and B cells) were not altered during zinc supplementation. Duchateau et al. (Ref. 49), reported that zinc supplementation with 150 mg day for one month had a normalizing effect on LPR, increasing the response in individuals with initial low response but inhibiting LPR in individuals with initial values above the average.

Zinc intake in the range of 100 to 300 mg per day is reported to induce copper deficiency with attendant anemia, impaired immune function, and adverse effects on the low density lipoprotein/ high density lipoprotein (LDL/HDL) cholesterol ratio (Ref. 25). There is also evidence that use of zinc supplements at lower levels (15 to 100 mg per day) may have adverse effects on copper balance and HDL-cholesterol which are similar to the problems of higher zinc doses (Refs. 9 and 50). Supplemental zinc ingestion, even at levels close to the RDA, appears to block the effect of exercise on raising serum HDL-cholesterol in elderly individuals (Ref. 51). The effect of zinc intake on lowering HDL-cholesterol has been confirmed in other reports (Refs. 48 and 52).

3. Conclusions

There are publicly available data for seven human studies in which elderly subjects were supplemented with zinc to determine the influence on immune system function. The earliest published study (Ref. 29) suggested a zinc-associated enhancement of several measures of immune function. Three additional studies in which a measure of cell-mediated immunity showed improvement with zinc supplementation selected initially anergic or zinc deficient subjects (Refs. 30 through 32). The results of the later studies are not relevant because they involved very few individuals, and the tested subjects were not representative of the general elderly population. The results discussed in these initial reports have not been substantiated by more recent, larger studies of more rigorous experimental design (Refs. 34 and 35). The later, larger studies showed no improvement of immunocompetence from zinc supplementation in the elderly. Furthermore, zinc supplementation at levels in excess of 100 mg per day can result in suppression of immune system function (Ref. 48). Thus, the publicly available data on the role of zinc in immune system function do not provide a sufficient scientific basis from which to conclude that immune function in the general elderly U.S. population can be improved by zinc supplementation.

Several comments requested that the agency also consider whether claims relating intakes of zinc by other age groups to improved immune function would meet the standard set forth in the 1990 amendments. Because of time and resource constraints, the agency did not broaden the scope of its considerations to include other age groups or nutrients. The 1990 amendments clearly identified zinc and immune function in the elderly as one of 10 specific topic areas for which the agency was to determine the validity of health claims.

In summary, proper dietary zinc levels are essential for adequate functioning of the immune system. Dietary zinc intake, serum zinc, and cell-mediated immunity all decline with advancing age. However, the available data do not provide a basis on which to conclude that increased zinc intake can reverse the age-related decline in immunocompetence in the general healthy elderly population in the United States. In fact, it may suppress immune function.

III. Tentative Decision to Deny a Health Claim Relating Zinc and Immune Function in the Elderly

The agency reviewed the publicly available scientific data and recent consensus documents on the association between the ingestion of zinc-containing supplements and immune system function in the elderly. The agency finds that the evidence provides no basis upon which to permit a health claim.

In 1988, the Surgeon General's report (Ref. 22) concluded that the available evidence was insufficient to determine if any age-related losses in immune function were caused by nutritional deficiencies. The human evidence that has become publicly available since the publication of that document does not provide adequate data to support a health claim relating the ingestion of zinc to improved immune system function in the elderly. Furthermore, the National Academy of Sciences publications, "Diet and Health" (Ref. 24) and "Recommended Dietary Allowances" (Ref. 25), raised safety concerns associated with oral zinc supplements. Finally, claims that zinc would prevent or treat any disease or health condition in the elderly would be a drug claim (FDA Health Fraud Bulletin No. 11, August 17, 1987).

The standard that FDA is proposing, in a companion document published elsewhere in this issue of the **Federal Register**, to apply to all foods is that there be significant scientific agreement that any health claim is supported by the publicly available evidence. For the topic of zinc and immune function in the elderly, the weight of the evidence is insufficient to support the claim, and there is no basis for scientific agreement that this claim is supported by the available evidence. Thus, the agency is proposing to add § 101.71(e) to deny the use on food, including dietary supplements, of health claims relating to an association between zinc supplementation and immune function in the elderly.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

VI. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. Section 101.71 is amended by adding new paragraph (e) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(e) Zinc and immune function in the elderly (insert cite and date of publication in the **Federal Register** of the final rule).

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27163 Filed 11-26-91; 8:45 am]

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21 CFR Part 101

[Docket No. 91N-0103]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements: Omega-3 Fatty Acids and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing not to authorize the use on foods, including dietary supplements, of health claims relating to the association between omega-3 fatty acids and coronary heart disease (CHD). FDA has reviewed the scientific data on this topic and has tentatively concluded this evidence does not provide a basis upon which to authorize such a health claim. Examination of the epidemiological research on this topic revealed that the available studies applied only to the consumption of fish, which contain omega-3 fatty acids, and that it was not possible to ascribe any effects specifically to the omega-3 fatty acids. Examination of data from clinical studies revealed that the effects on blood lipids of fish oils containing omega-3 fatty acids were primarily a reduction of blood triglycerides, a blood lipid variable not considered to be an independent risk factor for CHD, but they had no effect on serum cholesterol, low-density lipoprotein (LDL) cholesterol, or high-density lipoprotein (HDL) cholesterol, the blood lipid variables most closely associated with risk of CHD. The scientific data are ambiguous on the effects of omega-3 fatty acids on blood pressure and other risk factors for CHD. Finally, the scientific data reveal unresolved safety issues: the potential for omega-3 fatty acids to increase LDL cholesterol of hyperlipidemics and to worsen control of blood glucose in diabetics.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John C. Wallingford, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-0835.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments), which amends the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorize the Secretary of Health and Human Services (the Secretary), and by delegation, FDA, to issue regulations authorizing nutrient content and health claims on the label or labeling of foods. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under section 403(r) (i) (B) of the act (21 U.S.C. 343(r) (1) (B)).

Published elsewhere in this issue of the **Federal Register** is a proposed rule to establish general requirements for health claims that characterize the relationship of nutrients, including vitamins and minerals, herbs, and other nutritional substances (referred to generally as "substances") to a disease or health-related condition on food labels and in labeling. In this companion document, FDA has tentatively concluded that such claims would only be justified for substances in dietary supplements as well as in conventional foods if it determines, based on its review of the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The 1990 amendments also require (section 3(b)(1)(A)(ii), (b)(1)(A)(iv), and (b)(1)(a)(x)) that within 12 months of enactment, the Secretary shall issue

proposed regulations to implement section 403(r) of the act (21 U.S.C. 343(r)), and that such regulations shall determine, among other things, whether claims respecting 10 topic areas, including omega-3 fatty acids and heart disease, meet the requirements of the act. The 1990 amendments defined the subject topic area as the relationship between omega-3 fatty acids and heart disease, without defining heart disease. For the purpose of this document, heart disease is considered to be CHD, defined in the International Classification of Diseases as ischemic heart disease and related diseases, most notably heart attacks (Ref. 33). In this document, the agency will consider whether a claim on food or food products, including conventional foods and dietary supplements, about the relationship between omega-3 fatty acids and CHD, would be justified under the standard and criteria proposed in the companion document entitled "Food Labeling: General Requirements for Health Claims for Food."

B. Public Health Aspects

1. Coronary Heart Disease

Cardiovascular disease (disease of the heart or blood vessels) is a major public health problem in the United States. Cardiovascular diseases, primarily CHD and stroke, kill nearly as many Americans as all other diseases combined. Cardiovascular disease is also among the leading causes of disability. These facts hold despite the fact that over the past 15 years, the death rate for cardiovascular disease has declined dramatically: 35 percent for all cardiovascular diseases, 40 percent for CHD, and more than 50 percent for stroke (Ref. 36). Changes in lifestyles, risk factor reduction, and medical intervention were major contributors to this decline (Ref. 36).

CHD (disease of the arteries supplying blood to the heart muscle) is generally considered to be the most common, the most serious, and the earliest form of cardiovascular disease, frequently producing symptoms and health problems in middle-aged adults (Ref. 115). Despite a declining death rate from CHD since the mid 1960's, CHD still accounts for more deaths than any other disease or group of diseases (Ref. 34). More than 1.25 million heart attacks occur each year (two-thirds occur in men), and more than 500,000 people die as a result (Ref. 34). Significant degrees of CHD without easily detectable symptoms are also very common in the United States (Refs. 36 and 37). Thus the total affected population is considerably higher than the statistics on death and illness would indicate. In addition to its impact on the nation's health, CHD costs the U.S. economy over $50 billion annually (Ref. 37).

Because of the importance of cardiovascular disease, including CHD, as a public health problem, identification of modifiable risk factors has received considerable research and public health policy attention since the early part of this century. Fatty streaks and cholesterol were identified many years ago as prominent components of the blood vessel (arterial) lesions whose buildup caused a narrowing or blockage of the blood flow to the heart (Ref. 36). Following those early observations, a large base of scientific evidence has accumulated on the relationship of different types of dietary fats to the risk of CHD. Based on the weight of the scientific evidence now available, virtually all recent dietary guidelines for Americans, whether from the Federal government or from the health profession community, have noted the high dietary fat intake by the U.S. population and also the strong association of diets high in fat, particularly saturated fat, and cholesterol with increased risk of CHD (Refs. 34, 36, and 115).

An elevated blood cholesterol level has been implicated as a factor in the development of atherosclerosis (inadequate circulation of blood to the heart due to narrowing of the arteries), a major contributor to CHD. In atherosclerosis, a buildup of solid material in and on the walls of blood vessels occurs that restricts the flow of blood. This material, referred to as "plaque," usually contains an appreciable amount of cholesterol.

For many individuals, there appears to be a correlation between the severity of the plaque deposits and the levels of cholesterol in the blood. Furthermore, it is now established that a particular fraction of blood cholesterol, that associated with LDL, conveys an increased risk of atherosclerosis, while cholesterol associated with a different lipoprotein, HDL, conveys reduced risk of atherosclerosis and CHD (see companion document on health claims for cardiovascular disease and lipids, published elsewhere in this issue of the **Federal Register**). The relationship between atherosclerosis and very low-density lipoproteins (VLDL), independent of LDL, is not clear (Refs. 35, 36, and 115).

There does not appear to be a strong relationship between atherosclerosis and blood triglycerides (another type of blood lipid, although not a fraction of blood cholesterol). Any relationship between blood triglycerides and CHD found in studies disappears once the blood cholesterol components known to be related to CHD are taken into account (Refs. 4, 35, 36, and 115). A National Heart, Blood, and Lung Institute consensus conference is planned for the beginning of 1992 to reexamine the relationship between blood triglycerides, HDL, and CHD. Many questions about the buildup of plaque remain unanswered, however, including why plaque deposits are formed and to what extent the consumption of individual dietary components influence blood cholesterol levels.

2. Omega-3 Fatty Acids

Omega-3 fatty acids are lipids (fats) consisting of polyunsaturated fatty acids with three or more double bonds. The differences between saturated fatty acids and unsaturated fatty acids are discussed in the document on nutrient content claims on fat, saturated fat, and cholesterol published elsewhere in this issue of the **Federal Register**. Their unique characteristic is the location of the first double bond, which occurs at the third carbon from the methyl (or omega) end of the fatty acid. The family of omega-3 fatty acids includes linolenic acid (18 carbons, 3 double bonds), which is found predominantly in plant oils, and eicosapentaenoic acid (EPA, 20 carbons, 5 double bonds) and docosahexaenoic acid (DHA, 22 carbons, 6 double bonds), which are found in fish and other marine animals. Linolenic acid is a precursor of the two longer chain omega-3 fatty acids. However, not all linolenic acid is converted to EPA or DHA. Omega-3 fatty acids cannot be synthesized in humans from other classes of fatty acids. Thus, they must be supplied by dietary sources.

The most common food source of longer chain omega-3 fatty acids is fatty fish, such as salmon and mackerel (Ref. 83). Another important dietary source of omega-3 fatty acids in the United States is chicken that have been fed fish meal. Bulk and encapsulated preparations enriched with omega-3 fatty acids are now available in the United States.

3. Relationship of Omega-3 Fatty Acids and CHD

Although polyunsaturated fatty acids other than omega-3 fatty acids may affect the risk of CHD, the 1990 amendments direct FDA to consider the relationship of omega-3 fatty acids to CHD (section 3 (b) (1) (A) (x) of the 1990 amendments). Most of the relevant research testing the hypothesis that omega-3 fatty acids reduce the risk of

CHD has been conducted using fish or fish oils rich in EPA and DHA because these particular fatty acids are known to have physiological effects. For this reason omega-3 fatty acids are defined as EPA and DHA in this document. Other omega-3 fatty acids related to EPA and DHA are not generally found in amounts as high as EPA and DHA, and their activity is thought to be via metabolism to EPA or DHA.

Two major mechanisms have been hypothesized for beneficial effects of omega-3 fatty acids, reduction in atherosclerosis and decreased formation of blood clots (thrombosis) either because of increased coagulation times or with concomitant increased dissolution of clots that may be formed.

Much of the data on omega-3 fatty acids has been collected in populations with risk factors for CHD, including high dietary saturated fat, hyperlipidemia (high blood cholesterol or triglycerides), high blood pressure, tobacco smoking, stress, and sedentary lifestyle.

A reduction in risk of CHD following consumption of foods that contain omega-3 fatty acids is not sufficient to support a relationship between omega-3 fatty acids and CHD, because foods that contain omega-3 fatty acids contain many other substances that may affect the risk of CHD. Furthermore, consumption of foods rich in omega-3 fatty acids may displace other foods from the diet that contain dietary components related to CHD. To establish a relationship between omega-3 fatty acids and CHD, any observed effect must be shown to be specifically from the specific omega-3 fatty acid component of the food.

C. Omega-3 Fatty Acids: Regulatory History

In the **Federal Register** of July 31, 1986 (51 FR 27461), FDA published a notice of the filing of a petition seeking affirmation that the use of menhaden oil and partially hydrogenated menhaden oil as direct human food ingredients is generally recognized as safe (GRAS). In the **Federal Register** of September 15, 1989 (54 FR 38219), FDA affirmed that hydrogenated and partially hydrogenated menhaden oil are GRAS (21 CFR 184.1472) for use as an edible fat or oil, as defined in 21 CFR 170.3(n) (12). The agency has not yet acted on the GRAS status of the use of nonhydrogenated menhaden oil.

In recent years, fish oil products bearing claims for beneficial cardiovascular effects appeared in the marketplace. In 1988, FDA issued regulatory letters concluding that claims for cholesterol-lowering properties of fish oil supplements were drug claims, and that the evidence did not support the claims (Ref. 45). In response, the industry contended that the claims on fish oil supplements were not intended to be drug claims but were intended to comply with FDA's proposed rule on health messages (52 FR 28843, August 4, 1987), subsequently withdrawn and reproposed (55 FR 5176, February 13, 1990). Although additional information was submitted in support of these health messages (hereinafter referred to as health claims), FDA informed the industry in 1990 that the additional data were not adequate to support the claims, because of the preliminary nature of the evidence and because of unresolved safety concerns (Ref. 46). In an advance notice of proposed rulemaking published in the **Federal Register** of August 8, 1989 (54 FR 32610), FDA requested comments on, among other things, how to reasonably permit the use of claims on food labels linking food components to the risk of chronic diseases. The agency did not, however, specifically mention the topic of omega-3 fatty acids and CHD.

D. Evidence Considered in This Review

The agency has reviewed all relevant scientific evidence relating to omega-3 fatty acids and CHD. The scientific evidence reviewed by the agency included recent comprehensive reviews and recommendations of the Federal government: "The Surgeon General's Report on Nutrition and Health" (Ref. 34); the National Institutes of Health's National Cholesterol Education Program (NCEP) Report on "Detection, Evaluation and Treatment of High Blood Cholesterol in Adults" (Ref. 35); and the NCEP Report "Population Strategies for Blood Cholesterol Reduction" (Ref. 36). Other comprehensive reports were also reviewed: the National Academy of Sciences 1989 Report "Diet and Health: Implications for Reducing Chronic Disease Risks" (Ref. 115); the 1986 FASEB report on "Review of the Epidemiological and Clinical Evidence on the Role of Omega-3 Fatty Acids in Health and Disease" (Ref. 83); the 1989 Mitre Report on "Health Effects of Refined Menhaden Oil" (Ref. 72); and the 1991 FASEB report on "Cardiovascular Effects from Omega-3 Fatty Acids" (Ref. 100). The agency updated the conclusions reached by these documents by reviewing all human studies published subsequent to these documents and all new review articles (Refs. 10, 21, 82, 84, 89, 91, 111, 112, 127, 161, and 162). However, surveys and cross-sectional or prospective studies, other than intervention studies, that had been published before 1988, which were used to generate the hypothesis of a relationship between omega-3 fatty acids and CHD, were also reexamined. Animal studies were considered to the extent that they clarified human studies or suggested possible mechanisms of action.

E. Comments Received in Response to FDA Request for Scientific Data and Information

To ensure that its review was complete, in the **Federal Register** of March 28, 1991 (56 FR 12932), FDA requested scientific data and information on the 10 topics, including omega-3 fatty acids and CHD, identified by section 3 (b) (1) (A) of the 1990 amendments. The agency received a total of 15 comments in response to this request. All relevant scientific information submitted was considered in the FDA scientific summary.

One comment was from a private citizen, who submitted a computer search of medical literature.

Three comments were from professional organizations, informing FDA of their position on health claims. A comment from the Association of Food and Drug Officials expressed concern that there be significant scientific agreement for any claim and enumerated steps to protect against unfounded claims. A comment from the Association of State and Territorial Public Health Nutrition Directors urged that the amount of nutrients in the total daily diet be an important consideration and expressed concern that labels might contain too much information to be helpful to the consumer. One comment from the American Health Foundation dealt with the relationship between omega-3 fatty acids and cancer. This comment is outside the scope of the rulemaking.

The Government of Canada stated that under Canadian law, proposed health claims regarding heart disease would be considered drug claims.

Ten comments (including one book) were submitted by professional or trade organizations for food/food supplement manufacturers or individual food or supplement manufacturers. One comment from a chemical manufacturer provided information regarding the requirement for vitamin E when supplemental omega-3 fatty acids are consumed. Three comments from manufacturers or distributors of dietary supplement products and one trade organization for dietary supplement products commented on approaches for regulating health claims. Five comments from trade organizations, food manufacturers, or manufacturers/

distributors of dietary supplement products described properties of omega-3 fatty acids and provided bibliographic information for scientific information of the topic. One supplement manufacturer provided a listing of proposals for research on omega-3 fatty acids and an unpublished paper on the utility of fish oils in providing dietary omega-3 fatty acids. One comment from a trade organization included a copy of proceedings of an international conference on the effects of omega-3 fatty acids on bleeding. No original data about the effects of omega-3 fatty acids on CHD were presented in any comment. The information submitted will be considered in the agency's discussion of the relevant scientific evidence.

II. Review of the Scientific Evidence

A. Federal Government Documents

"The Surgeon General's Report on Nutrition and Health" (Ref. 34) described studies that correlated increased fish intakes with reductions in risk of CHD, while noting that not all studies found a relationship. Regarding plasma lipids, the report stated that diets rich in omega-3 fatty acids:

> * * * generally showed variable reductions in total cholesterol and LDL cholesterol. In some cases, LDL increased; HDL levels were either unchanged or increased * * * The most consistent effect has been a reduction in triglyceride and VLDL.

The report acknowledged the significance of research into the relationship between omega-3 fatty acids and CHD but did not make any specific recommendations regarding the consumption of omega-3 fatty acids. Additionally, the report cautioned that the benefits in the cited studies had not been shown to be attributable to omega-3 fatty acid intake and could be from some other factor associated with fish consumption.

A similar position was taken by the NCEP of the National Institutes of Health (Ref. 35):

> * * * There is little evidence that omega-3 fatty acids are useful for reducing LDL-cholesterol levels. Although it has been postulated by some that they will reduce the risk for CHD, this has not been established. Furthermore, it is not known whether long-term ingestion of these fatty acids will lead to undesirable side effects. The use of fish-oil capsules as a supplement in a therapeutic diet for high-risk cholesterol levels is not recommended here * * *
> (Ref. 35, p. 33).

Furthermore, this NCEP document distinguished reported protective effects of fish consumption from alleged protective effects of omega-3 fatty acids from fish:

> * * * Consumption of omega-3 fatty acids should be differentiated from that of fish. Some fish are rich in omega-3 fatty acids while others are not. Epidemiological data suggest that frequent consumption of fish of any type, seemingly independent of omega-3 fatty acids, is associated with reduced CHD risk. Whether this is true or not, fish can serve as a useful substitute for meats that are richer in saturated fats, * * *
> (Ref. 35, p. 33).

The NCEP's Expert Panel on Population Strategies for Blood Cholesterol Reduction (Ref. 35) did not comment on the relationship between omega-3 fatty acids and CHD but like the two other reports above, noted that:

> * * * Supplementation of the diet with omega-3 polyunsaturates, without altering the intake of saturated fatty acids, does not cause a lowering of LDL-cholesterol, * * *
> (Ref. 35, p. 38).

"The Surgeon General's Report on Nutrition and Health" (Ref. 34) and the NCEP reports encouraged consumption of fish, but none found adequate evidence that omega-3 fatty acids could reduce the risk of CHD. Further, the NCEP Reports (Refs. 35 and 36) specifically did not recommend fish oil supplements and cited the lack of evidence of beneficial effects and long-term safety and undesirable side effects.

B. Other Reports

The National Academy of Sciences (NAS) Committee on Diet and Health noted that reports of low rates of CHD among Greenland Eskimos, which provided the basis for interest in a possible relationship between omega-3 fatty acids and CHD, were poorly documented. The NAS cited eight major reviews and numerous individual papers on the effects of omega-3 fatty acids on plasma lipids and lipoproteins and cited the indepth review of Herold and Kinsella (Ref. 67) on eicosanoid effects of EPA and DHA on hemostasis and on metabolism of omega-3 fatty acids. NAS concluded that:

> * * * Their [omega-3 fatty acids] effects on LDL cholesterol vary, and data on the long-term health effects of large doses on omega-3 polyunsaturated fatty acids are limited. Limited epidemiologic data suggest that consumption of one or two servings of fish per week is associated with a lower CHD risk, but the evidence is not sufficient to ascertain whether the association is causal or related to the omega-3 polyunsaturated fatty acid content of fish.

The NAS Committee went on to recommend that omega-3 supplements should not be used, stating:

> * * * Although consumption of fish one or more times a week has been associated with a reduced risk of coronary heart disease, the committee does not recommend the use of concentrated fish oil supplements, because there is insufficient evidence that they are beneficial and the absence of long-term adverse effects has not been established.

In 1986, FDA contracted with the Life Sciences Research Organization (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) to review the evidence for the role of omega-3 fatty acids in health and disease (Ref. 83). The report concluded that fish consumption provided:

> * * * some degree of protection against the development of cardiovascular disease. Most studies have found an inverse relationship between fish consumption and coronary heart disease mortality. The omega-3 fatty acids in fish have been presumed to be responsible for these effects, but whether other compounds in fish may be involved remains to be determined.

The LSRO report also concluded that:

> * * * Clinical trials of the use of omega-3 fatty acids to reduce serum lipid levels in patients with various genetic and induced hyperlipidemias have generally been positive,

apparently meaning triglycerides and VLDL, given the full text of the report.

The LSRO report also cautioned that:

> * * * Animal studies indicate the potential for several deleterious effects. Toxicological evaluation of products containing these fatty acids, especially fish oil concentrate and derivatives, is needed.

FDA contracted for another report by the Mitre Corporation to define health effects of refined menhaden oil, a rich source of omega-3 fatty acids. This report (Ref. 72) identified major effects of omega-3 fatty acids as alterations in production of various bioactive compounds, increased bleeding (with particular concern for various bleeding conditions such as childbirth, ulcers, hemophilia, and menstruation), reduced platelet aggregation, and attenuation of inflammatory response. It also noted that effects on blood lipids other than triglycerides were not clearly established.

A second LSRO report contracted by FDA as part of FDA's information gathering effort divided the topic into six areas: Hypertension; thrombosis; the growth of the atherosclerotic plaque; hyperlipidemia and lipoprotein disorders; diabetes mellitus; and clinical trials in coronary patients. Brief synopses of selected scientific reports were presented in each section, followed by a summary of the full report and conclusions. LSRO concluded that there may be a decrease in total cholesterol and LDL concentrations without HDL being decreased but did

not explain how these conclusions were reached (Ref. 100). It concluded that there was an effect of omega-3 fatty acids on the development of the atherosclerotic plaque but cited only animal studies as evidence. It concluded that omega-3 fatty acids affect platelet function but did not provide evidence that the altered platelet function would or would not reduce the risk of CHD in humans. It described an effect of omega-3 fatty acids on blood pressure but did not distinguish between healthy and hypertensive subjects. Finally, it concluded that there was a basis in international epidemiological findings for a relationship between fish consumption and CHD but did not demonstrate that the omega-3 fatty acids in fish were the components responsible for the association.

In summary, omega-3 fatty acids were considered separately from total fat and polyunsaturated fat by the Federal government and other comprehensive reports, because these fatty acids may produce protective effects on CHD. None of these documents except the LSRO report found the evidence for a relationship between omega-3 fatty acids and CHD to be persuasive.

C. Review of the Scientific Literature

1. Evidence Reviewed

A number of human studies have been reported since publication of the Federal government and other comprehensive reports described above. FDA conducted a thorough review of the literature published between January 1988 and August 1991 and found numerous research papers directly and indirectly related to the topic.

The criteria that the agency used to select pertinent papers for its review were: (1) Presentation of primary data and adequate descriptions of study design and methodologies sufficient to allow an evaluation of the quality and relevance of the study, (2) availability in English, (3) a quantitative estimate of the amount of omega-3 fatty acids used, and (4) quantitative data on CHD or a marker associated with CHD. In general, FDA considered randomized, double-blind, placebocontrolled trials to be more valuable than other types of human studies because they were less susceptible to bias, and because they allowed inference about specific effects of omega-3 fatty acids.

Epidemiologic evidence for an association between omega-3 fatty acids and heart disease is of two types, descriptive and analytical. Descriptive epidemiology studies include correlational studies in which grouped population data are examined. Analytical epidemiology studies examine exposure and outcome in the same individual. These include cross-sectional studies in which dietary exposure (e.g., fish consumption) is measured at a single point in time and compared to a health outcome such as CHD, prospective studies in which dietary exposure is measured at the beginning of the study and the subjects are followed over time to compare exposure and health outcome, and intervention studies.

The criteria used in evaluating epidemiological studies included the following: (1) The reliability and accuracy of the methods used in food intake analysis and measurement of disease endpoints, (2) the choice of control subjects (e.g., hospital-based versus population-based), (3) the representativeness of subjects, (4) the control of confounding factors in data analysis, (5) the potential for misclassification of individuals with regard to dietary exposure or disease endpoints, (6) the presence of recall bias and interviewer bias, and (7) the degree of compliance and how compliance was assessed.

FDA evaluated the weaknesses and strengths of individual studies (see "Assessment" column of Tables 1 and 2). It then assessed the strength of the overall combined evidence (e.g., epidemiologic studies including clinical trials and animal studies), taking into account the strength of the association, the consistency of findings, specificity of the association, evidence for a biological mechanism, and presence or absence of a dose-response relationship. FDA's conclusions reflect the strength of the data and consistency of the results.

FDA considered encapsulated fish oils concentrated in omega-3 fatty acids to be a valid test material because such use provided some basis to find that the component responsible for observed effects was the omega-3 fatty acids. The agency also gave greater weight to studies in which compliance was documented with a biological marker of treatment, e.g., plasma or tissue phospholipid content of EPA and DHA, when measurements demonstrated internal validity of the study, and when the amount of omega-3 fatty acids in the total diet was assessed than to studies that were not as carefully done. FDA considered the level of dietary intake of omega-3 fatty acids used in a study, because the agency considered it important that if this substance is to be considered to be a food, intake levels should be consistent with an amount that could be consumed in a normal diet.

While FDA considered studies using healthy populations to be the most relevant to the issue, it also considered studies in subpopulations with CHD or risk factors for CHD. FDA extrapolated positive results from at-risk populations cautiously, however. While FDA assumes that the same mechanism of CHD risk is affected by omega-3 fatty acids in both high risk and generally healthy populations, the agency believes that the high risk population may be more sensitive to showing an effect. When it did make extrapolations, FDA considered it essential that data showing the same effect in the general population were also available.

FDA evaluated the weaknesses and strengths of individual studies reviewed (Tables 1 and 2). FDA then assessed the strength of the overall combined evidence (e.g., epidemiologic studies and animal studies) in light of five factors, strength of association, consistency of findings, specificity of the association, presence or absence of a dose-response relationship, and biologic plausibility of an association.

2. Epidemiologic Evidence

a. *Correlational and cross-sectional studies.* A protective effect EPA and DHA on the development of CHD was hypothesized based on data comparing rates of heart disease among Greenland Eskimos and Danes (Ref. 39). Greenlanders residing in Greenland had approximately tenfold lower death rates from ischemic heart disease than Greenlanders who had migrated to Denmark. Dietary factors were hypothesized to explain this difference. Compared to immigrant Greenlanders living in Denmark, those living in Greenland consumed comparable amounts of total fat but ate less than half the saturated fat; over 50 percent more monounsaturated and polyunsaturated fat; and nearly five times the amount of omega-3 fatty acids. However, since whale blubber and seal (also sources of omega-3 fatty acids) were consumed by the Greenlanders much more frequently than fish, components of the Eskimo diet other than omega-3 fatty acids may be important determinants of CHD risk.

Three studies found an inverse relationship between fish consumption and CHD, from rural Japanese, urban Japanese, Japanese Americans, and Caucasian Americans (Ref. 76) and among various Japanese communities (Refs. 68 and 75).

However, other similar studies have not found a relationship between fish consumption and CHD. An international correlational study found only a modest association between fish consumption and CHD mortality across widely

different populations (Ref. 23), and when other dietary variables were controlled, the relationship was no longer apparent. CHD mortality in two provinces in Canada was not correlated to per capita fish intake in those provinces (Ref. 74), nor was a correlation found in two Norwegian communities (Ref. 141) with different fish consumption.

b. *Prospective studies.* A prospective study of 852 men found that an average consumption of 30 grams (g) of fish per day over a 20-year period reduced the risk of CHD by more than 50 percent (Ref. 87). Two reports from the United States also found a beneficial effect attributable to fish consumption (Refs. 38 and 137).

Other studies in Honolulu (Ref. 25) and Norway (Ref. 158) did not find any relationship between fish consumption and risk of CHD. Also, a study from Sweden (Ref. 113) reported an effect, but it was not statistically significant. These nonintervention epidemiologic studies are summarized in Table 1.

One type of evidence that would support a causal relationship between two factors is a dose-response relationship, where the degree of effect of an active component is related to the amount of the component. In those studies that reported a protective effect of fish consumption on CHD, each found the effect was related to the amount of fish consumed (Refs. 87 and 137). One study related the risk to the calculated amount of omega-3 fatty acids in the diet (Ref. 38). The effect of fish consumption on CHD is seen with small amounts of fish (i.e., about 30 g per day (g/day)), and therefore, small amounts of omega-3 fatty acids (Ref. 88). The results from these studies are viewed by FDA as ambiguous. Not all the studies found a relationship between consumption of fish containing omega-3 fatty acids and CHD. Only one study related the protective effect to the calculated amount of dietary omega-3 fatty acids rather than to consumption of fish (Ref. 38). Other dietary variables known to be related to CHD were also correlated with fish consumption in these studies. For example, in the prospective study of 852 men (Ref. 87), a number of other dietary variables that may indeper dently be related to the risk of CHD were also related to fish consumption. In this study, men who consumed the largest amounts of fish also consumed significantly more alcohol and monounsaturated and polyunsaturated fatty acids than men who did not eat fish. Thus, dietary factors associated with fish intake other than omega-3 fatty acids may account for the observed positive correlations.

Furthermore, the estimated content of omega-3 fatty acids in the amount of fish reported to be protective against CHD is very low, so low that their level calls into question whether the omega-3 fatty acids in fish are the component responsible for the reported protective effect. Also, the dose-response relationships reported differ somewhat. In Kromhout et al. most of the reduction in risk occurred when only 1 to 14 g/day of fish were consumed (about 0.3 g EPA plus DHA) (Ref. 87). In contrast, the study that related CHD risk to estimates of omega-3 fatty acids consumed (rather than fish) found the effect was pronounced only among those who consumed the greatest amount of omega-3 fatty acids, 0.66 g/day on average (Ref. 38).

Finally, in the studies in which 20- or 25-year mortality from CHD was related to fish consumption (Refs. 87 and 137), dietary data were collected only during the first year of the study. Thus, these studies do not distinguish between a protective effect of fish consumption at an early point in life and an effect from chronic fish consumption. The shorter duration followup Multiple Risk Factor Intervention Trial (MRFIT) study estimated dietary consumption from 24-hour recall data collected approximately yearly over the 6-year followup and supports that continued consumption of omega-3 fatty acids, rather than simply early life consumption of fish, has a protective effect (Ref. 38).

Overall, these studies are considered to be ambiguous because they are not capable of distinguishing the effects that are specific to omega-3 fatty acids from those that are related to fish consumption.

c. *Intervention studies.* Although experimental trials are considered to be the most useful to infer causal relationships, only one study of this type has been completed on omega-3 fatty acids and CHD (Ref. 16). The study was conducted among 2,033 male survivors of previous heart attacks who were advised to increase their consumption of fish and of fiber and to decrease fat intake. All combinations of these three types of advice were given. Another group, serving as a control, received no advice at all. Mortality was assessed over the following 2 years. Those subjects who were advised to increase fish consumption had a 29 percent lower death rate, attributable entirely to deaths from CHD, than subjects advised to increase fiber or decrease fat consumption but not advised to increase fish consumption. However, the rate of occurrence of a second heart attack was not different between the fish-advice and nonfish-advice groups. Fish consumption was measured by a dietary questionnaire in a subset of subjects in the fish-advice group. The amount of fish reported by Burr et al. to be protective was modest, approximately 200 to 400 g fish per week (Ref. 16).

Some (14 percent) of the men at 6 months into the trial, and more (22 percent) at the end of the 2-year trial, consumed encapsulated fish oil rather than the prescribed amount of fish (300 g per week, or about 2.5 g EPA per week). However, separate data for the fish consumers and fish oil consumers were not presented, so the effects of fish oils cannot be compared to the effects of fish consumption. No dose-response analysis was performed, and no biochemical data were reported documenting the ingestion and incorporation of omega-3 fatty acids. Data were not reported on the effects of advice about fish consumption on markers of CHD, i.e., serum cholesterol (although it was noted that the fish-advice group had increased total serum cholesterol at 6 months and unchanged total cholesterol after 2 years), making it difficult to put the results of this study into context of other studies reporting similar data.

3. Evidence Relating Omega-3 Fatty Acids to Intermediate or Surrogate Markers of CHD

Most information about the effects of omega-3 fatty acids on CHD has been derived from clinical trials using concentrated fish oils enriched in EPA and DHA and, in some cases, in purified methyl or ethyl esters of EPA and DHA. These studies have not measured occurrence of heart attack or CHD death as an endpoint but instead used surrogate markers for CHD, e.g., serum lipids, blood pressure, measures of clotting, and clot dissolution. While these markers are limited in their ability to predict CHD, they are easily measured and provide important information about intermediates in the disease processes. The amount of omega-3 fatty acid intake in studies using fish oils is usually greater than the amount of omega-3 fatty acids in fish diets associated with reduced risk of CHD.

The clinical effects of omega-3 fatty acids from fish oils are generally evaluated relative to two categories: Effects on atherosclerosis and on blood lipids closely correlated with atherosclerosis, and effects on thrombosis (aggregation of blood platelets and fibrin leading to blood clot formation) and hemostasis (the arrest of bleeding). However, there are other potential effects of omega-3 fatty acids

that could affect risk of CHD that also require evaluation, e.g., whether omega-3 fatty acids reduce blood pressure. Table 2 is a summary of data from clinical trials published since 1987.

a. *Atherosclerosis*—i. *Blood lipids.* The effects of fish oils and high fish diets on blood lipids have been studied because such effects, if demonstrated, would represent a mechanism by which omega-3 fatty acids could reduce risk of CHD. Although some studies of high fish diets reported reductions of serum cholesterol and LDL and VLDL cholesterol, these studies also involved substantial changes in other components of the diet, primarily the replacement of saturated fat with unsaturated fat (Refs. 17, 62, and 117). Thus, the effects could not be definitively attributed to omega-3 fatty acids. Most recent studies have used fish oil supplements containing omega-3 fatty acids rather than fish and have used a placebo containing alternate polyunsaturated fatty acids in an attempt to avoid confounding effects of other diet components.

The predominant blood lipid effects of fish oils in normal subjects, in subpopulations with diseases or medical conditions associated with increased risk of CHD, and in subjects with diagnosed CHD are decreased plasma triglycerides and VLDL which is rich in triglyceride and cholesterol. However, these blood lipids are not generally considered independent risk factors for CHD (Refs. 35, 36, and 115). The effects on total cholesterol, LDL cholesterol, and HDL cholesterol have been variable.

Most studies of normal, healthy adults show no significant effect that can be specifically attributed to fish oil on serum total cholesterol, LDL, or HDL cholesterol (Refs. 9, 14, 15, 17, 20, 24, 31, 43, 48, 49, 53, 54, 59, 73, 98, 99, 104, 109, 146, 150, 156, and 166). Only four of these studies were carried out in a randomized, double-blinded, placebo-controlled design (Refs. 6, 24, 54, 73, and 166), although other studies either randomized the subjects (Refs. 9, 14, 49, and 54) or matched test subjects and controls (Refs. 15, 20, 31, and 156). Some used a crossover design (Refs. 14 and 17). Some studies reported no effects of fish oils or used relatively small numbers of subjects, and may not have had sufficient statistical power to detect a difference (Refs. 15, 24, 31, 48, 59, 99, 104, and 146). Two studies used fish as the source of omega-3 fatty acids (Refs. 17 and 156) which does not provide a basis on which to separate the effects of omega-3 fatty acids from the effects of other components of fish or on which to separate the effects of polyunsaturated fatty acids from the effects of omega-3 fatty acids. The studies ranged in duration from only 3 weeks of treatment to 12 weeks.

The studies with the most rigorous design and largest number of subjects found that supplementation with fish oils, or increasing dietary fish consumption, resulted in decreased blood triglycerides among normal, healthy subjects (Refs. 9, 49, 54, and 156). The only studies among normal subjects where no decrease in triglycerides was found either used very small doses in a small numbers of subjects (Croset et al. 1990 used 100 mg EPA/d in 8 subjects; Lox 1990b used 900 mg EPA plus DHA/d in 9 subjects), or the decrease was marked but not statistically significant (Refs. 99 and 73).

The studies with the most rigorous design and largest number of subjects also found that there was no effect of fish oils on total serum cholesterol (Refs. 6, 9, 14, 49, 54, 73, and 166). The only study reporting decreased total cholesterol fed 30 to 40 percent of calories from fish oil, confounding effects of omega-3 fatty acids and polyunsaturated fatty acids (Ref. 59).

These same studies found no change in LDL cholesterol, except that Fumeron et al. (1991) reported increased LDL cholesterol. Similarly, most studies did not find a significant effect on total HDL cholesterol (Refs. 6, 9, 14, 31, 54, 73, and 166). Flaten et al. (1990) and Takimoto et al. (1989) reported a decrease in total HDL cholesterol at 6 weeks of supplementation, but these studies used relatively high doses (7.7 g EPA plus DHA/d and 8.2 g EPA plus DHA/d, respectively). Neither study controlled for polyunsaturated fatty acids. Compared to saturated fat diets, fish diets may reduce HDL cholesterol (Ref. 17), although an increase in HDL cholesterol was reported after fish paste, compared to meat paste supplements, were added to the diet (Ref. 17). Some investigators (Refs. 9 and 54) have reported that supplementation with fish oils increased HDL_2 cholesterol, the particular subfraction of HDL that is most closely related to decreased CHD risk (Ref. 3), whereas others found no change (Refs. 14 and 49).

Data have also been reported on the apoproteins associated with LDL (apoB) and with HDL (apoA), in contrast to the cholesterol associated with these lipoproteins. No effect of fish oils has been found (Refs. 6, 54, and 73). Although there are fewer data reported, it appears that apoprotein components of lipoproteins respond in the same manner as the cholesterol component, i.e., lower after feeding polyunsaturates, including fish oils, than after a saturated fat diet (Refs. 43 and 53).

Thus, except for a study in which very large amounts of fish oils were fed, recent studies have not found fish oils to modify total serum cholesterol, LDL cholesterol, HDL cholesterol, or the apoproteins associated with these lipoproteins in normal subjects. The possibility of a selective increase by fish oils containing omega-3 fatty acids of HDL_2 (a fraction of HDL) cholesterol, which is inversely related to CHD, is the most promising change in blood lipids yet reported, but the data reported to date are equivocal.

There have been many studies recently on the effects of fish oils on serum lipoproteins among hyperlipidemic subjects (people with elevated blood cholesterol with or without elevated triglycerides), hypertriglyceridemic subjects (people with high blood triglycerides), and subjects who already have CHD. Most of these studies had strict designs, including randomization with or without crossover, blinding, and placebo treatments (Refs. 26, 29, 43, 61, 63, 80, 105, 114, 119, 121, 129, 140, 150, 164, and 166), but similar results were found in less rigorously controlled studies (Refs. 28, 60, 107, 130, 146, and 148). As in normal, healthy persons, the most reproducible effect of fish oils containing omega-3 fatty acids in these subpopulations is a decrease in serum triglycerides with the most marked reductions for those subjects with highest starting values. In addition, in common with the results in normal subjects, most studies in hyperlipidemics found no change in total serum cholesterol. In contrast to normal subjects, however, most studies on hyperlipidemic subjects reported an increase in LDL cholesterol following fish oil supplementation (Refs. 26 (for males), 60, 61, 63, 80, 94, 114, 119, 121, 130, 140, 146, 164, and 166), although a few found no change compared to olive oil (Refs. 29, 105, and 107) or may not have had sufficient statistical power to detect a difference (Ref. 43). One reported a decrease (Ref. 148). The level of apoB has also usually been found higher after fish oil consumption (Refs. 29, 43, 60, 61, 133, and 140). HDL cholesterol is usually reported as not changed (Ref. 114), but some increases and decreases have been reported (Refs. 26 (males), 29, 63, and 130). Takimoto et al. (1989) and Radack et al. (1990) reported lower HDL_2 cholesterol.

ii. *Vessel wall effects.* Another way that omega-3 fatty acids could affect the process of atherosclerosis is through

changing the way cells of blood vessels respond to factors that promote atherosclerosis. The cells of blood vessels produce compounds from omega-3 fatty acids that have many functions related to the health of the blood vessel (Refs. 41, 48, 160, also see animal studies in Refs. 50, and 138). Some of these functions are keeping the muscle cells of the blood vessel wall relaxed, keeping the vessel elastic and pliant, and dissolving small blood clots attached to blood vessels. An increase in consumption of omega-3 fatty acids results in increased production of the compounds that relax or dilate the vessel wall at the same time that they decrease the formation of compounds that constrict the vessel wall (Ref. 28).

Through the compounds they form in the blood vessel wall, omega-3 fatty acids may prevent the infiltration of certain white blood cells, called monocytes, into the vessel wall, and monocytes themselves produce compounds that increase the inflammatory process (Refs. 82 and 162). Recent studies reported that white blood cells taken from normal men and hyperlipidemic men who consumed fish oil containing EPA plus DHA at levels as low as 1.3 g/day for 6 weeks have a reduced chemotactic response, i.e., they are not as strongly attracted to stimulants (Refs. 135 and 136).

An area studied recently is the effect of fish oils on restenosis, that is, the reclosing of a vessel after mechanical opening. Although the use of omega-3 fatty acids in this context is clearly a drug usage, these studies have been cited as evidence of the role of omega-3 fatty acids in the maintenance and normalization of vessel function. One study found reduced rates of restenosis when fish oil was given in addition to two other anticoagulant drugs beginning about the time the subjects underwent angioplasty (the term for the procedure used to open the vessel) (Ref. 30). However, this study was not blinded, and the results are limited to fish oil used in combination with other drugs. Other studies where double-blind conditions were maintained, where placebo controls were used, and where restenosis was confirmed by angiography, show no effect of fish oils (Refs. 56, 106, and 120).

In summary, the recent data on blood lipid responses of persons and among groups at high risk of CHD do not support the use of omega-3 fatty acids to reduce the risk of CHD. There is no effect of omega-3 fatty acids on blood cholesterol, LDL cholesterol, or apoB or apoA, and the effect on HDL cholesterol is ambiguous. There is very little data on the effects of omega-3 fatty acids on blood vessel integrity in humans, and it has not been established whether the type and magnitude of effects of compounds produced from omega-3 fatty acids results in a reduced risk for CHD.

b. *Thrombosis and hemostasis.* The other primary area in which omega-3 fatty acids may affect the risk of CHD is through their hypothesized effect on the formation and dissolution of blood clots (thrombosis and hemostasis). A decrease in clot formation, or an increase in the breakdown of clots, is generally believed to help prevent CHD deaths.

i. *Bleeding times.* One effect of omega-3 fatty acids is an increase in the time it takes for a small cut to stop bleeding. Bleeding times are often used as an indicator of the balance between necessary clotting (to prevent excessive bleeding) and excessive clotting (which may occlude blood flow). Increased bleeding times were observed among Greenland Eskimos by Dyerberg and Bang (Ref. 39) and were interpreted to be one of the reasons these people had reduced CHD risk. Many studies since have reported that fish oil supplementation increases bleeding times in normal subjects (Refs. 98 and 166) and in subjects either with risk factors for CHD or with diagnosed CHD (Refs. 28, 59, 95, 144, 145, and 166). However, some of these studies used quite high doses. Harris et al. used 28 g EPA plus DHA/d (Ref. 59). Levinson et al. used 50 milliliter (mL) maximum EPA or 18 g EPA plus DHA/d or used anticoagulants concurrently (Ref. 144). Others reported no effect (Ref. 57).

The bleeding time increase with fish oils is additive with increased bleeding following aspirin (Ref. 64). However, most reports suggest that serious bleeding is not an issue in patients supplemented with omega-3 fatty acids from fish oils even when fish oils were used in conjunction with aspirin (Refs. 22, 28, 56, 106, and 144). One recent review concluded that bleeding times are not correlated with serious bleeding (Ref. 125).

ii. *Platelet aggregation.* Another measure of clotting affected by omega-3 fatty acids is the aggregation of platelets, blood components that initiate clotting. This is an important area of study because spontaneous platelet aggregation has been reported to be inversely related to occurrence of heart attacks and CHD deaths in a population of survivors of a heart attack (Ref. 152). Platelet aggregation is generally considered to be decreased by fish oil consumption (Refs. 67, 70, 86, 159, and 162 for reviews; also in normal subjects see Refs. 2, 6, 24, 54, 96, 143, and 166). There were two studies among normal healthy subjects that found no effect (Refs. 73 and 150), but that result may be attributable to the small sample size. Reduced platelet aggregation has been reported for diseased populations (Ref. 28), except that there are other studies in which no effect was found (Ref. 93 through 95, and 134), possibly because of small numbers of subjects.

Other measures of platelet function, e.g., platelet activation, adhesiveness, and survival, are also affected by fish oils. Fish oil reduces platelet activation and adhesiveness and increases platelet survival (Refs. 94, 96, and 144).

Also, other blood-related properties besides platelets are affected by fish oils. Red blood cell deformability is increased and blood viscosity is decreased after consumption of fish oils (Refs. 18, 42, 145, and 160), which may affect the consequence of formation of small clots.

The relationship between platelet aggregation and the risk of heart attacks or CHD death in the general population is an important line of evidence that would support drug claims and perhaps health claims for omega-3 fatty acids. Although there is some evidence that changes in platelet aggregation may help prevent second heart attacks (Refs. 66 and 112), it has not been shown that changes in platelet aggregation in the general population will reduce the risk of CHD. The importance of other platelet or blood effects of omega-3 fatty acids on risk of CHD also has not been established.

iii. *Regulators of bleeding.* Markers for CHD other than cholesterol and blood lipids have also been found. One is the level of a plasma protein called fibrinogen, which is involved in blood clotting (Ref. 102). The effects of fish oils containing omega-3 fatty acids on fibrinogen were evaluated in 10 studies. One study had no control (Ref. 134), and one was confounded by concurrent anticoagulant therapy (Ref. 144). One compared fish paste to meat paste, so the effect of omega-3 fatty acids cannot be distinguished from other components in fish (Ref. 40). Among the remaining seven studies, six were randomized studies and one was a matched, controlled study. Four found a significant reduction in fibrinogen levels compared to olive oil (Refs. 49, 71, and 117) or soybean oil (at a high dose of omega-3 fatty acids only, not at a low dose, Ref. 57). One study found reduced fibrinogen in the group fed fish but not in the group fed fish oil (Ref. 20), raising the possibility that components of fish

other than the omega-3 fatty acids were responsible for the effect. In the remaining two studies, no effect was found compared to a corn oil placebo (Refs. 11 and 118), and one study showed that both corn oil and fish oil reduced fibrinogen comparably (Ref. 118), suggesting that the effect was produced by polyunsaturated fatty acids, not specifically omega-3 fatty acids.

Similarly, no clear relationship between omega-3 fatty acids and factors involved in dissolving blood clots has emerged (Refs. 29, 104, 150, and 131). Finally, a particular component of one of the lipoproteins, lipoprotein (a) is also considered a marker for atherosclerotic disease by its regulation of fibrinolysis, but the effects of omega-3 fatty acids on lipoprotein (a) have only been reported in abstracts.

iv. *Blood pressure.* One of the most consistently reported effects of omega-3 fatty acids from fish oils is a decrease in blood pressure. Among normal healthy subjects, reductions have been reported for systolic blood pressure (Refs. 6, 24, 49, and 80); reductions in diastolic blood pressure have not been significant (except Haglund et al. 1990, but the data for Haglund et al. 1990 are confounded because separate data were not reported for healthy subjects and subjects with CHD (Ref. 57)). One study among normal, healthy men showed that a mixed dietary supplement containing fish oil reduced systolic blood pressure, whereas no effect was seen when the supplement contained linseed oil or safflower oil (Ref. 80). Other studies in normal, healthy adults found that the reduction in blood pressure following consumption of fish oils was comparable to the reduction after consumption of other polyunsaturated oils (Refs. 20 and 49) or found no significant change after consumption of fish oils (Refs. 9 and 73).

In one report of a study of hypertensives (Ref. 11), a moderate dose (5.1 g/day) of purified ethyl esters of EPA and DHA for 10 weeks reduced blood pressure proportionally to the increase in plasma omega-3 fatty acids. Interestingly, no effect of fish oil was found among those subjects who habitually consumed three or more meals of fish per week. Controlled studies among hypertensives and among diabetics found reductions in both systolic and diastolic blood pressure (Refs. 11, 77, 85, 101, and 147). Very high amounts of fish oil (50 mL/day) were used in two of these studies (Refs. 85 and 95), and the placebo in one study was olive oil, not a high polyunsaturated oil (Ref. 77), so it is not clear if the effect of fish oil was because of polyunsaturated fatty acids or omega-3 fatty acids.

Whether the magnitude and duration of any decrease in blood pressure persist after longer term consumption of omega-3 fatty acids is not known. The longest duration of supplementation in the above studies was 12 weeks.

These results for effects of omega-3 fatty acids on blood pressure of normal subjects are ambiguous. Some studies found a reduction in systolic blood pressure after consumption of fish oils containing omega-3 fatty acids, whereas others did not. None of the studies found a significant reduction in diastolic blood pressure. Therefore, it also remains to be established that the normal, healthy population will reduce their risk of CHD via a reduction in blood pressure following consumption of omega-3 fatty acids.

In summary, there are a few established effects of omega-3 fatty acids from fish oils on thrombosis and hemostasis. Standardized bleeding times are increased, and platelet aggregation and function are reduced. However, direct relationships between the changes in bleeding times or platelet function and risk of CHD have not been established. While there is an established relationship between blood pressure and CHD, it has not been shown that omega-3 fatty acids specifically affect blood pressure in normal subjects in a way that would provide a protective benefit toward the risk of CHD. Effects of omega-3 fatty acids on other markers linked with CHD, e.g., fibrinogen or lipoprotein (a), have not been established.

4. Other Relevant Information

a. *Animal studies.* Animal studies, where the atherosclerosis may be measured directly, provide some evidence of an anti-atherogenic effect for omega-3 fatty acids. Studies in rabbits (Refs. 65 and 165), pigs (Ref. 81), rhesus or African green monkeys (Refs. 27 and 116), and dogs (Ref. 90) reported that incorporation of omega-3 fatty acids in a diet designed to promote atherosclerosis actually reduced development of atherosclerotic disease. However, other animal studies showed no reduction, or an increase, in atherosclerotic disease after dietary supplementation with omega-3 fatty acids (Refs. 19, 47, 51, 69, 97, 122, 123, 126, and 151). Thus, there are some data from studies in animals which suggest the possibility of a beneficial effect of omega-3 fatty acids on CHD, however, the data are equivocal.

b. *Safety considerations.* Trials of the effects of fish oils containing omega-3 fatty acids among diabetics show that total cholesterol, LDL cholesterol, or apoB may increase (Refs. 7, 77, 79, 108, 110, and 128). While some studies among insulin-dependent diabetics found no significant effect of fish oils on the ability to maintain desired levels of blood glucose (Refs. 77 and 124), others reported impaired glucose control (Ref. 55). Other studies on noninsulin-dependent diabetics reported that fish oil resulted in increased-blood glucose (Refs. 44, 52, 128, and 130). Adverse effects on blood glucose control have been reported for subjects who were both hypertriglyceridemic and diabetic, either insulin-dependent (Ref. 94) or noninsulin dependent (Ref. 146). In one study there was an increase in the blood triglyceride level over and above the initial level after fish-oil supplementation was discontinued (Ref. 124). Thus, use of fish oils containing omega-3 fatty acids may pose particular additional risks among diabetics, regarding both serum lipids and glycemic control.

III. Tentative Decision not to Authorize a Health Claim Relating Ingestion of Omega-3 Fatty Acids to Reduced Risk of Coronary Heart Disease

In evaluating the scientific evidence, FDA considered the strength of association of omega-3 fatty acids with CHD or surrogate markers for CHD, the consistency of findings among the many studies, the specificity of the outcome to omega-3 fatty acids, the presence or absence of a dose-response relationship, and biologic plausibility of an association.

FDA has determined that there is inadequate evidence to show that increased consumption of omega-3 fatty acids will reduce the risk of CHD. Furthermore, the review of scientific information reveals potential serious safety concerns about the use of fish oils containing omega-3 fatty acids by subpopulations who are at increased risk for CHD.

FDA attempted to determine whether there was significant scientific agreement among experts that the totality of publicly available scientific evidence supported the claim that omega-3 fatty acids reduce the risk of heart disease. FDA reviewed the position taken in numerous Federal government and other authoritative scientific reports and evaluated the totality of publicly available scientific evidence that has become available since those reports were written. The tentative decision to deny a health claim is based on the conclusions reached

following review of these various sources of information and conclusions.

"The Surgeon General's Report on Nutrition and Health," the National Academy of Science's Report on "Diet and Health: Implications for Reducing Chronic Disease Risk," and the National Cholesterol Education Program's "Detection, Evaluation and Treatment of High Blood Cholesterol in Adults" each concluded that there was inadequate evidence of a relationship between consumption of omega-3 fatty acids and CHD. FDA has rereviewed all the relevant cross-sectional data from which a relationship between omega-3 fatty acids and CHD was hypothesized, and all clinical intervention data published since these Federal government and other authoritative reports documents to determine whether the additional evidence is adequate to support a health claim for omega-3 fatty acids.

The LSRO report reached a different conclusion than the other authoritative reports by finding a relationship between omega-3 fatty acids and CHD. The report used only selected evidence, much of it from animal experiments with no clinical counterpart. Furthermore, it did not distinguish between the normal population and diseased subpopulations. Finally, it relied on international epidemiologic findings of a relationship between fish consumption and CHD that was not shown to be specific to omega-3 fatty acids.

The surveys, cross-sectional studies, and non-intervention prospective studies do not support a relationship between consumption of omega-3 fatty acids and CHD. Only a few studies found an association between fish intake and CHD, while others have found no association. Thus, there was not consistency of findings. None of the studies that reported a relationship distinguished fish consumption from other factors associated with fish consumption, and therefore they did not demonstrate specificity. Even in those studies reporting a relationship between fish consumption and CHD, it was not clear that the effects were because of the omega-3 fatty acids in fish. Also, the omega-3 fatty acid content of the fish diet associated with reduced CHD was so low that the importance of omega-3 fatty acids is questionable, i.e., calling into question the biologic plausibility of the relationship.

The data from intervention studies also do not establish a relationship between omega-3 fatty acids and risk of CHD. The most compelling type of evidence to support a diet-disease relationship is a prospective, double-blinded, placebo-controlled intervention study, using CHD morbidity and mortality as endpoints. To date, there is only one such trial (Ref. 16). The results of that study showed that increased consumption of fish does not reduce the risk of a second heart attack but may reduce the risk that the attack will be fatal. However, as with the nonintervention study data, this study did not provide evidence to attribute the benefit to omega-3 fatty acid intake rather than some other factor associated with fish consumption (specificity). Furthermore, no data were reported for biochemical surrogate markers of CHD (blood lipids, measures of thrombosis or hemostasis), so this report cannot easily be integrated with results of studies where such data were reported (consistency).

Less persuasive than prospective studies in which CHD is measured, but still very useful, are prospective clinical trials in which surrogate markers for CHD are measured. These studies have usually used encapsulated fish oils providing omega-3 fatty acids in amounts comparable to or higher than the amount that would be consumed on a high fish diet (approximately one g EPA plus DHA per day), for periods of weeks to 6 months. These studies have not been designed to show an effect on the development of atherosclerosis, so evidence is lacking on that topic. Recent studies have not found beneficial effects on blood lipids from intake of omega-3 fatty acids in normal, healthy persons or in persons at risk for CHD, the same conclusion reached in the Federal government and other authoritative reports (Refs. 34 through 36, 63, and 115) regarding the effects of fish oils on serum lipids. This conclusion was also reached in numerous studies (consistency), some of which were large or multicenter (strength of association).

An increase in bleeding times and a decrease in platelet aggregation have been observed consistently in normal healthy individuals as well as in diseased persons who consumed fish oils. The effects of decreased platelet aggregation are plausibly related to the intake of omega-3 fatty acids, and there is a dose-response relationship. What has not been established, however, is that platelet aggregation is a bona fide surrogate risk factor for CHD in the general population.

Omega-3 fatty acids have been shown to reduce blood pressure in hypertensive people to a small degree, which may bear on a relationship between omega-3 fatty acids and CHD. The effect was not of large magnitude, but it is specific to omega-3 fatty acids, has been reported by a number of investigators, a dose response was found, and the effect is plausible. However, it has not been established that omega-3 fatty acids reduce blood pressure in normal subjects (lack of consistency, weak effect, absence of dose-response relationship). Additionally, it has not been demonstrated that the magnitude and duration of changes in platelet function or blood pressure observed in short-term studies will persist during long-term consumption of omega-3 fatty acids. Finally, the potential that omega-3 fatty acids may further increase the risk of CHD, through increases in LDL cholesterol or apoB among diabetics and hyperlipidemics, and the potential that omega-3 fatty acids may worsen control of blood glucose in diabetics, are significant safety concerns.

In conclusion, the totality of scientific evidence does not support the claim that omega-3 fatty acids reduce the risk of CHD.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

VI. Comments

Interested persons may, on or before January 27, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR Part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371)

2. Section 101.71(f) is amended by adding new paragraph (f) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(f) Omega-3 fatty acids and coronary heart disease (insert cite and date of publication in the **Federal Register** of the final rule).

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

TABLE 1.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: SURVEYS, CROSS-SECTIONAL, AND CORRELATIONAL STUDIES

Reference	Design	Subjects	Duration	Base diet	Method	Comments	Findings
Bang et al. 1980 Advances in Nutrition Research 3:1.	Three expeditions: Dietary and blood lipids surveys. Comparison of CHD mortality rates and blood lipids between Greenlanders and Danes.	Cross-sectional studies including dietary survey. Blood lipids for 130 people, CHD rates based on hospital records.	3 short expeditions.	Greenlanders consumed 13.7 g omega-3 fatty acids/d and 5.4 g omega-6 fatty acids/d. Danes consumed 2.8 g omega-3 fatty acids/d and 10.0 omega-6 fatty acids/d.	Correlational	Other major risk factors for CHD including smoking, exercise, were not controlled. Sample size was small. Good hypothesis generating studies.	CHD rates and blood cholesterol were lower among Greenlanders in Greenland, who had high consumption of omega-3 fatty acid in marine foods, than among Greenlanders who migrated to Denmark, and who had lower omega-3 fatty acid consumption.
Crombie et al. 1987 European Heart Journal 8:560.	Cross-sectional	WHO mortality data and organization for economic cooperation and development statistics (Commodity).	Short-term	Per capita food consumption statistics.	Correlation between food consumption statistics and mortality rates from CHD in 15 nations.	Major CHD risk factors, spoilage, export of foods, genetic differences.	Some nations with high fish consumption had high rates of CHD mortality and some nations with low fish consumption had low CHD mortality rates.
Curb and Reed 1985 New England Journal of Medicine 313:821.	Prospective study	7,615 healthy Japanese men.	12 years	Reported fish consumption (24 hour recall).	Adjusted for major risk factors associated with CHD.	Letter to the editor	No significant trend for CHD and fish consumption.
Dolecek and Grandits 1991 World Reviews of Nutrition and Dietetics 66:205.	Prospective study with periodic dietary surveys.	6,258 men	9 years	24 hour recall of dietary intake.	Adjusted for major risk factors associated with CHD.	One of few studies to evaluate omega-3 fatty acid intake. Individuals with a history of CHD excluded from this study.	Mortality due to CHD inversely proportional to 20:5, 22:5 and 22:6 omega-3 fatty acids. Dose response effect reported.
Hirai et al. 1980 Lancet ii:1132.	Cross-sectional data used to correlate diet with CHD mortality rates in two villages with different fish consumption patterns.	42 healthy subjects from both fishing and farming communities in Chiba, Japan.	Short-term	Normal diet	Estimated fish, omega-3 fatty acid intake related to platelet aggregation, blood viscosity.	Hypothesis generating study; need cohort studies.	Inverse relationship between fish intake and rate of CHD mortality in the community.
Hunter et al. 1988 American Journal Preventive Medicine 4:5.	Nutritional survey data for fish consumption and CHD mortality data Canadian Atlantic provinces and Prairies.	Per capita average intakes of fish.	Short-term	Normal diet	Correlation of diet with CHD mortality rates.	Data do not relate to individuals, not adjusted for major risk factors for CHD. Need cohort data on food intake/CHD mortality.	Comparison did not indicate a measurable difference in CHD mortality rates despite greater fish consumption in Atlantic Provinces.
Iso et al. 1989 Internal Journal of Epidemiology 18:374.	Diet, clinical survey data correlated with CHD mortality rates. Cross-sectional design. Habitual fish intake questionnaire.	136 men total 34–55 years old: rural Japanese, urban Japanese, Japanese Americans, Caucasian Americans.	Short-term	Normal diet	8–12 hour fasting blood samples for blood lipids. Systolic and diastolic blood pressure.	Good survey techniques. Need cohort data on CHD mortality. This is primarily a hypothesis generating study.	Progressive decline in fish consumption from rural Japan to urban Japan, Japanese Americans and Caucasian Americans. There was an inverse correlation between CHD rates and fish consumption in these populations. Serum omega-3 fatty acids correlated most strongly with dark meat fish intake.
Kagawa et al. 1982 Journal Nutritional Sciences and Vitaminology 28:441.	Cross-sectional study	77 elderly persons on Kohame Island.	Short-term	Normal diet	Correlation	This is primarily a hypothesis generating study.	Higher serum levels of eicosapentaenoic acid and high density lipoprotein, lower salt intake and blood pressure in Islanders than mainland Japanese. Mortality due to hypertension and chronic heart disease lower than mainland Japan.

TABLE 1.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: SURVEYS, CROSS-SECTIONAL, AND CORRELATIONAL STUDIES—Continued

Reference	Design	Subjects	Duration	Base diet	Method	Comments	Findings
Kromhout et al. 1985 New England Journal of Medicine 312:1205.	Prospective study dietary questionnaire.	852 healthy men in Zutphen, Holland.	20 years	None	Adjusted or major CHD risk factors.	Inverse relationship between fish consumption and CHD mortality.	First study to report dose response. Noted lean fish, low in omega-3 fatty acids, had some protective effect against CHD.
Kromhout 1989 Journal Internal Medicine (suppl) 225:	Prospective study (number of subjects not given in paper). Review article presenting brief summary of previously unpublished information.	16 cohorts in 7 country study. Categorization of fish intake as group rather than as individuals.	15 years	Questionnaire at entry to survey level of fish consumption quintiles from <10 g/day to 200 g/day.	Correlation	Author suggested that CHD mortality not primarily dependent on level of fish consumption. Other behaviors including level of saturated fat in the diet are important. Need cohort data, unable to determine fish consumption in individuals with CHD mortality from this analysis.	Low mortality <20 deaths due to CHD per 1000 reported in all quintiles of fish intake. One cohort reported 60 g/day average intake and had <120 deaths per 1000 due to CHD. Controlling these factors, fish consumption at a low level may be of importance in the prevention of CHD.
Norell et al. 1985 British Medical Journal 293:426.	Prospective	10,966 Swedes born between 1886–1925.	14 year followup.	Mail questionnaire	Adjusted for age, smoking, weight, sex, marital status, geography. Excluded people with history of hypertension, heart disease.	The author suggested the study supported a protective effect of fish consumption for CHD mortality. The data for this conclusion were weak.	The trend for CHD mortality versus fish consumption was barely significant at the 90% confidence level. The Chi square trend was not significant.
Shekelle et al. 1985 New England Journal of Medicine 313:820.	Prospective dietary questionnaire.	1931 middle aged men	25 years	Normal diet	Adjusted for major risk factors associated with CHD.	Letter to the editor	Inverse trend for risk of death and fish consumption.
Simonsen et al. 1987 Acta Medica Scandinavica 222:237.	Correlation of diet and serum lipids with CHD mortality rates in these communities.	14 males each from farming and fishing community.	Short-term	Normal diet	Correlation	Smoking, sample size, medical records.	No differences in CHD rates in the two communities despite 2.5 fold greater fish consumption in the coastal group.
Vollset et al. 1985 New England Journal Medicine 313:820.	Prospective study	11,000 healthy, middle aged men.	14 years	Questionnaire on diet, fish consumption.	Adjusted for major risk factors associated with CHD.	Letter to the editor	No relationship between fish consumption and CHD except in men under 45 years old.

Abbreviations used: CHD, coronary heart disease; d, days.

TABLE 2.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: CLINICAL STUDIES

Reference	Design	Duration	Amount	Subjects	Findings	Comments
Abbey et al. 1990 *Arteriosclerosis* 10:85.	Randomized, double-blind, 3 oils.	6 weeks	3.4 g EPA plus DHA (MaxEPA) v safflower, linseed oils.	11 normotensive mildly hypercholesterolemic males.	NS Chol, HDL, IDL; ↑ LDL; ↓ TGs, VLDL TG and chol, apoB, apoA-I, apoA-II; ↑ ratio of apoA-1/apoA-II.	Concurrent linoleic acid (omega-6) and linolenic acid (omega-3) control groups allow conclusions about omega-3 fatty acid specific effects. Dietary intake was controlled, compliance was monitored by plasma fatty acids. Comparisons v baseline values, following 3-week safflower oil run-in ↓ HDL on linseed oil only. See Kestin et al. 1990
Agren et al. 1990 *Thrombosis Research* 57:565	Randomized, dose response.	12 weeks	0.25, 0.5, 0.6 and 1.1 g EPA + DHA from freshwater fish.	100 healthy male students.	↓ platelet aggregation to collagen, ADP in two highest fish consumption groups; ↓ TXB, in high amount, longest time group; NS bleeding.	Effects on 1.5 fish meals/weeks (0.5 g EPA plus DHA) with 12-week duration of exposure. Moderate amount of freshwater fish intake can modified platelet function. Concurrent 0.4 fish meal/week control group was present. Dropouts not explained; N=13, 14, or 15 in Table 2. Design doesn't allow conclusions about omega-3 fatty acid specific effects.
Azar et al. 1989 *Kidney International* 36 (suppl 27):S239.	Non-blinded, uncontrolled.	1 month	6 g MaxEPA/d	7 male and 6 female hemodialysis patients	NS Chol, apoA; ↓ TGs, apoB, and apoB/apoA ratio.	Hyperlipidemia of hemodialysis patients received 6 g/d of MaxEPA for 1 mo had beneficial effect. The investigator suggested that long-term multicenter studies are needed to confirm the efficacy and tolerance of FO. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Bach et al. 1989 *Annals of Nutrition Metabolism* 33:359.	Randomized double-blind placebo-controlled trial.	5 weeks	1.3 or 2.5 g EPA plus DHA from salmon oil/d v Miglyol 812.	30 healthy adults	NS Chol, LDL, HDL, TGs; ↓ BP, plasma viscosity, RBC rigidity, platelet aggregation.	The control oil (Miglyol 812) consists of TG of primarily octanoic acid and decanoic acid. No fatty acid composition of the control and the test diet was given. The compliance of the diet was not monitored.
Bagdade et al. 1990 *Diabetes* 39:426.	Non-blinded uncontrolled.	3 months	6 g EPA plus DHA, SuperEPA.	8 normolipidemic insulin-dependent diabetic women.	↓ TGs; ↑ Chol, HDL_2, apoA; NS LDL, apoB, HDL_3.	IDDM and NIDDM may respond to omega-3 fatty acids differently. No deterioration of diabetes control. Long-term benefits/toxicity not established. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Blonk et al. 1990 *American Journal Clinical Nutrition* 52:120.	Randomized, dose-response.	12 weeks	1.5, 3, 6 g EPA plus DHA ethyl esters/d.	45 normotriglyceridemic males.	↓ TGs, HDL_3; ↑ HDL_2, HDL_2: HDL_3; NS Chol, VLDL, LDL, total HDL; NS BP, bleeding time, RBC deformability, leukocyte killing.	Normal diets, with < 1 fish meal/week. Includes a 12-week washout, showing return to baseline for most variables. Compliance indicated by plasma phospholipids. Most of the observed changes occurred on the lowest dose.
Bonaa et al. 1990 *New England Journal Medicine* 322:795.	Randomized non-blinded, placebo controlled.	10 weeks	5.1 g EPA plus DHA as ethyl ester/d v corn oil.	157 hypertensive healthy, age 34 to 60.	NS Chol, HDL; ↓ BP linear with change in plasma EPA plus DHA; NS bleeding, fibrinogen.	FO decreased BP varies in different demographic and biochemical subgroups. In this study, 32% of the subjects did not decrease BP, despite an increased intake of EPA.

TABLE 2.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: CLINICAL STUDIES—Continued

Reference	Design	Duration	Amount	Subjects	Findings	Comments
Borkman et al. 1989 *Diabetes* 38:1969.	Randomized, double-blind, placebo controlled.	3 weeks each.	10 g MaxEPA/d or 10 g safflower oil, with 3-week washout between.	10 non-insulin dependent diabetics.	NS Chol, LDL, HDL; ↓ TGs for hypertriglyceridemics only; NS c-peptide, fasting insulin, insulin sensitivity.	Controlled (diabetic) diet; ↑ fasting glucose comparable on both oils.
Bowles et al. 1991 *Angiology* ZZ:187.	Non-blinded uncontrolled.	6 months	2.8 g EPA in FO/d	120 vessels in 105 patients undergoing angioplasty.	NS v historic rates of restenosis.	Numerous shortcomings, including inclusion, exclusion criteria, unblinded uncontrolled, poor compliance.
Brown et al. 1990 *American Journal Clinical Nutrition* 52:825.	Randomized crossover.	6 weeks	5 g MaxEPA/d or lean fish (0.2 g EPA) plus 5 g MaxEPA.	12 healthy males	↓ TGs, VLDL; NS Chol, LDL, HDL_2, HDL_3.	Uncontrolled weekend evening meals, otherwise diet was controlled. Compliance was measured by the level of EPA in RBC The calorie intake of the control group (2968 Kcal) was 10% more that the FO (2633 Kcal) group.
Brown and Roberts 1991 *Arteriosclerosis and Thrombosis.*	Matched, single-blind, placebo controlled.	6 weeks	5 g FO v olive oil	11 healthy subjects on FO, 14 controls.	NS Chol; ↓ TGs on FO, HDL on olive oil.	Eructation revealed group to all FO subjects, but none of controls. ↓ post prandial lipemia in FO subjects. FO not characterized. Compliance by RBC fatty acids. Drop-outs accounted.
Burr et al. 1989 *The Lancet* ii:757.	Randomized, parallel, multi-center.	2 years	Fish advice (or MaxEPA at 0.9 g EPA plus DHA/d) v fat advice v fiber advice.	2033 men post heart attack.	↓ total deaths in fish advice v other groups, attributed to CHD death; NS second MI.	This is the only study to date which assessed effect of omega-3 fatty acids on CHD per se. Design doesn't allow conclusions about omega-3 fatty acid-specific effects, because effects of fish are not distinguished from effects of omega-3 fatty acids.
Childs et al. 1990 *American Journal of Clinical Nutrition* 52:632.	Non-blinded multiple crossover.	3 weeks	4 diets w 36% fat with EPA plus DHA as: 0.2%, butter; 6.7%, pollack; 9.4%, tuna; 6.2%, salmon blend.	8 normolipidemic males.	↓ TGs, VLDL, Chol, apoA-I and apoA-II on all fish diets, LDL on all but the pollack diet; HDL_2 ↓ on pollack, ↑ on salmon; HDL_3 on pollack, tuna.	Daily energy intake varied (2550–3618 kcal/d) among individuals. Saturated fat diet was used as positive control, no concurrent polyunsaturated fat control. The differential effects of pollack v other fish may be due to its higher ratio of EPA:DHA.
Clark et al. 1989 *Kidney International* 36:653.	Non-blinded uncontrolled.	5 weeks	6 g or 18 g MaxEPA/d.	12 subjects with systemic lupus erythematosus.	↓ TGs, VLDL; ↑ HDL, ↑ PGI_3; NS Chol PGI_2; ↓ platelet aggregation, blood viscosity, RBC flexibility; NS platelet serotonin, serotonin release.	All patients were receiving prednisone at doses ranging from 10 mg on alternate days to 20 mg daily. The results did not indicate an improvement in clinical outcome for patients with lupus nephritis.
Cobiac et al. 1991 *American Journal of Clinical Nutrition* 53:1210.	Matched, parallel design.	5 weeks	4.5 g EPA plus DHA from salmon plus sardines in sild oil v MaxEPA v palm, safflower olive oil mix.	25 mildly hypertensive men.	NS Chol, LDL; apoB, apoA-I, apoA-II, BP; ↓ TGs, VLDL; ↑ HDL on both fish and FO ↓ fibrinogen, TXB, ↑ bleeding on fish only.	3 week run-in on controlled diet including liquid supplement. Stratified by BP, TGs, Chol to matched groups; fish, FO or control (basal) diets. Fish diet EPA:DHA was 1:2, MaxEPA is 2:1. The BP effects were comparable in the 3 treatments. Bleeding, fibrinogen and thrromboxane changes occurred only on the fish diet, suggest they are EPA-specific effects.
Croset et al. 1990 *Thrombosis Research* 57:1.	Randomized, double-blind, placebo controlled trial.	2 months	100 mg EPA/d as purified TG plus tocopherol v vitamin E.	8 healthy elderly subjects, 8 controls.	NS Chol, TGs; ↓ platelet aggregation; NS arachidonic acid metabolites; ↑ tocopherol in platelets; NS fibrinolytic activity; ↓ systolic BP.	Decrease in platelet aggregation occurred on this very low dose (100 mg/d), despite no change in platelet or plasma EPA concentration Purified EPA containing TG as unique EPA source.

TABLE 2.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: CLINICAL STUDIES—Continued

Reference	Design	Duration	Amount	Subjects	Findings	Comments
Dart et al. 1989 *Atherosclerosis* 80:119.	Double-blind, placebo controlled crossover.	2 months	20 mL MaxEPA v olive oil.	14 male and 7 female hypercholesterolemic subjects.	NS Chol; ↓ TGs, VLDL; for males ↑ LDL and HDL, for females NS LDL, HDL.	Sex differences in HDL response appears real Body weight gain on placebo in both men and women
DeCaterina et al. 1990 *Circulation* 82:428.	Non-blinded uncontrolled.	28 days	3 g EPA plus 1 g DHA/d (PGE technology, MA).	13 males 2 females with coronary artery disease.	↓ TGs; NS Chol; ↑ PGI_2; ↓ TXB_2; platelet aggregation ↑ bleeding.	No placebo-treated concurrent control group Assays of tissues from supplemented subjects indicate direct and indirect effects of omega-3 fatty acids on production of platelet function regulators
Deck and Radack 1989 *Archives of Internal Medicine* 149:1857.	Randomized double-blind placebo controlled crossover.	8 weeks	4.6 g EPA plus DHA/d source not specified v olive oil.	8 hypertriglyceridemics.	↓ TGs; ↑ apoB, HDL; NS LDL.	Small sample size may limit the ability to detect statistically significant changes in LDL cholesterol
Dehmer et al. 1988 *New England Journal of Medicine* 319:733.	Randomized non-blinded.	1 week prior to angioplasty for 6 months.	5.4 g EPA plus DHA/d (MaxEPA—).	82 male candidates for angioplasty.	↓ restenosis rates	Concurrent use aspirin (325 mg/p/d) and dipyridamole (225 mg/p/d) in the control and test groups
DeLany et al. 1990 *American Journal of Clinical Nutrition* 52:477–85.	Non-blinded, matched by serum cholesterol.	5 weeks	3 diets; basal; 5; or 20 g FO substituted for margarine (Sanomega).	15 healthy male college students.	20 g FO ↓ TGs; NS Chol, HDL, apoA-I, apoB on both FO diets.	The trial was conducted in healthy males consuming a constant controlled diet. Implementation of controlled diet alone decreased serum TG. A further reduction of serum TG was observed in 20 g FO
Demke et al. 1988 *Atherosclerosis* 70:73.	Randomized, double-blind placebo controlled.	28 days	5 g MaxEPA v safflower oil placebo.	31 hypercholesterolemic subjects.	↑ Chol, LDL, HDL, HDL_2; NS TG, bleeding, TXB_2; no changes in placebo.	The results of the experiment question the benefit of FO supplement to the hypercholesterolemic patient It is one of the few studies reporting ingestion of oil supplement has adverse effects; indigestion, diarrhea, headache abdominal cramps, etc Dietary intake was not controlled.
Emeis et al. 1989 *Blood* 74:233.	Stratified, randomized.	6 weeks	Fish paste (1.7 g EPA plus 3 g DHA) v meat paste.	37 normal healthy males in fish group, 39 in meat group.	NS TPA, fibrinogen, c-reactive protein, insulin, plasminogen activity; ↑ PAI-1 activity.	Design doesn't allow conclusions about omega-3 fatty acid-specific effects. 2-week run-in on the meat diet. Compliance monitored by urinary lithium. ↑ PAI is a risk factor for reinfarction
Endres et al. 1989 *New England Journal of Medicine* 320:265.	Non-blinded uncontrolled.	6 weeks	18 g MaxEPA	9 healthy adults	↓ interleukin 1, tumor necrosis factor.	Initial study group consisted of 6 subjects, three more persons entered the study six months later Since the results were similar the data was pooled. No concurrent control. No dietary control and the mean calorie varied from 2000 to 3000 kcal/d. The FO effect on the synthesis of IL-1b continued 10-week-after omega-3 fatty acids supplementation.
Ernst 1989 *Journal of Internal Medicine Supplement* 225:129.	Randomized, double blind, placebo controlled.	6 weeks, 2 weeks each of 0.6 g EPA, 1.2 g EPA and 1.8 g EPA sequentially.	Neither the FO or the placebo were characterized.	20 healthy men	Reduced blood viscosity at 4 and 6 weeks.	Initial data demonstrating comparability of the treatment and control groups not shown. Other dietary controls not used, and values for the placebo group were lower at 4 and 6 weeks, but NS.

TABLE 2.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: CLINICAL STUDIES—Continued

Reference	Design	Duration	Amount	Subjects	Findings	Comments
Fallor et al. 1988 *Metabolism* 37:1021.	Non-blinded crossover, parallel control group.	3 weeks each w 3-week washout.	Saturated fat v safflower v salmon (and salmon oil).	4 familial combined hyperlipidemics, 4 normal controls.	↓ TG, apoA-1 in normals Familiial combined hyperproteinemia ↓ TGs.	Good experimental design. Dietary intake 3was recorded and compliance was monitored by RBC omega-3 fatty acids measurement. Small n may be the reason some differences were not found.
Fasching et al. 1991 *Diabetes* 40:583.	Non-blinded randomized, crossover to no supplement.	2 weeks each with 3-week washout.	30 mL FO/d EPAX 5000, Fabrikker, Oslo,6.3 g EPA + DHA.	8 subjects with impaired glucose tolerance.	↓ TGs, Chol, LDL, apoB; NS HDL, apoA-I; NS insulin, blood glucose.	1 kg gain (NS) in 2 weeks! Suboptimal control; Doesn't separate effects of omega-3 fatty acids from other oil components/cals.
Fisher et al. 1990 *American Journal of Clinical Nutrition* 51:804.	Non-blinded uncontrolled.	6 weeks	6 g EPA plus DHA/d, (30 mL cod liver oil).	9 normal subjects	↓ monocyte free radical production.	Dietary intake was not controlled. Design doesn't allow conclusions about omega-3 fatty acid-specific effects. The potential mechanisms of foam cell formation and its relationship with omega-3 fatty acids were discussed.
Flaten et al. 1990 *American Journal of Clinical Nutrition* 52:300.	Non-blinded randomized.	6 weeks	14 g FO (7.7 g EPA plus DHA)/d (Fabrikkar, Norway) v olive oil.	64 healthy males	↓ TGs, NS Chol; ↓ HDL, HDL_2; NS glucose; NS BP; 12% ↓ fibrinogen; NS gamma glutamyl transferase, monocyte LDL receptor activity.	Olive oil was the concurrent oil control group. Compliance was checked by RBC total omega-3 fatty acids composition. Calorie and major nutrient intake were comparable for the control and test group.
Friday et al. 1989 *Diabetes Care* 12:276.	Non-blinded uncontrolled.	8 weeks	8 g EPA plus DHA methyl esters/d (RES-Q1000).	8 non-insulin-independent diabetics.	↓ Chol, TGs, VLDL; NS LDL, HDL insulin; ↑ glucose.	No fatty acid composition was given on the Marine-lipid concentrate (RES-Q 1000, a methyl ester of EPA and DHA). Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Friday et al. 1991 *Arteriosclerosis and Thrombosis* 11:47.	Randomized, non-blinded, placebo-controlled multiple treatment trial.	3 weeks each with 3-week washouts.	12 g EPA plus DHA/d (salmon oil) v safflower oil.	5 familial hypercholesterolemics, 5 normal controls.	Comparable results for FH and normals, ↓ TGs, Chol, LDL, HDL v butter diet.	Precisely matched diets, small numbers but large changes in lipids. The n-3 content is quite high.
Fumeron et al. 1991 *American Journal of Clinical Nutrition* 54:118.	Randomized, butter-controlled.	3 weeks each.	6 g MaxEPA/d	36 normal, young, healthy males.	↓ TGs, VLDL-TG; NS Chol, apoB, apoA-I, total HDL, but ↑ HDL_2, apoE, LDL; ↓ platelet aggregation, ↓ PAI; PAI correlated to LDL.	Among the few studies showing ↑ HDL in normals (v butter). The ↑ PAI activity and LDL may offset ↓ platelet aggregation and ↑ HDL_2 regarding net CHD risk.
Glauber et al. 1988 *Annuals of Internal Medicine* 108:663.	Non-blinded uncontrolled.	4 weeks	18 g MaxEPA/d	6 males insulin-dependent diabetics.	↑ fasting glucose; ↓ glucose tolerance, fasting insulin, insulin response.	Deterioration of NIDDM patients' diabetic state by FO supplement but no evidence of adverse effect by fish. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Grigg et al. 1989 *Journal of American College Cardiology* 13:665.	Randomized, double-blind placebo-controlled.	4 months	3.0 g EPA plus DHA/d from MaxEPA v 50% olive oil, 50% corn oil.	108 subjects undergoing angioplasties.	↓ TGs, NS chol; NS in restenosis rate.	Restenosis evaluated by angiography.
Haglund et al. 1990 *Journal of Internal Medicine* 227:347.	Non-blinded uncontrolled, partial crossover.	3 to 4 weeks or 6 months.	15 or 30 mL ESKIMO-3 (Cardinova, Sweden) soybean oil placebo.	33 subjects either healthy or with coronary artery disease.	↓ TGs, Chol; ↑ HDL; ↓ BP, fibrinogen in high dose group; NS bleeding.	Data for normal and CHD patients are pooled. Similarly, tables compare results for each treatment to pooled initial values for all subjects.
Hardarson et al. 1989 *Journal of Internal Medicine* 226:33.	Non-blinded crossover intervention.	6 weeks	20 mL cod liver oil/d.	18 males 33-70 yrs	NS arrythmia	Subjects were an average of 8 days after onset of symptoms. Various drugs were taken by the patients. Dietary intake was not controlled.
Harris et al. 1988a *Journal of Lipid Research* 29:1451.	Multiple, sequential, non-blinded intervention.	4 weeks and 3 weeks.	24 g or 28 g EPA plus DHA/d from salmon oil Max EPA respectively.	7 and 8 normal subjects.	↓ TGs, VLDL; ↓ LDL v saturated fat diet, but NS v vegetable oil diet; NS HDL.	No wash out period between each test periods. High amount of omega-3 fatty acids.

TABLE 2.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: CLINICAL STUDIES—Continued

Reference	Design	Duration	Amount	Subjects	Findings	Comments
Harris et al. 1988b *Annals of Internal Medicine* 109:465	Single-blind, placebo controlled	6 weeks	12 mL SuperEPA/d v safflower oil.	11 hypertriglyceridemics, 7 with hypercholesterolemia.	↓ TGs; ↑ LDL, apoB; NS HDL.	Plasma lipoprotein changes should be monitored and long-term effects should be evaluated.
Harris et al. 1988c *American Journal of Clinical Nutrition* 48:992.	Non-blinded uncontrolled, crossover	6 weeks each.	18 g MaxEPA or same amount of EPA and DHA from SuperEPA.	8 male type IV hyperlipidemics.	↑ TGs; NS Chol, ↑ LDL, apoB.	Methyl ester of EPA and DHA causes the same effects as TG-EPA and TG-DHA. This is a test for more concentrate omega-3 fatty acids supplement.
Harris et al. 1990 *American Journal of Clinical Nutrition* 51:399.	Non-blinded uncontrolled, dose response	6 weeks	15, 25 or 40 mL MaxEPA/d.	10 hypertriglyceridemic subjects.	↓ TGs on each, little additional effect at high doses, ↓ VLDL; ↓ Chol but no effect of high doses; ↑ LDL, HDL on higher 2 doses.	High doses confound effects of increased calories. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Hostmark et al. 1988 *British Medical Journal* 297:180.	Randomized double-blind placebo-controlled supplement.	6 weeks plus 6 weeks.	14 g FO/d; 6.5 g EPA+DHA (Apothekernes Labs AS, Norway) v olive oil.	64 males ages 35-40.	↓ fibrinogen 13% at 3, 6 weeks.	The reduction in fibrinogen was less at 6 weeks than at 3 weeks. Longer-term studies are needed for assessment of effects of chronic consumption of omega-3 fatty acids.
Hughes et al. 1990 *Atherosclerosis* 84:229.	Randomized, double-blind, placebo-controlled two way crossover.	30 days each, with 30-day washouts.	5 g EPA plus DHA/d (Promega), wheat germ oil control.	13 normal and 15 hypertensive males.	↑ Chol, LDL, apoB in hypertensives only; NS TG, BP, serum androgens, plasma glucose, insulin, platelet aggregation.	The hypertensives had ↑ apoB and ↓ HDL and ↓ androgens v normals at baseline. Reductions in TGs and VLDL were nearly 50% in normals and 40% in hypertensives, but did not reach statistical significance due to large variations.
Inagaki and Harris 1990 *Atherosclerosis* 82:237.	Non-randomized uncontrolled.	4 weeks	6 g EPA plus DHA/d (SuperEPA).	6 hypertriglyceridemics.	↓ TGs, VLDL, apoC; NS, LDL, apoA, apoE; ↑ HDL, apoB.	Useful regarding mechanism of changes in lipoprotein levels, separated TG from Chol and apoproteins.
Jensen et al. 1989 *New England Journal of Medicine* 321:1572.	Randomized, double-blind placebo-controlled crossover.	8 weeks	4.6 g EPA plus DHA/d from a water soluble cod liver oil preparation v olive oil.	14 males, 4 females insulin-dependent diabetics.	NS Chol, HDL; ↑ LDL; ↓ VLDL, TGs; ↓ BP;.	Concurrent olive oil control group was present Dietary intake was not controlled. Eight weeks washout period was long enough to restore the parameters tested to the pre supplementary level. No change in insulin or blood glucose.
Kasim et al. 1988 *Journal of Clinical Endocrinology Metabolism* 67:1	Non-blinded longitudinal.	8 weeks	1.6 g EPA plus 1.1 g DHA/d (MaxEPA).	22 insulin-independent diabetics w/o hyperlipidemia.	NS Chol, LDL, HDL; ↑ apoB; ↓ BP.	All patients received hypoglycemic agents. Compliance was monitored by questionnaires and counting the FO capsules. No plasma fatty acids composition was analyzed.
Kestin et al. 1990 *American Journal of Clinical Nutrition* 51:1028	Randomized, double-blind, 3 oils.	6 weeks	3.4 g EPA plus DHA (maxEPA), v safflower, linseed oils.	11 normotensive mildly hypercholesterolemic males.	NS Chol, HDL; ↑ LDL; ↓ TGs, VLDL.	Concurrent linoleic acid (omega-6) and linolenic acid (omega-3) control groups were present. Dietary intake was controlled, compliance was monitored by plasma fatty acids. Comparisons v baseline values, following 3 week safflower oil run-in ↓ HDL on linseed oil only. See Abbey et al. 1990.
Knapp and FitzGerald 1989 *New England Journal of Medicine* 320:1037.	Randomized, non-blinded.	4 weeks	10 or 50 mL MaxEPA v safflower oil of a mixed vegetable oil.	8 hypertensive males in each of 4 groups.	↓ BP on high dose only	No total calorie/d was given but one of the dose level used in the study was quite large (50 mL/d).

TABLE 2.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: CLINICAL STUDIES—Continued

Reference	Design	Duration	Amount	Subjects	Findings	Comments
Lehtonen et al. 1989 *Gerontology* 35:311.	Non-blinded, comparison to isocaloric diet.	3 weeks	70 to 80 mL MaxEPA/d.	17 healthy geriatric patients.	↓ Chol, VLDL, LDL, TG, apoA, HDL; NS apoB.	The fat content of the isocaloric control period is not given. This is a very large amount of FO. The majority of the patients discontinued the study due to unpleasant taste of the supplement oil.
Lempert et al. 1988 *American Journal of Kidney Diseases* 11:170.	Non-blinded, uncontrolled.	4 weeks and 20 weeks post-supplementation.	25 mL MaxEPA/d	11 stable dialysis patients, hypercholesterolemic, hypertriglyceridemic.	↓ TG, HDL; ↑ LDL; NS bleeding, platelet aggregation.	↓ HDL found 20 weeks after discontinuation, but little other data regarding treatment/condition during the washout. The nature of the disease and concurrent dialysis in this population make it impossible to extrapolate to the general population.
Levine et al. 1989 *Archives of Internal Medicine* 149:1113.	Non-blinded uncontrolled.	6 weeks	20 mL cod liver oil	10 hyperlipidemics	↑ Chol, LDL; NS HDL, TGs; ↑ platelet survival; NS platelet aggregation.	All the patients had long-standing history of hyperlipidemia. No concurrent oil control group. This study is one of the few studies that found plasma TG did not change after omega-3 fatty acids ingestion (20 mL/d).
Levinson et al. 1990 *American Journal of Hypertension* 3:754.	Randomized double-blind placebo-controlled parallel.	6 weeks	50 mL MaxEPA v palm oil, corn oil mix.	8 hypertensives	↓ TGs; NS Chol, HDL, LDL apoA and apoB; ↑ bleeding; NS platelet aggregation; ↓ Bp.	One patient receiving FO withdrew because of GI discomfort. Because of adverse effects, the daily dose of oil was reduced by 20% and 25% in two patients in the FO group, and by 20% in one patient in the vegetable oil group.
Li and Steiner 1990 *Blood* 76:938.	Non-blinded parallel	25 days	6 g EPA from MaxEPA.	8 normal adults	↓ platelet aggregation, adhesiveness.	Elegant study showing an effect on platelet adhesiveness. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Lox 1990a *General Pharmacology* 21:241.	Non-blinded uncontrolled.	30 days	0.9 g EPA plus DHA/d (MaxEPA).	9 healthy males	↓ Chol, LDL; NS TGs; ↑ HDL; ↑ bleeding; NS platelet aggregation.	Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Lox 1990b *General Pharmacology* 21:295.	Non-blinded uncontrolled.	30 days	0.9 g EPA plus DHA/d (MaxEPA).	43 healthy females, with or without oral contraceptive use, 13 menopausal females.	↓ Chol, ↑ LDL in non-oral contraceptive users; ↓ TGs in oral contraceptive users.	The difference between oral contraceptive users and non-oral contraceptive users may be important.
Margolin et al. 1991 *American Journal of Clinical Nutrition* 53:562.	Randomized, double-blind crossover.	8 weeks	9 g FO (RES-Q1000) v corn oil.	46 elderly hypertensive subjects.	↓ TGs; ↑ LDL; NS Chol, HDL; ↓ BP.	Inclusion BP was systolic >160 or diastolic >90. Excellent design with 3 week wash out between the 8 week treatments.
Mehta et al. 1988a *American Journal of Medicine* 84:45.	Randomized, double-blind placebo-controlled crossover.	4 weeks	3.2 g EPA 2.2 g DHA/d (MaxEPA) v lecithin.	8 males w CHD 52-73 yrs.	↓ TGs; NS Chol, HDL, LDL; ↓ BP, ↓ neutrophil aggregation, chemotaxis.	Placebo not characterized in this paper, identified from companion paper (see Mehta 1988, American Heart Journal). There was large variation of TG level in the placebo group.
Mehta et al. 1988b *American Heart Journal* 116:1201.	Randomized, double-blind placebo-controlled crossover.	4 weeks	3.2 g EPA 2.2 g DHA/d (MaxEPA) v lecithin.	8 males w CHD 52-73 yrs.	↓ PAI; NS TPA	Various parameters were compared between CAD patient and normal subjects. Lecithin was the concurrent control. Dietary intake was not controlled.

TABLE 2.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: CLINICAL STUDIES—Continued

Reference	Design	Duration	Amount	Subjects	Findings	Comments
Miller et al. 1988 *Clinica Chimica Acta* 178:251.	Multicenter, randomized double-blind placebo-controlled.	3 months	10 g MaxEPA/d v olive oil.	48 hypertriglyceridemics.	↓ TGs; NS Chol, LDL, HDL	This is a multicenter 3 mo study. In the summary section the investigator reported minor GI disturbance in both groups but in the discussion section the author stated that 10 g MaxEPA/d was well tolerated. Compliance was not monitored.
Milner et al. 1989 *American Journal of Cardiology* 64:294.	Randomized	6 months	4.5 g EPA plus DHA/d (MaxEPA) v no supplement.	84 post-angioplasty patients.	↓ restenosis by symptoms, NS by angiography.	All patients received aspirin and calcium blockers American Heart Association phase III diet. Design doesn't allow conclusions about omega-3 fatty acid-specific effects. Concomitant use of other medications, reduction in smoking. Reocclusions not assessed by angiography.
Mølgaard et al. 1990 *Atherosclerosis* 81:1.	Non-blinded, placebo control.	16 weeks	15 g MaxEPA/d v olive oil.	9 type III hyperlipoproteinemics.	↓ Chol, TG, VLDL, apoB; NS LDL, HDL, apoA-I.	The European Atherosclerosis Society diet was recommended to the patients. No compliance was monitored. Concurrent olive oil control group.
Mori et al. 1988 *Clinical Experimental Pharmacology Physiology* 15:333.	Non-blinded uncontrolled.	3 weeks	15 g MaxEPA/d	10 insulin-dependent male diabetics.	↑ Chol, LDL, HDL; ↓ TGs	Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Mori et al. 1989 *Metabolism* 38:404.	Non-blinded, parallel control.	3 weeks	15 g MaxEPA/d v same in non-diabetics.	10 insulin-dependent male diabetics, 10 normal controls.	↑ Chol, LDL, HDL, HDL_2 ↓ TGs among diabetics; NS Chol, LDL, HDL, HDL_2 TGs among normals; Chol, LDL and TG still different 6 weeks after discontinuation.	Compliance by platelet phospholipids fatty acids and pill count. Usual diet, activity were to be maintained.
Nozaki et al. 1991 *American Journal of Clinical Nutrition* 53:638.	Non-blinded uncontrolled.	24 days	20 g Promega/d	12 male hypertriglyceridemics.	↓ TGs, VLDL; ↑ LDL; NS HDL.	No alcohol and isocaloric controlled diet was used in the protocol. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Radack et al. 1989 *Annals of Internal Medicine* 111:757.	Randomized double-blind placebo-controlled supplement.	20 weeks	1.1 or 2.2 g EPA plus DHA/d (source not specified) v olive oil.	25 hyperlipidemic, disease free.	↓ fibrinogen	Excellent design. Compliance was assessed by plasma fatty acid analysis.
Radack et al. 1990a *Journal of American College Nutrition.*	Randomized, double-blind crossover.	8 weeks each 4-week washout, 6-week run-in.	4.6 g EPA plus DHA, olive oil during washout, corn oil control.	8 hyperlipoproteinemics types IIb or IV.	↓ fibrinogen comparably on FO and corn oil; NS TPA, PAI, bleeding.	Excellent design; although the n was small, the mean values do not suggest differences missed due to small sample, nor is any difference between corn oil and FO suggested.
Radack et al. 1990b *American Journal of Clinical Nutrition* 51:599.	Randomized, double-blind placebo-controlled.	20 weeks	2.2 or 1.1 g FO/d from McNeil, 41% as n-3 fatty acids v olive oil.	10, 7 and 8 hypertriglyceridemics, respectively.	↑ LDL, ↓ HDL_2 on 2.2 g/d group, ↑ apoB on both doses of FO.	Excellent design includes 6 week run in, AMA diet, 92% compliance, appropriate subjects for claims.
Reis et al. 1989 *The Lancet* ii:177.	Randomized, double-blind placebo-controlled.	6 months	6 g EPA plus DHA/d (SuperEPA or Promega).	204 patients for coronary angioplasty.	NS effect on restenosis	In a randomly selected subset of 42 patients (42/186), plasma PL was analyzed. Higher GI side-effect was significantly higher in FO group (48%) than placebo group. Placebo not characterized.
Reis et al. 1990 *American Journal of Cardiology* 66:1171.	Randomized, double-blind placebo-controlled.	6 months	6 g EPA plus DHA/d (SuperEPA or Promega) v olive oil.	89 patients for coronary angioplasty.	↓ TGs; ↑ LDL in Promega group and hypertriglyceridemic subjects of Super-EPA group.	Only subset of patients had LDL separated by ultracentrifugation. Most of LDL chol levels were calculated rather than measured.

TABLE 2.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: CLINICAL STUDIES—Continued

Reference	Design	Duration	Amount	Subjects	Findings	Comments
Rillaerts et al. 1989 *Diabetes* 38:1412.	Non-blinded, uncontrolled.	10 weeks	2.7 g EPA plus DHA/d (MaxEPA).	12 stable insulin-dependent diabetics.	↓ TGs, VLDL; ↑ HDL; NS LDL during washout ↑ TGs, VLDL.	Dietary intake was controlled, exchanging sunflower, corn or safflower oil with omega-3 fatty acids. Calorie intake varied from 1800 to 2200 kcal, depend on individual needs. Approximately 5.6 g omega-6 fatty acids/d was exchanged with 2.7 g omega-3 fatty acids/d.
Schectman et al. 1988 *Diabetes* 37:1567.	Single-blind crossover.	1 month	4.0 or 7.5 g EPA plus DHA (MaxEPA).	13 non-insulin dependent diabetics v safflower oil.	↓ TGs, VLDL, NS Chol, LDL, HDL; ↑ apoB; ↑ fasting glucose, ↓ glucose tolerance.	Subjects were on their usual diet (uncontrolled). Compliance was obtained by capsule counting. Increase LDL chol and apoB were not dependent on amount of omega-3 fatty acids.
Schectman et al. 1989a *Arteriosclerosis* 9:345.	Single-blind crossover.	1 month	4.0 g/d EPA plus DHA (MaxEPA) for 1 month, 1-month washout, followed by 7.5 g/d for 1 month v safflower oil.	18 hypertriglyceridemic subjects.	↓ TGs; NS Chol, HDL, apoA-I on both treatments; NS on control.	Significant body weight gain on each treatment. Saturated fat was held constant.
Schectman et al. 1989b *Annals of Internal Medicine* 110:346.	Non-blinded uncontrolled.	6 months	10 g EPA plus DHA/d months 1 to 3; 4 g/d months 4 to 6 (Omega-500).	16 hypertriglyceridemics (5 also hypercholesterolemic); 6 noninsulin-dependent diabetics.	Initially ↓ TGs, but less each month, by 6 months only ↓ 11%; worse glucose tolerance, ↑ glycosolated hemoglobin in diabetics; ↑ HDL on high dose.	Dietary intake was not controlled. GI side effects were considered and reported. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Schmidt et al. 1988a *Artery* 15:316.	Non-blinded randomized after placebo.	12 weeks	4.5 g EPA plus DHA/d v vegetable oil.	14 patients with angina.	NS plasminogen, PAI; ↑ fibrinolysis.	Concurrent vegetable oil control was used. No fatty acid composition of control and test oil was given. Uncontrolled use of omega-3 fatty acids supplementation in patients with stable angina pectoris was cautioned by the investigator.
Schmidt et al. 1988b *Scandinavian Journal of Clinical and Laboratory Investigations*, Suppl.	Randomized, double-blind, placebo controlled.	12 weeks	4.8 g EPA plus DHA/d (MaxEPA) v vegetable oil.	36 patients with angina.	NS antithrombin III, protein C.	4-week run-in on vegetable oil control.
Schmidt et al. 1989a *Thrombosis and Haemostasis* 62:797.	Non-blinded uncontrolled.	6 weeks	6 g n-3 (3.3 EPA, 1.8 DHA) (Jahre, Norway).	17 hyperlipidemics (9 type IIa, 8 type IV.	↓ TGs; NS Chol, LDL, HDL; ↑ apoB, ↓ apoA-I; ↑ protein C in type IIa, ↓ type IV;.	No concurrent oil control group, uncontrolled dietary intake and large amount of test oil. Dietary compliance was not monitored and GI side effect was not reported. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Schmidt et al. 1989b *Journal of Internal Medicine* 225 (Suppl 1):201.	Non-blinded uncontrolled.	6 weeks	4 g EPA plus DHA/d (Jahre, Norway).	10 insulin-dependent diabetics.	NS fibrinogen, TPA, PAI, platelet aggregation; ↑ neutrophil, NS monocyte chemotaxis.	Very few changes in this population; the chemotaxis results are different than for normals. The meaning of changed neutrophil chemotaxis is unclear. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Schmidt et al. 1989c *Atherosclerosis*.	Non-blinded uncontrolled.	6 weeks	5.3 g cod liver oil/d	12 normal, healthy males.	↓ neutrophil, monoctye migration toward autologous serum or chemical attractant.	Usual diets throughout. The lack of a control oil prevents firm conclusion about the specificity of the effect as due to omega-3 fatty acids.

TABLE 2.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: CLINICAL STUDIES—Continued

Reference	Design	Duration	Amount	Subjects	Findings	Comments
Schmidt et al. 1991 *Arteriosclerosis and Thrombosis* 11:429.	Randomized, non-blinded dose-response.	6 weeks	6 g or 1.3, 4 or 9 g n-3 fatty acids (Fabrikker, Oslo).	17 hyperlipidemics and 10 healthy men.	↓ monocyte chemotaxis in all, ↓ neutrophil in type IIa and in normals, not type IV on 1.3 g/d.	Virtually all the effect is with the lowest dose. The authors interpret this to mean the effect was probably not due to polyunsaturated fatty acids, but a polyunsaturated fatty acid control would have allowed a stronger conclusion.
Skeaff and Holub 1988 *Thrombosis Research* 51:105.	Non-blinded v washout.	6 weeks	20 mL MaxEPA/d	8 normal males	↓ platelet aggregation	A methodology and protocol for biochemical mechanism of action of omega-3 fatty acids on platelet function. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Silverman et al. 1991 *American Journal of Clinical Nutrition* 53:1165.	Non-blinded, crossover.	2 individual meals.	6.16 and 5.15 g EPA plus DHA from FO (Promega) or tuna, respectively.	10 normal, healthy males.	↓ platelet aggregation to one of four agonists; NS bleeding, membrane omega-3 fatty acids.	The study was undertaken primarily to measure absorption of omega-3 fatty acids from FO v fish EPA absorption from fish was about 3 fold greater than from FO, but there was no difference in DHA absorption rate.
Simons et al. 1990 *Australia New Zealand Journal of Medicine* 20:689.	Randomized double-blind placebo-controlled crossover.	12 weeks	2 or 4 g EPA plus DHA/d HIMEGA (ethyl esters) v olive oil.	13 hypertriglyceridemics and 9 hypercholesterolemics.	↓ TGs; HDL, and ($p < 0.06$) Chol; NS LDL, apoA-1, apoB.	Himega is ethyl ester preparation of FO fatty acids The study shows comparable results for the new and traditional FO.
Simonsen et al. 1988 *Acta Medica Scandinavica* 223:491.	Non-blinded, uncontrolled.	3 weeks	20 mL cod liver oil, about 5 g EPA plus DHA.	2 groups of 15 normal healthy males.	NS Chol, bleeding, TXA_2 ↑ HDL in the population with low fish consumption.	There was an alternate oil control.
Smith et al. 1989 *Thrombosis Research* 53:467.	Non-blinded, uncontrolled.	4 weeks	3.4 g EPA plus DHA as ethyl esters (K85, Norsk Hydro).	35 male and 5 female survivors of myocardial infarction.	↓ TGs; NS HDL, blood glucose, PAI; ↑ Chol, LDL, bleeding, fibrinogen.	Points out interaction of omega-3 fatty acids with anticoagulants.
Solomon et al. 1990 *Current Medical Research Opinion* 12:1.	Randomized double-blind placebo-controlled parallel longitudinal.	3 months	2.8 g EPA, 2 g DHA (MaxEPA) v olive oil.	10 stable angina patients.	NS angina	Concurrent olive oil control was used. The subject number (5/group) was too small. Subjects kept their usual diet and life-style. Compliance was assessed by RBC-PL fatty acid analysis. No side effects were reported.
Stacpoole et al. 1989 *Metabolism* 38:946.	Non-blinded uncontrolled, two doses.	6 months, 3 months on 2 diets.	1.1, 2.3, or 4.5 g EPA plus DHA/1000 Kcal (MaxEPA).	21 hyperlipoproteinemics 6 diabetics, 6 normals.	In diabetics ↓ TGs; ↑ LDL; NS Chol, HDL; TG and LDL changes show dose-response; Glycemic control worse in 4 insulin-dependent diabetics; In controls ↓ TG, VLDL; NS Chol.	Two kinds (MaxEPA or SuperEPA) of omega-3 fatty acids test materials were used. Compliance was monitored by monthly visiting the clinic and evaluated by a physician and dietitian rather than plasma fatty acids composition American Heart Association phase III diet was used as basal diet.
Steiner et al. 1989 *Journal of Hypertension* 7 (suppl 3):S73.	Randomized, placebo-controlled crossover, followed by non-blinded, uncontrolled phase.	8 weeks blind, 4 weeks open.	1.6 g EPA plus DHA blind v salad oil, 3.2 g EPA plus DHA non-blind.	28 hypertensives, including 10 with hypertriglyceridemia or hypercholesterolemia.	↓ BP for self-recorded and casual clinic-recorded; NS prostacyclin, thromboxane.	Considerable systematic difference between self-reported and clinic-reported BP data suggests significant patient bias, detectable by fish-smell belching. Quantitative data not presented, making comparison with other BP studies difficult.
Subbaiah et al. 1989 *Atherosclerosis* 79:157.	Non-blinded uncontrolled.	30 days	7.5 g EPA plus DHA/d as SuperEPA.	14 hypercholesterolemics w/o hypertriglyceridemics.	↓ TGs, VLDL, LDL; ↑ HDL	Patients on American Heart Association phase I diet for at least 3 mo before entering the study and continue the same diet during the test period.

TABLE 2.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: CLINICAL STUDIES—Continued

Reference	Design	Duration	Amount	Subjects	Findings	Comments
Sweny et al. 1989 *Nephrology Dialysis Transplantation* 4:1070.	Non-blinded uncontrolled.	6 months	60 mg EPA plus DHA/kg (MaxEPA).	14 adult transplant recipients.	↓ TGs, NS Chol	No concurrent oil control group, uncontrolled dietary intake except dietary protein intake was kept constant. Compliance was not monitored and GI side effect was not reported. Antihypertensive and immunosuppressive drugs were administered.
Takimoto et al. 1989 *Thrombosis Research* 54:573.	Non-blinded uncontrolled, partial crossover.	30 days	20 mL MaxVita 5.6 g EPA 2.6 g DHA.	14 normal healthy subjects, 4 were hypercholesterolemic and hyperlipidemic.	↓ Tgs, HDL; NS Chol	There was no side effect or GI disturbance was reported when 20 mL control or test oil was taken in a single dose. Wheat germ oil containing alpha linolenic acid was used as control oil.
Urakaze et al. 1989 *Nephron* 53:102.	Non-blinded uncontrolled, controlled for ciclosporin.	6 months	1.5 g EPA 0.7 g DHA/d (source not specified).	14 renal allograft patients.	↑ RBC filterability, prevented ↑ in platelet aggregation in controls.	Non specified sardine oil concentrate was used. Food intake was not monitored during the study but EPA content in RBC was measured for compliance. Antihypertensive and immunosuppressive drugs were administered.
Vacek et al. 1989 *Biomedicine and Pharmacotherapeutics* 43:375.	Double-blind placebo-controlled crossover.	6 weeks	9 g EPA plus DHA from (MaxEPA) v 1:1 palm: cottonseed oil.	8 CHD patients	↓ TGs; NS Chol, LDL, HDL; NS angine.	The control was a mixture of palm and cottonseek oils. No fatty acid composition was given of this control oil. Dietary intake was not controlled.
Valdini et al. 1990 *Journal of Family Practice* 30:55.	Randomized, double-blind, placebo-controlled crossover.	12 weeks each.	1.8 g EPA plus DHA/d (MaxEPA) v olive oil.	25 hypercholesterolemics.	↓ TGs; NS Chol, LDL, HDL	Usual diets, small but practical dose; some patients were on lipid altering medication concurrently.
van Houwelingen et al. 1990 *American Journal of Clinical Nutrition* 51:393.	Multicenter, matched controls by TGs and blood pressure.	6 weeks	mackerel (4.7 g EPA+DHA) or meat paste.	84 healthy males	NS Chol, LDL; ↓ TGs at 3 and 6 weeks; at 6 weeks ↑ apoB v meat paste; NS v initial on meat paste.	Excellent design, includes 2 week run in; doesn't distinguish fish from n-3 fatty acids, large amt of n-3s.
Vessby and Boberg 1990 *Journal of Internal Medicine* 228:165.	Randomized double-blind placebo controlled crossover.	8 weeks	10 g MaxEPA v olive oil.	14 non-insulin dependent diabetics.	both oils ↓ VLDL, Chol, apoA-II; MaxEPA also ↓ TGs, BP, but NS between treatments; HbA_{1c}, glucose disappearance ↑ on MaxEPA, ↓ on olive oil.	Indicates potential adverse effect on glucose by omega-3 fatty acids.
Wahlqvist et al. 1989 *The Lancet* ii:944.	Non-blinded uncontrolled.	7 day diet records.	100 g fish/week	31 healthy 22 non-insulin-dependent diabetics.	↑ arterial compliance in fish group; ↓ posterior tibial artery resistance in healthy subjects.	Very small amount of fish (rather than FO supplement) was used in this study. Fish eaters were defined as those who ate one serving (100 g) or more of fish in a week. No total and/or a range of omega-3 fatty acids was given in the study.
Weintraub et al. 1988 *Journal of Clinical Investigation* 82:1884.	Non-blinded uncontrolled.	25 days	3 diets; saturated fat; safflower oil; FO at 30% of fat.	8 healthy normolipidemic males.	↓ TGs, Chol more by FO than safflower; ↓ VLDL, LDL, HDL comparable v saturated fat diet except apoA ↓ on FO v saturated fat.	The fat content (42%) of the diet was too high but the study design using two controls, saturated fat and omega-6 fatty acids was good.
Wilt et al. 1989 *Annals of Internal Medicine* 111:900.	Randomized, double-blind placebo-controlled crossover.	12 weeks each with 4-week washout.	20 g MaxEPA v safflower oil.	38 males w hypercholesterolemia.	↓ TGs; ↑ LDL; NS Chol, HDL, apoA, apoB.	Patients were on American Heart Association step one low cholesterol, low sat fat diet and large amount of FO (20 g/p/d) was used. No GI side effect was reported. Compliance was monitored by blinded pill count and questionnaire rather than plasma lipid analysis.

TABLE 2.—OMEGA-3 FATTY ACIDS AND CORONARY HEART DISEASE: CLINICAL STUDIES—Continued

Reference	Design	Duration	Amount	Subjects	Findings	Comments
Zucker et al. 1988 *Artherosclerosis* 73:13..	Randomized, crossover.	6 weeks.....	3.2 g EPA 2.2 g DHA (MaxEPA) v safflower oil.	9 normal, 16 hyperlipoproteinemics.	↓ TGs, VLDL; ↑ LDL in type IV hyperlipoproteinemics; NS Chol, TG, LDL, HDL among normals.	Safflower oil was used as control oil. The study design was double blind but many of the subjects reported identifying the FO by its characteristic aftertaste. This is one of the very few article reported FO aftertaste in a double blind study.

Abbreviations used: NS, not statistically significantly different; Chol, cholesterol; VLDL, very low-density lipoprtein cholesterol; LDL, low-density lipoprotein cholesterol; HDL, high-density lipoprotein cholesterol, TGs, triglycerides; apoA, apoprotein A (a protein in high-density lipoprtoein); apoB; apoprotein B (a protein in low-density lipoprotein); apoE, apoprotein E (a protein in many lipoproteins, most notably VLDL and HDL; CHD, coronary heart disease; FO, fish oil; TXB, thromboxane; TPA, tissue plasminogen activator; PAI, plasminogen activator inhibitor; v, versus; /d per day.

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21 CFR Part 101

[Docket No. 91N-0094]

RIN 0905-AB67

Food Labeling: Health Claims; Calcium and Osteoporosis

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to authorize the use on food labels and in labeling of health claims relating to the association between calcium and osteoporosis. FDA has reviewed the available scientific data under the provisions of the Nutrition Labeling and Education Act of 1990. Based on its review, FDA has tentatively concluded that there is significant scientific agreement among qualified experts that this data supports that calcium intake has a significant impact on bone health. The agency proposes that for a product to be eligible to bear such a claim, one serving of the product must contain a minimum of 20 percent of the Recommended Daily Intake (RDI) for calcium or 180 milligrams (mg) in an assimilable form.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mona S. Calvo, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-9564.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (Pub L. 101-535) (the 1990 amendments), which amend the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorize the Secretary of Health and Human Services (the Secretary) to issue regulations authorizing nutrient content or health claims on the label or labeling of foods. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)).

Published elsewhere in this issue of the **Federal Register** is a proposed rule to establish general requirements for health claims that characterize the relationship of nutrients, including vitamins and minerals, herbs or other nutritional substances (referred to generally as "substances") to a disease or health-related condition on food labels and in labeling. In this companion document, FDA has tentatively determined that such claims would be justified only for substances in dietary supplements as well as in conventional foods if the agency determines based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The 1990 amendments also require (section 3(b)(1)(a)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x)) that, within 12 months of their enactment, the Secretary shall issue proposed regulations to implement section 403(r) of the act (21 U.S.C. 343(r)), and that such regulations shall determine, among other things, whether claims respecting 10 topic areas, including calcium and osteoporosis, meet the requirements of the act. In this document, the agency will consider whether a label or labeling claim on food or food products, including conventional foods and dietary supplements, on the relationship between calcium and osteoporosis would be justified under the standard proposed in the companion document entitled "Food Labeling: General Requirements for Health Claims for Food."

FDA has followed the general concepts and criteria proposed in the companion document in considering whether to propose to authorize the use on the labels and labeling of food of health claims for calcium and osteoporosis. In the companion document, FDA has proposed that, in evaluating whether support exists for a health claim, it will consider the levels and safety of a nutrient within the context of its use in the daily diet. Before a health claim for a particular nutrient will be authorized, it is necessary that the nutrient be safe and lawful for use in food at the level found to have an effect on a disease or health condition.

The topic of calcium and osteoporosis involves a substance which has recognized uses both as a component of food and of drugs. The agency has looked at all data relevant to this topic whether the data involved tests at dietary levels or at therapeutic levels. The agency thought this necessary to

ensure the completeness of its review. However, the agency emphasizes that this proposal is only about whether a claim has been justified for calcium and food. A component of food must be safe in the context of the daily diet. On the other hand, drugs may be used even if they present questions of safety to the general population, and even to the population being treated, on the basis that there is a benefit from its use that outweighs the potential risk.

B. Definition and Disease Prevalence, Morbidity, Mortality, and Health Costs

Osteoporosis is a disease characterized by low bone mass, where the internal structure of the bone has been eroded to the extent that even slight trauma will cause the bone to fracture easily (Ref. 7). An estimated 75 million people are afflicted with osteoporosis in the United States, Europe, and Japan (Ref. 7). These estimates include one in three women over 65 years and more than half the elderly men and women over 75 years.

Osteoporosis causes more than 1.3 million fractures per year in the United States, typically involving the spine, wrist, hip and ribs (Ref. 109). Because life expectancy in the United States will soon average in the eighties, osteoporosis is expected to affect an even larger proportion of our population (Ref. 20). By age 80, approximately 40 percent of all women will have sustained a wedge-type fracture of the spine, a common source of pain, disability, and deformity, resulting in progressive loss of height with age (Ref. 109).

Fractures of the hip, however, have the greatest health and economic impact. In 1985, approximately 250,000 hip fractures occurred in the United States, primarily in persons over age 45 (Refs. 20 and 101). An estimated 12 to 20 percent of the hip fracture victims die within the year following the fracture (Ref. 83). Among those that do survive, a significant proportion never regain their prefracture independence and require varying degrees of nursing and often permanent custodial care (Ref. 7).

Estimates of the annual financial costs of osteoporosis in the United States, based primarily on the cost of hospitalization and acute and long-term care services were $6.1 billion dollars in 1984 (Ref. 5) and are currently thought to exceed $10 billion dollars (Ref. 8).

C. Risk Factors and Populations at Risk

The most important risk factors for osteoporosis and associated bone fractures are age, gender, race (Caucasian or Asian), and hormonal status (Refs. 1, 2, 3, 5, 7, 10, 83, and 109). For women, hormonal changes associated with menopause (natural or premature cessation of the menstrual cycle) places them at increased risk (Ref. 118). In addition, evidence exists identifying low dietary calcium, cigarette smoking, and alcohol intake as factors in the development of osteoporosis (Refs. 2, 8, and 109). In general, factors that impair maximum bone formation early in life and those that underlie excess postmenopausal and age-associated bone loss later in life will predispose persons to osteoporosis.

D. Calcium's Nutrient and Physiologic Function

The human body contains approximately 1,000 grams (g) of calcium, 99 percent of which is found in the skeleton and a small but very important 1 percent is found in the plasma and soft tissues (Ref. 21). Calcium is an essential nutrient. In terms of its physiological function, calcium is probably one of the most critical minerals in the body. Within bone, calcium provides structure and support. The bone's exchangeable calcium pool allows for calcium storage that can be readily released in times of need. When this pool is exhausted, bone can be resorbed, that is, physically broken down to release needed calcium (Ref. 100). Within plasma and cells, calcium functions in bone mineralization, blood clotting, membrane stability and permeability, nerve conduction, muscle contraction, cellular secretion, regulation of ion transport, enzymatic activity, and cell growth and differentiation (Refs. 21 and 100). Plasma calcium levels are maintained within a very narrow range through the interaction of three hormones whose actions raise or lower the calcium levels appropriately in order to maintain proper physiologic function (Ref. 100).

While bone can serve as a temporary source of calcium during acute physiologic need, the body is dependent on dietary intake as the ultimate source of calcium to replete the skeletal reserves (Ref. 67). When increased demand for calcium results in excessive resorption of calcium from bone, the structural support function of bone is compromised, and the bone breaks easily (Refs. 21 and 30).

Because of its essential function in the maintenance of plasma calcium within such narrow limits, bone is constantly turning over and remodeling and thus remains a dynamic tissue throughout life. The process of bone remodeling consists of the tightly coupled actions of bone resorption and bone formation. It is thought that through changes in bone remodeling activity, factors such as dietary calcium, exercise and hormonal activity modulate the rate of bone loss or gain (Refs. 34 and 64).

The need for calcium throughout life varies with bone remodeling activity and is reflected in the dietary guidelines for calcium intake, which suggest highest intake during adolescence and early adult life when the greatest net growth of bone occurs (Ref. 3). Many experts argue that because of the increase in the bone resorption component of the remodeling activity that occurs at menopause in women, there is also a need for greater calcium intake at this stage of life (Refs. 23 and 67).

E. Importance of Peak Bone Mass and Its Relation to Calcium

Peak bone mass, the total quantity of bone present at skeletal maturity, may have the greatest bearing on whether or not a person is at risk of developing osteoporosis later in life. Most bone experts support the idea that the best way to reduce the risk of osteoporosis is to maximize the amount of bone formed at skeletal maturity which occurs by approximately age 35 (Refs. 2, 10, 16, 64, and 91). Experts agree that two factors, adequate calcium intake and physical activity, are critical to maximizing the amount of bone formed at skeletal maturity (Refs. 67, 91, 109, and 118). It is also widely held that if calcium intake is not adequate during childhood, adolescence, and early adulthood, full skeletal potential may not be attained (Refs. 16, 37 and 64).

Throughout life, bone is constantly changing and remodeling, but the components of bone remodeling, that is the rates of bone resorption and formation, differ at different stages of the life cycle. At puberty, bone formation occurs at an accelerated rate which results in an increase in both the length and density (mass) of bone (Ref. 118). While little to no further growth in length is experienced after the pubescent growth spurt, bone continues to grow in width and in mass adding approximately 10 percent or more mass over the next 10 to 15 years (Refs. 63 and 118). This later phase is known as the period of consolidation and continues until about 35 years of age, at which time a person is considered to be at peak bone mass or skeletal maturity (Refs. 10 and 118).

At midlife, between the ages of about 35 to 45, bone continues to remodel, but bone mass is maintained without change (balanced rate of resorption and formation). Thereafter, bone is lost at a constant rate of 0.3 to 0.5 percent per

year in both men and women (greater rate of bone resorption) (Ref. 20). Prior to and after menopause, women lose bone at a faster rate (2 to 5 percent per year) than men, but eventually return (between about 60 and 70 years of age) to the same rate of bone loss as men (Ref. 20). During the menopause, a decrease in the female hormone estrogen is the factor underlying this rapid rate of bone loss (Refs. 20, 90, and 118).

The postulated mechanism underlying the relationship of adequate calcium intake and optimal peak bone mass to the reduced risk of osteoporosis relates to the assumption that since all persons lose bone with age, those with higher bone mass at maturity take longer to reach the critically reduced mass at which fractures occur with minimal trauma (Ref. 20). Genetic factors probably have the greatest influence on setting the upper limit of an individual's peak bone mass (Ref. 64). One explanation why men have a lower incidence of osteoporosis than women is that men are genetically programmed to have a higher peak bone mass (Ref. 74).

Racial differences observed in the incidence of osteoporosis are also thought to be related to differences in genetically determined upper limits of bone mass. For example, Caucasian women, particularly those of northern European ancestry, experience the highest incidence of osteoporosis related bone fracture, while American women of African heritage have greater bone density and significantly lower (approximately 50 percent) fracture rates (Refs. 28, 4, 118, and 136). Experts suggest that the greater initial bone density (peak bone mass) observed in African Americans explains why they have fewer osteoporotic fractures than Caucasians and Asians (Ref. 28, 41, 89, and 118). Nevertheless, weight bearing exercise and diet can also influence the maximal amount of bone achieved, and unlike genetic factors, diet and exercise can be easily manipulated (Refs. 10, 78, 102, and 109).

F. Role of Calcium After Peak Bone Mass

Bone density later in life depends on both the amount of bone made during growth (peak bone mass) and the subsequent rate of bone loss after maturity. The impact of dietary calcium on bone loss that occurs between ages 35 to 45 or after peak bone mass is achieved but before menopause, is unclear, because limited data are available characterizing the rate of bone loss that occurs. Maintenance of an adequate calcium intake during the onset of menopause at about 45 to 50 years of age is important and may help to slow the rapid loss of bone at this time (Refs. 47 and 102). However, because the rapid rate of bone loss that occurs early in menopause is largely the result of the hormonal changes associated with the onset of menopause, a high dietary calcium intake alone will not effectively slow the rate of loss during this period of early hormone withdrawal in women (Refs. 7, 52, 109, and 120). Failure of men to experience this period of accelerated bone loss resulting from hormonal withdrawal is another explanation for the sex difference observed in the incidence of osteoporosis (Refs. 20 and 118).

G. Summary of Mechanism of Action of Calcium

Current scientific thought suggests that there are two mechanisms through which calcium intake may influence bone remodeling and ultimately, the risk of osteoporosis and related bone fracture. The first mechanism involves maximizing the amount of bone that is formed at skeletal maturity and the second involves slowing the rate of bone loss with age. Both mechanisms would allow an individual to maintain a higher bone mass later in life, thereby reaching the critical fracture threshold much later in life.

H. Regulatory History

1. Calcium

Calcium-containing food ingredients are used in food for a number of functional effects. In preparing this proposal, the agency identified those ingredients currently in use and their functions, conditions of use, and limits on the level for which they can be added to food (Ref. 33). For the uses of these ingredients in food to be lawful, they must be either generally recognized as safe (GRAS), or affirmed as GRAS by FDA, listed in the food additive regulations, or subject to a prior sanction. Of the 36 or more calcium-containing ingredients identified by the agency as currently in use, only the following 10 compounds have been demonstrated to FDA's satisfaction to be safe and lawful for use in a dietary supplement, or as a nutrient supplement by FDA: calcium carbonate, calcium citrate, calcium glycerophosphate, calcium oxide, calcium pantothenate, calcium phosphate, calcium pyrophosphate, calcium chloride, calcium lactate, and calcium sulfate.

FDA also allows the addition of calcium-containing compounds to certain foods for the purpose of fortification, under standards of identity. Examples of the foods in which calcium fortification (in mg per pound (mg/lb)) is allowed, and the permitted levels of fortification in mg per pound (mg/lb), include: 136.115 *Enriched bread*, permits the addition of 600 mg/lb; 137.260 *Enriched flour*, may contain 960 mg/lb; 137.260 *Enriched corn meal*, may contain up to 750 mg/lb; 137.350 *Enriched rice*, may contain up to 1,000 mg/lb; 139.115 *Enriched macaroni*, 139.155 *Enriched vegetable noodle product*, and 139.165 *Enriched noodle products*, may contain up to 625 mg/lb respectively; 139.120 *Milk macaroni*, calcium-containing milk solids content not less than 3.8 percent of the weight of the finished product; 139.121 *Nonfat milk macaroni products*, finished product contains up to 25 percent calcium-containing, nonfat milk solids; 163.130 *Milk chocolate;* 163.135 *Buttermilk chocolate;* 163.140 *Skim milk chocolate;* and 163.145 *Mixed dairy product chocolates*, contain not less than 3.66 percent and up to 12 percent by weight calcium-containing milk solids.

2. Health Claims

In the **Federal Register** of August 4, 1987 (52 FR 28843), FDA published a proposal to amend the food labeling regulations to codify and clarify the agency's policy on the appropriate use of health claims on food labeling. The comments received on this proposal strongly opposed the use of the health claims. In the **Federal Register** of August 8, 1989 (54 FR 32610), FDA published an advance notice of proposed rulemaking that asked for public comment on how to reasonably permit the use of health claims on food labels that link food components to reduction of risk of chronic disease. In the **Federal Register** of February 13, 1990 (55 FR 5176), FDA withdrew the 1987 proposal and reproposed a regulation outlining how the agency would allow health claims. Calcium and osteoporosis were among the specific diet and disease relationships mentioned in these documents. However, on November 8, 1990, as stated above, Congress passed the 1990 amendments. This action is being taken in response to those provisions.

I. Evidence Considered in Reaching the Decision

The agency has reviewed all relevant scientific evidence on calcium and osteoporosis. This evidence included several recent Federal government reports: "The Surgeon General's Report on Nutrition and Health" (Ref. 1); the National Institutes of Health's (NIH) "Osteoporosis Report of the 1984

Consensus Development Conference on Osteoporosis" (Ref. 6); the NIH 1984 and 1986 "Osteoporosis—Cause, Treatment, Prevention" (Ref. 5); FDA "Proceedings of the National Conference on Women's Health Series—Special Topic Conference on Osteoporosis" (Ref. 10); the Department of Health and Human Service's (DHHS) "Healthy People 2000: National Health Promotion and Disease Prevention Objectives" (Ref. 11); the 1990 International Conference sponsored in part by NIH, "Consensus Development Conference: Prophylaxis and Treatment of Osteoporosis" (Ref. 7); and the DHHS "Osteoporosis: Research, Education, and Health Promotion" (Ref. 8).

Other authoritative documents used included: the National Academy of Science's (NAS) "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 2); the NAS "Recommended Dietary Allowances" (Ref. 3); the World Health Organization's (WHO) "Diet, Nutrition, and the Prevention of Chronic Diseases" (Ref. 9); the Life Science's Research Organization (LSRO) "Calcium and Osteoporosis Report" (Ref. 13); and the NAS "Nutrition During Pregnancy Report" (Ref. 12).

The agency considered the conclusions reached by these documents in light of the findings of human studies and new review articles in the scientific literature published subsequent to these documents. To assure that its review of relevant evidence was complete, FDA requested in the **Federal Register** of March 28, 1991 (56 FR 12932), scientific data and information on the 10 specific topic areas identified in the 1990 amendments. The topic of calcium and osteoporosis was among the 10 subjects on which the agency requested information.

J. Comments in Response to FDA Request for Data and Information

In response to FDA's March 28, 1991 request for information other than that available in the authoritative documents cited in the **Federal Register**, the agency received comments from 17 sources. These sources included seven manufacturers of calcium supplements or calcium containing food products, three products or commodity interest groups, two consumer-public health interest groups, two academic institutions, two private citizens, and representatives of the Canadian government. These comments are described briefly here and will be considered, as appropriate, throughout the text of this document.

The majority of the comments supported a health claim proposal relative to calcium and osteoporosis, with only two comments, from a private citizen and from the Canadian government, opposing. A comment from a consumer advocate group urged FDA to be cautious and consider the consumer first and foremost when making its decision. Comments from an academic institution and from supplement manufacturers provided information purporting to demonstrate the effectiveness of a particular type of calcium supplement or food additive (fortificant) because of claimed superior bioavailability. The majority of the comments provided references or reviews of the calcium and osteoporosis relationship all of which were taken into consideration in preparing the science review.

II. Science Review

A. Federal Government and Other Reports

FDA identified seven documents in the **Federal Register** of March 28, 1991, that reviewed or made recommendations relative to the calcium-osteoporosis health relationship (Refs. 1 through 6, and 10). In addition, FDA considered the published conclusions of several recent government-sponsored conferences and reports and authoritative reviews (Refs. 7, 8, 9, 11, 12 and 13).

Comparing the conclusions from the first consensus conference on osteoporosis sponsored by NIH in 1984 (Refs. 5 and 6) to the most recent NIH-sponsored consensus conference held in October 1990 (Ref. 7), there is an evolution in thought concerning the importance of calcium intake to osteoporosis.

Changes in the recommended levels of calcium intake, and also changes in target population emphasis have in large part mirrored important clinical and epidemiological findings over the last decade. Initial emphasis was on a higher calcium intake for adults, with particular focus on postmenopausal women (Refs. 5 and 6). The 1984 NIH report suggested that all adults should consume more than the 1980 Recommended Daily Allowance (RDA) of 800 mg of calcium: "Adult women and probably adult men should have a total daily intake of 1,000 mg of calcium and women past menopause, not on estrogen therapy, need 1,500 mg daily" (Ref. 5).

NIH republished this document in 1986 (Ref. 5) with the following caveat: "It has not yet been proven by convincing scientific evidence that a high calcium intake will prevent osteoporosis." This qualification reflected the results of studies that failed to show that calcium intakes above the RDA or high calcium intake slowed bone loss in postmenopausal women (Refs. 109, 119 and 120).

The current focus presented at the 1990 "Consensus Development Conference: Prophylaxis and Treatment of Osteoporosis" shifts the emphasis on calcium intakes from older to younger individuals who are still actively laying down bone and recognizes that dietary calcium intakes below 1,000 mg per day of dietary calcium are adequate for adults (Ref. 7). The panel concluded that adequate calcium intake at all stages of life was a prerequisite for normal bone growth and attainment of peak bone mass. However, it also concluded that a high calcium intake is not as effective as a combination of adequate dietary calcium and estrogen therapy in blunting the accelerated bone loss during menopause. The panel also recognized that inadequate calcium intake is a risk factor for osteoprosis, citing a minimum intake of 800 mg calcium per day for all adults, and that "higher amounts are required in childhood, adolescence, pregnancy, lactation, and old age."

While the authoritative documents may present varying guidelines for adequate calcium intake, ranging from 800 to 1,500 mg per day for adults, they are unanimous in their recommendation that preventive efforts focus on maximizing peak bone mass (Refs. 1 through 3, 5, 6, 8 through 13). All of these documents emphasize that calcium intake is only one factor in this multifactorial disease, and that the exact nature of the association between calcium and osteoporosis is still unclear. The documents also agree that low calcium intake is a risk factor in the development of osteoporosis and may contribute to a lower peak bone mass or accelerate the rate of bone loss with aging (Refs. 1 through 3, 5, 6, 8 through 13). In addition, all these documents emphasize that during the interval of rapid bone loss that occurs early in menopause, both an adequate dietary intake in calcium and estrogen therapy are required and recognize the need for men and women to maintain adequate calcium intake later in life (Refs. 1 through 3, 5, 6, 8, through 13).

The 1987 FDA conference recognized that calcium is a threshold nutrient, i.e., deleterious effects may occur below a certain, unknown level of intake (Ref. 10). The NAS report on "Diet and Health: Implications for Reducing Chronic Disease Risk" emphasized, however, that potential benefits of calcium intakes above the RDA's to

prevent osteoporosis are not well documented (Ref. 2).

The recommendations for a particular level of dietary calcium intake are a key point of difference among the documents that set guidelines (Refs. 2, 3, 5, 7, and 11). "Recommended Dietary Allowances," published by NAS recommended an extra allowance of calcium to permit full mineral deposition through age 24, rather than through age 18, as in the 1980 edition of the calcium RDA (Ref. 3). The NAS made this change "to ensure a calcium intake that allows the development of each individual's genetically programmed peak bone mass during the formative years" (Refs. 2 and 3). Earlier recommendations of 1,000 to 1,500 mg calcium per day for peri- and postmenopausal women (Ref. 5) did not prevail, and the 1989 RDA for all adults of more than 25 years of age remained at 800 mg per day. This level for adults was recommended in the 1990 consensus conference, with higher, unstated levels for childhood, adolescence, pregnancy, lactation and old age (Ref. 7).

In summary, these documents show general agreement that, despite the lack of conclusive evidence, the data are sufficiently compelling to suggest that maintaining an adequate calcium intake during adolescent and early adult life may help to maximize peak bone mass and ultimately to reduce the risk of osteoporosis. Adequate calcium intake during the peri- and postmenopausal period in women and in elderly men is important, but alone, high calcium intakes will not prevent the accelerated rate of bone loss which normally occurs in peri- and early post menopause.

B. Recent Scientific Review of the Literature

1. Evidence Reviewed

A number of important studies have been published since the publication of the major authoritative and government documents described in the previous section. A thorough review of the literature from 1988 to March of 1991 revealed a number of review, commentary, and research papers dealing with various aspects of this subject. The criteria that the agency used to select studies required them to:

(1) Present primary, clinical data carried out in normal, healthy, nonpregnant, or nonlactating adolescents or adults;

(2) Be available in English;

(3) Include direct measures of bone status such as bone mineral density; and

(4) Include a measure or estimate of calcium intake or level of calcium supplementation.

The first criterion selected is consistent with the goals of the health claim in that it will be applied to a healthy normal population and is not to be a therapeutic claim. The second criterion is for convenience and was compelled by the timeframes imposed by the 1990 amendments. The third is consistent with the goal of the health claim in that it represents a direct measure of the health status of bone. The fourth criterion represents measurement of the nutrient for which evidence is sought to link adequate intake to the reduced risk of osteoporotic bone fracture.

FDA found that some of the papers identified in the literature search were not pertinent because they were carried out in subjects that were either not considered normal for their sex and age as a result of recent bone fractures or due to the diagnosis of osteoporosis or some other endocrine or dietary disorder (Refs. 14, 39, 40, 43, 56, 57, 84, 85, and 126). FDA did not consider others because subjects were inappropriately young (infants) (Refs. 81, 112 and 117), or the study failed to include a direct measure of bone status or calcium intake (Refs. 38, 62 and 135).

Furthermore, animal studies were not included in this review because "there is no completely satisfactory animal model of age-related or postmenopausal osteoporosis" (Ref. 2). While the extrapolation of animal studies to the human condition may not be appropriate, the results of studies in all animal models repeatedly show that low calcium intake causes reduced bone mass and osteoporosis (Refs. 46, 76, 77, and 127).

2. Criteria Used in Evaluating Studies

The criteria used in evaluating human epidemiological and clinical studies included:

(1) Reliability and accuracy of the methods used in food intake analysis and in assessing subjects, calcium intake for the day of study, lifetime, or their habitual intake, that is, the usual amount of calcium consumed;

(2) Choice of control subjects (e.g., age, sex, and race matched or matched for years since menopause);

(3) Representativeness of subjects;

(4) Control of confounding factors, particularly the level of activity or physical exercise must be controlled;

(5) The sensitivity of the endpoints measured, particularly with reference to the type of bone measured (cortical bone versus cancellous bone) or the bone site measured, (the rate of bone loss differs between types of bone and bone sites);

(6) Presence of recall bias and interviewer bias; and

(7) Degree of compliance and how compliance was assessed.

FDA evaluated the weaknesses and strengths of individual studies (see "Assessment" column of the Table). It then assessed the strength of the overall combined evidence (e.g., clinical intervention studies and epidemiologic studies) taking into account the strength of the association, the consistency of findings, specificity of the association, evidence for a biological mechanism, and presence or absence of a dose-response relationship. FDA's conclusions reflect the strength, consistency, and preponderance of data.

3. Evaluation of Evidence

FDA's evaluation of the totality of the recent human studies meeting the criteria outlined above is presented in Table 1. In addition, FDA considered a number of recent thorough reviews of this subject written by well-recognized experts which are not included in the Table (Refs. 16, 18, 20, 21, 22, 23, 26, 45, 49, 67, 69, 92, 103, 104, and 133).

To update and evaluate the impact of new findings on the earlier conclusions established by the authoritative and consensus documents, FDA sought to answer three questions:

First, do any of the studies present evidence documenting the role of calcium in achieving peak bone mass? The most frequently cited study supporting the importance of adequate calcium intake to the attainment of peak bone mass studied bone status and rates of hip fracture (cross-sectionally or at one point in time) in two areas of rural Yugoslavia (Ref. 96). The two communities were similar in several factors that could influence bone health and fracture rates (similar age, racial profiles, and levels of physical activity), but differed significantly in their usual calcium intake (about 400 versus 1,000 mg per day). Bone mass was significantly greater in both men and women by the age of 30 in the community with the higher calcium intake. More importantly, the incidence of hip fracture was significantly lower in the high calcium intake community with the higher peak bone mass. Experts concluded from this study that high life-long calcium intakes did not prevent bone loss since differences in bone mass as a function of age were constant in both groups, but it did increase peak cortical bone mass and significantly reduced the incidence of hip fracture later in life.

All the recent studies that examined subjects over a wide range of ages either

cross-sectionally (at one point in time) or longitudinally (several points over time) contributed some evidence relating to peak bone mass (Refs. 18, 25, 48, 60, 78, 82, 94, 97, 98, 99, 111, 123, and 125). Matkovic et al., (Ref. 97) demonstrated a trend toward an increase in bone density measured in two different skeletal sites in young teenagers who consumed higher levels of calcium over a period of 2 years relative to an age-matched control group. The controls consumed their usual, self-determined, or what is termed "habitual" calcium intake. However, the difference in bone mineral density between the high and low calcium groups was not statistically significant. This failure to show statistical significance could have been attributable to the small number of subjects studied (28 total). In another clinical trial, Baran et al., (Ref. 25) demonstrated no change in bone loss in women (30 to 42 years old) consuming 1,300 to 1,500 mg of calcium per day over 3 years, as compared to a control group that did not consume added dairy products and that showed a significant 2.9 percent loss of bone.

In a large supplementation study in women 35 to 65 years of age, Smith et al., (Ref. 123) demonstrated that daily supplementation of 1,500 mg calcium per day over 4 years in premenopausal women significantly reduced the loss of bone mineral relative to controls. Several cross-sectional studies in premenopausal women showed significantly higher bone density in women consuming higher calcium intakes (Refs. 60, 78, 94, and 111), yet others have failed to demonstrate a significant positive correlation between bone density and calcium intake (Refs. 19, 48, 86, 98, 99, and 125). In one study in men (Ref. 82), calcium intake was found to be an excellent predictor of bone density of the spine.

A critical concern in evaluating the effectiveness of dietary calcium intakes on bone density is that calcium intakes at the time of interview do not always correlate well with bone density measures that reflect a lifetime of a variety of influences. This lack of correlation between intake and bone density is particularly true for postmenopausal women (Refs. 94 and 124). However, in two studies where lifetime or historical calcium intake (intake estimated at age 20) was determined, there was strong positive correlation between high lifetime calcium (>500 mg per day) intake and bone mineral density of the mid and distal radius (Ref. 60) and the lumbar spine (Ref. 111). Cauley et al. (1988) showed that postmenopausal women who reported high lifetime intakes of calcium had significantly greater bone density than those who reported lower lifetime intakes (Ref. 36). Reliability of calcium intake estimates, either current, habitual, or lifetime estimates, is also a concern because these data are usually the weakest factor in these studies.

While the results of the more recent studies do not provide definitive evidence linking high calcium intake to achievement of maximum peak bone mass, they do provide evidence demonstrating a trend for increased bone mass in a carefully controlled, clinical trial (Ref. 97), and evidence of a strong positive correlation to bone density when lifetime calcium intakes were estimated (Refs. 36, 60 and 111). Moreover, the results of some of these studies demonstrate that a high calcium intake is beneficial in reducing the rate of bone loss in premenopausal women shortly after peak bone mass is achieved (Refs. 25, 78, and 111). A large intervention trial that utilized subjects over a wide range of ages showed a positive correlation between calcium intake and bone mass (Ref. 123). However, the results did not indicate whether this occurred through a maximization of peak bone mass or through a slowing effect on the rate of bone loss after skeletal maturity. Thus, the recent data, although not definitive, are sufficiently compelling to support the link between adequate calcium intake and achievement of peak bone mass.

The second question asked in reviewing these studies is whether added calcium or high calcium intake reduces the risk of fracture, or slows the rate of bone loss in younger or older subjects. Variation in results from the older studies underscores the lack of conclusive evidence that high calcium intake delays the development of osteoporosis. As stated in the NAS report on "Diet and Health Report: Implications for Reducing Chronic Disease Risk" (Ref. 2):

> Many published reports have shown either no relationship or only a modest relationship between dietary calcium and cortical bone mass. * * * evidence that calcium supplementation prevents trabecular bone loss associated with menopause is at best weak. There is strong evidence that calcium supplementation has a modest influence in preventing cortical bone loss, but * * * evidence relating calcium supplementation to fracture prevalence is scanty.

The lack of consistency in results in these older studies is the result in part of the various confounders that are also, regrettably, present in some of the more recent studies. Higher calcium intakes were shown to slow the rate of loss in premenopausal women consuming more dairy foods (Ref. 25) and in those consuming calcium supplements (Ref. 123). In postmenopausal women, calcium supplementation had no effect on spinal bone loss early in their menopause, but for women late in their menopause, the rate of bone loss was significantly reduced with calcium supplementation if initial habitual calcium intakes were lower than 400 mg per day (Ref. 47). This finding presents strong evidence supporting what others have shown—that spinal bone (predominantly cancellous bone at this site) loss in early postmenopause is less responsive to calcium supplementation than cortical bone of the hip or radius (Ref. 120). Stevenson et al., (Ref. 124) also found that dietary intake of calcium did not influence the rate of bone loss after 12 months of supplementation in women studied during the first 5 years of menopause.

In a large study examining women 35 to 65 years of age, calcium supplementation of postmenopausal women was shown to counteract a large portion of the annual bone loss that is attributable to menopause (Ref. 123). Others found that the rate of bone loss after 9 months of calcium supplementation (about 1,700 mg per day) in postmenopausal women was lower than in untreated controls, but the difference did not reach statistical significance (Ref. 113). In this study, when comparisons were made only between women within 10 years of the onset of menopause, there was a significant reduction in the rate of bone loss with calcium supplementation from dairy products. Others showed no relation between habitual calcium intake in postmenopausal women and bone mineral density of the radius in a cross-sectional study (Ref. 128) or of the radius, femoral neck or spine in a longitudinal study (Ref. 131). Habitual calcium intake exceeding 800 mg per day was not effective in preventing cortical bone loss in early menopause (Ref. 132).

It is apparent that a large part of the inconsistency observed in studies involving postmenopausal women may be the result of the overwhelming influence of the hormonal change early in menopause versus that of late menopause. With the exception of Polley et al., (Ref. 113), these findings suggest that subjects studied in early menopause are less responsive to increased calcium intake, but that women in late menopause are responsive. These findings suggest the

possibility that adaptational influences come into play later in menopause.

Another factor that may contribute to the inconsistency of study results is the differential response of the various skeletal sites measured. Fujita, et al., (Ref. 55) showed an increase in forearm bone density (primarily cortical bone at this site), but no change in spinal bone (mostly cancellous bone at this site), with calcium supplementation of subjects greater than 70 years of age (late menopause) for 2 years. Holbrook et al., (Ref. 72) found that the age-adjusted risk of hip fracture was associated with low estimates of dietary calcium intake in a large population of men and women aged 50 to 79 at the start of the 14-year study.

The results of the recent clinical trial of Nelson et al., (Ref. 102) underscores this point concerning the differential responses between cortical and cancellous bone to increased calcium intake. In this study, results showed a 1.1 percent loss of bone density in the femoral neck (cortical bone) in postmenopausal women consuming a moderate calcium intake, and a significant 2 percent gain in femoral neck bone density in women consuming a high calcium intake. However, calcium intake had no measurable effect on bone mineral density of the spine (cancellous bone) in this 12-month study.

Thus, as reported for earlier studies, inconsistencies also exist in the results of recent studies examining the effect of calcium intake on slowing the rate of bone loss. However, recognition of the facts that bone sites respond differently to high calcium intake, and that their responsiveness to calcium varies with time after menopause, requires that any evaluation of these studies place less weight on those that found no effect of calcium on spinal bone density in early menopause because of what is thought to be the overriding effect of estrogen withdrawal. Given the current understanding, evidence becomes more compelling in support of the hypothesis that adequate calcium intake slows the rate of bone loss in general in perimenopausal women (Refs. 25, 78, 111, and 123) and in predominantly cortical bone sites in women late in menopause (Refs. 36, 47, 55, 102, and 113).

The third question considered was whether or not any of the studies showed a threshold effect for the level of calcium intake associated with changes in bone mass. The concept that calcium is a threshold nutrient was discussed in the FDA sponsored conference on osteoporosis in 1987 (Ref. 10). Concern focused on the lower threshold suggesting that low dietary calcium is a permissive element rather than a causative element in the development of osteoporosis (Ref. 65). Only recently have the upper limits of the effect of calcium intake been explored.

Kanders et al. (Ref. 78), in their cross-sectional study, showed that bone mineral density of the spine did not increase with calcium intakes above 800 to 1,000 mg per day, which implies an upper limit of calcium intake on optimizing peak bone mass in premenopausal women. Halioua and Anderson (Ref. 60) observed similar results at levels above 800 mg of calcium per day in postmenopausal women. These studies support the concept of an upper level of calcium intake beyond which no benefit to bone status can be observed.

The more important aspect of the threshold concept is the lower level, the level of calcium intake below which bone health is impaired. The findings of Dawson Hughes et al. (Ref. 47), suggest that for women in their late menopause this level is probably around 400 mg per day. This question clearly needs further research and careful definition.

Another important consideration is the speculation presented by Kanders and her coauthors (Ref. 78) concerning their findings that bone mineral density of the spine can be influenced by both physical activity and optimal calcium nutrition during the period of consolidation in young adult women. The authors speculate that if their findings of an increase in spinal bone mass were applied longitudinally (over time), one may be able to delay the development of osteoporosis and related bone fractures for an estimated 10 years (Ref. 78).

To summarize these new findings, some aspects of the relationship between calcium and osteoporosis remain unclear, but with the growing understanding of how other factors confound these results, it is becoming increasingly evident that calcium intake has a significant impact on bone health. Study results must be interpreted in light of new findings concerning the sensitivity of specific bone sites to diet, the limitations of the effect of diet during early menopause, and the inherent weaknesses of measuring or estimating habitual, current, lifetime or historical calcium intake, the independent variables in the recent studies reviewed here. This issue of accurate determinations of calcium intake is discussed at length in the LSRO report on "Calcium and Osteoporosis" (Ref. 13), where the authors emphasized that the weakest point in determining the relationship between calcium intake and changes in bone mass rests with the inadequacies of determining this independent variable, notably an accurate and reliable estimate of calcium intake. It is now apparent that calcium's effect on retarding bone loss in postmenopausal women may be influenced by habitual calcium intake, where persons with lower habitual intakes show the greatest response (Ref. 47). Thus, recent findings were generally consistent and strengthened the conclusions and guidelines set forth in the government and authoritative documents.

III. Decision to Accept Health Claim

A. Public Health Context

Osteoporosis is a major health concern of the elderly, particularly women, since 25 to 30 percent of all postmenopausal women are affected (Ref. 18). The etiology of this disease is multifactorial with sex and race being the strongest influences (Ref. 118). Low calcium intake has been identified as a risk factor, although controversy exists concerning the extent of its effect (Refs. 65, 79, and 80). Many experts argue that a lifetime low calcium intake, that is at levels below the level of obligatory loss (calcium that the body must lose every day in fecal secretions and urine), which is usually 150 to 300 mg per day but which some have defined as 300 to 400 mg per day, may result in low peak bone mass and above average loss of bone mass in adults (Refs. 6 and 87).

B. Dietary Calcium Intake

National food intake surveys (Refs. 35, 54, and 105) provide evidence identifying calcium from dietary sources as a problem nutrient in a subpopulation at risk for osteoporosis, namely women between 11 through 35 years of age. These surveys show that men have a greater intake of calcium than women largely as the result of greater total caloric consumption by men rather than as a result of differences in types of foods consumed. These surveys suggest that as early as 9 years of age, mean calcium intake for women is well below the RDA and remains low from early to late adulthood. These dietary data alone, however, are insufficient to establish calcium status of women 9 years and older with low dietary calcium intakes.

C. Sources of Calcium

For the general population, diet is the primary source of calcium (Ref. 63). However, for some individuals, calcium in vitamin/mineral supplements or contained in drinking water or in certain chronically used medicines are

significant sources of their total daily calcium intake (Ref. 63). Calcium is not uniformly distributed in the food supply. Milk and milk products are among the richest sources of calcium and have been shown in recent surveys to contribute approximately 40 percent of the total dietary calcium ingested by adult men and women and nearly 65 percent of the daily calcium in children (Ref. 54).

D. Guidelines for Calcium Intake

The National Academy of Sciences set the RDA for men and women 19 years of age and older at 800 mg per day in 1980. However, acknowledging that greater calcium intake is needed during the period of consolidation to maximize peak bone mass, NAS redefined the adult age range to include men and women 25 years and older in the 1989 revision (Ref. 3). Because of differences in physiologic need, it set the RDA for adolescents 11 to 24 years of age at 1,200 mg per day; for children (1 to 10 years) at 800 mg per day; at 540 mg for infants (0.5 to 1 years); and at 360 mg per day for neonates (Ref. 3). By definition, the RDA for any nutrient contains a large margin of safety, representing adequacy for 95 percent of the healthy normal population (Ref. 3).

E. Safety of Calcium Guidelines

Calcium toxicity is not generally recognized as a problem in the United States population because normal healthy people have intrinsic control mechanisms that prevent excessive serum levels (Refs. 22, 63, and 73). The main control occurs at the level of absorption because calcium absorption becomes less efficient as calcium intake increases. The usual side-effects that are the hallmark of calcium toxicity include hypercalcemia (elevation of calcium in the blood) which has neurologic and neuromuscular effects, excessive calcium loss in urine, formation of kidney stones, and deposition of this mineral in soft tissue.

In 1979, an expert panel reviewed the data on the safety and effectiveness of various vitamin and mineral products and concluded that "calcium intakes ranging from 1,000 to 2,500 mg daily do not result in hypercalcemia in normal individuals" (Ref. 53). Calcium toxicity is, however, a concern for individuals who for some physiologic reason hyperabsorb calcium from the gut or from filtered urine. Most common among these individuals are those with a family history of kidney stones. For the normal healthy population, the guidelines for calcium intake (RDA) are considered well within the limits of safety.

F. Rationale Leading to the Decision to Accept Health Claim

FDA has proposed no specific provisions pertaining to the agency's assessment of conformance with the standard. Instead FDA envisions that to satisfy the scientific standard, a health claim must be supported by a sound body of scientific evidence that establishes the relationship between a dietary component and a particular disease or health related condition. The data must persuade FDA that the proposed claim is valid, and that the benefits featured in the claim pertain to the general U.S. population or to a significant segment of the U.S. population. Thus, the body of scientific data must be strong. A few unconfirmed studies, preliminary or incompletely documented data, or significantly contradictory findings do not constitute a sound body of evidence.

The standard requires that significant agreement exist among qualified experts that the claim is valid. "Qualified experts" include individuals whose training and experience have produced a general or specific scientific expertise in the diet/health topic being considered for a specific claim. FDA is not proposing to define "significant agreement" among experts because each situation may differ with the nature of the health benefit. The agency believes that any specific definition of such agreement might prove arbitrary when viewed in the light of the multiplicity of potential health benefits and the widely variable nature of expertise required to evaluate the significance of these benefits. Instead, FDA intends to use the discretion granted it by the 1990 amendments to assess the degree of agreement on a case-by-case basis. Nevertheless, FDA will take the full range of opinions among qualified scientific experts on a specific claim into account in determining whether significant agreement exists.

FDA does not prescribe a specific set, type, or number of studies as being sufficient to support a health claim for the procedure to assess conformance with the scientific standard. The agency will consider all relevant data on a topic, including clinical studies (human studies conducted in a controlled clinical setting), epidemiological data (data from uncontrolled human populations), and animal studies. However, the type, quality, and relevance of a study from which data are derived have an important bearing on how much weight is placed upon the data. Because of the many unknowns about the direct effect of a dietary substance on health or disease relative to the effects of other environmental and genetic variables, and given the limitations on the ability to accurately quantify dietary intake for some substances, indirect approaches are usually required to assess the scientific weight of a set of data.

The overriding principle will be to determine whether there are consistent results from different types of well-conducted human studies by different investigators in different populations. The strengths and weaknesses of each individual study will be evaluated. When experiments with animal models are appropriate, consistency of results between human and animal studies will also be considered. Such results will be interpreted in the light of any available evidence on the biological mechanism of the substance-disease relationship, evidence of a dose-response relationship, and similarity of the test substance with the nutrient or food component of interest. The significance of the disease from a U.S. public health standpoint will be also evaluated. In sum, FDA intends that its judgments concerning the overall quality of available data, the appropriateness of the study design, the consistency across different types of studies and laboratories, and the conclusions derived from the total body of evidence will be based on the generally recognized scientific procedures and principles that are most appropriate to the issues being addressed.

FDA has reviewed the conclusions in the Federal government and other documents (Refs. 1 through 13) and in recent review articles on calcium intake and osteoporosis (Refs. 16, 18, 20, 21, 22, 23, 26, 45, 49, 67, 69, 92, 103, 104, and 133). It also examined the totality of pertinent human studies published since the NAS report on "Diet and Health: Implications for Reducing Chronic Disease Risk" (Refs. 18, 25, 36, 47, 48, 55, 72, 78, 82, 86, 94, 97, 98, 99, 102, 111, 113, 123, 124, 125, 128, 131, and 132). In addition, the agency considered all comments received in response to the notice of request for scientific data in the **Federal Register** of March 28, 1991, on the link between calcium intake and osteoporosis. Based on the overwhelming concurrence among the experts in this area, FDA proposes to allow a health claim on the label of products that meet the regulatory specifications set forth in proposed § 101.72. The health claim will relay the message that an adequate intake of calcium throughout life may delay the development of osteoporosis and ultimately reduce the risk of bone fracture in some individuals later in life.

The tentative decision to allow the proposed claim is based on significant agreement among experts in the field concerning three important conclusions. First, experts conclude that maintenance of adequate calcium intake during all stages of life is important to normal bone health and to optimal peak bone mass, and that optimizing bone mass at skeletal maturity (at about 35 years of age) may help to delay the onset or reduce the risk of osteoporosis and related bone fracture. To produce definitive evidence directly linking calcium intake to optimized bone mass and ultimately to reduced risk of osteoporosis and the delayed onset of bone fracture would require a 50- to 60-year-long study. However, there is overwhelming agreement among experts and among the authoritative documents reviewing this subject that adequate calcium intakes are important in optimizing bone health and therefore in reducing the risk of osteoporosis. With a higher peak bone mass, individuals have a lower risk of reaching the critical fracture threshold. Review of recent data did not refute this conclusion; it strengthened it, demonstrating a trend toward increased bone mass with higher calcium intake.

Secondly, for older adults, experts have concluded that maintenance of adequate dietary calcium is crucial to slowing the rate of bone loss, notably during the first decade following menopause. However, for the postmenopausal women, calcium alone will not significantly slow the rapid rate of bone loss that occurs shortly after menopause. The recent literature also supports this conclusion with rigorously controlled intervention studies or studies with more accurate measures of estimated calcium intake. These recent studies demonstrate the bone loss-slowing effects of calcium on bone sites known to be responsive to this nutrient and in women late in menopause, when the overriding effect of estrogen withdrawal does not mask the beneficial effect of adequate dietary calcium.

Thirdly, bone experts have concluded that the recommended calcium intake levels are safe and there is a growing recognition that RDA guidelines are adequate and can be reached within the context of the total daily diet. Current evidence supports the concept that a threshold nutrient intake level exists for calcium, below which bone health is jeopardized, and the concept of an upper limit of intake, above which bone derives no further benefit (Refs. 10, 47, 64, 78).

Maintaining an adequate calcium intake is a concern in certain segments of the United States population. Estimates of daily calcium intake for men and women determined in the most recent nationwide surveys show that for men, mean calcium intake closely approximates the guideline for intake throughout their life span (Refs. 35 and 105). However, both surveys show that the average calcium intake for women falls well below the 1980 RDA guideline and remains below the RDA with increasing age. This low calcium intake in conjunction with high rates of osteoporosis in the elderly, female, U.S. population is of greatest concern in adolescent and young adult women, an age group with the highest calcium requirement and who comprise the population at greatest risk of developing osteoporosis (Refs. 2 and 3). Others at risk of osteoporosis because of low calcium intake include those individuals, notably women and elderly men, whose calcium intakes may be less than the amount of calcium that is naturally required to be lost each day in urine or in gastrointestinal secretions or sweat (Ref. 8). No individual should consume less calcium than they naturally lose in a day which is normally about 200 mg or in the range of 150 to 300 mg, but may range between 300 to 400 mg per day (Refs. 3, 8, 66, and 88). A decision to allow a health claim would help the public to meet one of the dietary goals established in the federally sponsored "Healthy People 2,000: National Health Promotion and Disease Prevention Objectives" (Ref. 11), since the labels will facilitate the recognition of calcium-rich products.

The newer evidence is supportive of, and does not contradict the scientific consensus reached earlier. However, from the findings of the documents and studies cited above, the role of calcium in reducing the risk of osteoporosis is most relevant for those subpopulations at greatest risk because of sex, race, or family history.

IV. Description and Rationale for Components of Health Claim

A. Relationship Between Calcium and Osteoporosis

Based on the totality of the evidence and significant scientific agreement among experts qualified by training and experience to evaluate such claims, FDA has tentatively determined that there is adequate scientific evidence that consumption of an adequate calcium intake throughout life may optimize peak bone mass during adolescence and early adulthood and help to slow the rate of bone loss later in life. By maximizing the amount of bone present in old age through higher peak mass and subsequent slower rate of loss, one may reduce the risk of osteoporosis and related bone fractures.

In proposed § 101.72(a), FDA describes the relationship between calcium and osteoporosis. Experts have identified low or inadequate calcium intakes as one of many risk factors in the development of osteoporosis (Refs. 21, 63, 95, and 118). Inadequate calcium intake is thought to contribute to low peak bone mass (Ref. 10). Peak bone mass is the total quantity of bone present at skeletal maturity which experts believe has the greatest bearing on whether a person will be at risk of developing osteoporosis and related bone fractures later in life (Refs. 21, 64 and 118). The rate of bone loss after skeletal maturity also influences the amount to bone present at old age and also influences an individual's risk of developing osteoporosis (Refs. 21 and 118).

Experts conclude that an adequate calcium intake maintained throughout life, particularly during adolescence and early adulthood, will help to achieve one's genetically programmed upper limit of bone density (Refs. 2, 3 and 64). The rationale linking adequate calcium intake and optimal peak bone mass to the reduced risk of osteoporotic fracture relates to the fact that all individuals lose bone as they age. However, those individuals with more bone present at maturity take longer to reach the critical reduction in bone mass at which bone fractures with little trauma (Ref. 20).

Bone density later in life depends on both the amount of bone made during growth (peak bone mass) and the subsequent rate of bone loss after maturity. Maintenance of an adequate calcium intake later in life has been shown to be important in reducing the rate of bone loss particularly in the elderly (Refs. 63 and 118) and in women during the first decade following menopause (Refs. 47, 63, 67, 102 and 118).

In proposed § 101.72(d)(3), FDA requires that the health claim state the mechanism of optimizing peak bone mass during adolescence and early adulthood and the mechanism of helping to slow the rate of bone loss at menopause in women and in the elderly by adequate consumption of calcium. These mechanisms link calcium intake to the disease state of osteoporosis. In the label statement, FDA proposes to allow the concept of achieving peak bone mass to be conveyed to the public with a simpler phrase such as "build and maintain good bone health."

B: Significance of Calcium

In proposed § 101.72(b), FDA is describing the significance of calcium in affecting osteoporosis. The agency has tentatively identified those factors that describe the multifactorial nature of osteoporosis and has identified those risk factors that identify subpopulations of individuals who would most benefit from a lifelong, adequate calcium consumption. In proposed §§ 101.72(b) and 101.72(d)(2), FDA tentatively proposes to require specific identification of those individuals within the general population at greatest risk of developing osteoporosis and for whom the proposed health claim would have greatest benefit. These individuals include Caucasian and possibly Asian women and adolescent girls between 11 and 35 years of age, men and women with family histories of osteoporosis, menopausal women (who may be identified as middle-aged women in the label statement), and elderly men and women.

Proposed § 101.72(d)(2) also tentatively requires that the health claim not convey the misconception that the risk of osteoporosis is equally applicable across the general United States population. Many individuals in the U.S. population are at much lower risk for the development of osteoporosis than the target populations described above. This fact was presented to the public as early as 1984, when NIH identified those individuals at greatest risk of osteoporosis in their publication, "Osteoporosis: Cause, Treatment, Prevention" (Ref. 5). Being Caucasian was cited as the third greatest risk factor following being a woman and early menopause (Ref. 5). The document further stated that "white women are at higher risk than black women and white men are at higher risk than black men and oriental women are also thought to be at greater risk for the disease, but there is not enough data to confirm this" (Ref. 5).

African Americans have a significantly lower incidence of osteoporosis-related bone fracture than Caucasian Americans (Refs. 28, 41, 118, and 136). This lower incidence of osteoporosis in African Americans is attributed to a significantly higher peak bone mass than Caucasian Americans (Ref. 28). Asian Americans are reported to have lower bone mineral content of the radius than age-matched Caucasians (Refs. 21 and 134). However, recent findings show that hip fracture rates among Asian Americans are approximately half that of Caucasians (Ref. 121). Data on time trends in the incidence of hip fractures are available for Caucasians and to a limited extent Asian populations (Ref. 136). These data indicate an increase in the incidence of hip fractures in Asian women and men. Information on the bone density and fracture incidence among Hispanics in America is limited but reported to be lower than Caucasians (Ref. 136).

The vast majority of studies examining calcium intake and bone status exclusively use Caucasian subjects (Ref. 13), largely because the incidence of the disease is higher in Caucasians. In addition, surveys indicate that other races such as African Americans have a much lower calcium intake purportedly because of their inability to digest the milk sugar, lactose (lactose intolerance) (Refs. 50, 51 and 63). In light of the facts that African Americans have genetically higher peak bone mass, significantly lower incidence of osteoporosis-related bone fracture, lower calcium intakes, and significantly higher incidence of lactose intolerance, they are at much lower risk of developing osteoporosis and presumably would not benefit by increasing their calcium intake. Moreover, with milk and milk-related products contributing the greatest portion of dietary calcium to daily calcium intake (Ref. 54), trying to consume because of dietary calcium may result in greater incidence of discomfort due to lactose intolerance. A similar statement could be made for other racial groups such as Hispanic Americans, although far less data is available concerning the incidence of osteoporosis-related bone loss in this population, but they have been identified as having low calcium intakes and lactose intolerance (Refs. 51, 63 and 137).

FDA does not want to mislead those individuals within the population for whom there is no apparent benefit to bone health from consuming relatively higher levels of calcium over a lifetime. However, this is a difficult concept to present on a label claim without confusing the general population. Thus, the agency solicits comment on alternative ways of presenting this information and tentatively proposes in § 101.72(d)(2) that the claim shall not convey the misconception that the risk of osteoporosis is equally applicable to the general United States population, and that the subpopulation clearly at greatest risk is identified. This subpopulation includes Caucasian females but may also include Asian females. The agency has proposed that the subject of appropriate population targeting for the calcium and osteoporosis health claim, and how to most clearly present this information to the public, as an objective of the focus groups assembled to examine the impact and interpretation of the new labeling.

Men have greater peak bone mass than women across all races, and in addition men do not undergo the rapid rate of bone loss that women experience at the onset of menopause (Refs. 74 and 136). These factors contribute to men having a significantly greater bone mass in later years than women. These differences in the rate of loss of bone and in the total bone mass at maturity help to explain the significantly lower incidence of osteoporosis in men compared to women (Refs. 20 and 118)

Calcium intake is not the only recognized risk factor in the development of osteoporosis. Other factors include a person's sex, race, hormonal status, family history, body stature, level of exercise, general diet, and specific life style choices, such as smoking and excess alcohol consumption. Experts have identified those individuals at greatest risk of developing osteoporosis as being older, Caucasian or Asian, female and menopausal (natural or premature), thin and slight in stature with a relatively sedentary lifestyle (Refs. 10, 83, 109 and 118). Cigarette smoking and high alcohol intake also increases individual risk for the development of osteoporosis (Refs. 64 and 83).

In proposed § 101.72(d)(1), FDA tentatively proposes to require that the claim make clear that calcium is not the only recognized risk factor in the multifactorial bone disease, osteoporosis, by identifying specific other risk factors including sex, race, family history, and the need for adequate exercise and a well-balanced diet. Because osteoporosis is multifactorial, FDA believes that it is not possible to quantitate the amount of reduced risk of osteoporosis that results from adequate calcium intake throughout life. Therefore, FDA is proposing in § 101.72(d)(4) to require that a claim not quantative the degree of reduced risk.

In proposed § 101.72(d)(5), FDA is providing that a claim shall state that a total dietary intake of calcium of greater than 200 percent of the RDI (1,800 mg) has no known additional benefit. This provision reflects the findings discussed above that calcium intakes of 800 to 1,000 mg of calcium a day appear to be the upper level of calcium intake beyond which no benefit to bone status has been observed (Refs. 60 and 78). The agency has tentatively set this level at 1,800 mg a day to reflect that higher

amounts of calcium are needed in old age (Ref. 7).

C. Proposed Qualifying Levels of Calcium

In proposed § 101.72(c)(2), FDA is proposing to identify the calcium content levels needed to qualify for a health claim. In the companion document on general requirements for health claims, published elsewhere in this issue of the **Federal Register**, FDA has tentatively concluded that for nutrients for which increases in intake are associated with a desirable health outcome, FDA's proposed criterion for a "high" amount of a nutrient shall be the basis for determining the minimum amount of the nutrient that must be in a food for the food to be eligible to bear a health claim. This criterion is described in the proposal on nutrient content claims, published elsewhere in this issue of the **Federal Register**. For calcium, a product must contain a minimum of 20 percent of the proposed RDI for calcium (see companion document on Mandatory Nutrition Labeling published elsewhere in this issue of the **Federal Register**) or 180 mg of calcium per reference amount customarily consumed and per labeled serving to meet this criterion. This amount may either be naturally occurring in foods or may be added to a food or a supplement.

In proposed § 101.72(c)(1), FDA is requiring that a product satisfy all the requirements of § 101.44. Among these requirements is that if a calcium-containing ingredient is added to a food or supplement, the use of that ingredient must be demonstrated by the proponent of the claim to be safe and lawful under the applicable food safety provisions of the act. This showing can be made in a number of ways, including a showing that the use of the substance is:

(1) GRAS as listed in 21 CFR part 182, or in accord with the general principles stated in 21 CFR 170.30, provided that the use of the ingredient remains at individual consumption levels consistent with its use prior to January 1, 1958; or

(2) Affirmed as GRAS in 21 CFR part 184, approved for use as a food additive, or subject to a sanction or approval granted by FDA or the U.S. Department of Agriculture (USDA) prior to September 6, 1958.

In addition, FDA is proposing in § 101.72(c)(3) that the calcium content of the product, either added or natural, be assimilable as required in the calcium and iron enrichment of cereal-grain products (21 CFR part 137). Benefits of calcium intake from foods and supplements can only be obtained if the calcium is available for metabolic use by the body. There is strong evidence that dietary intake of protein, fiber, phosphorus, and certain naturally occurring and added substances such as oxalate, phytate, and fiber interfere with calcium absorption or metabolism (Refs. 15, 63, 69, and 71).

FDA is concerned about the bioavailability (ability to assimilate) of the calcium contained in products that make a health claim. It would be misleading to put a health claim for a substance on a food if consumption of that food will not provide the substance. Spinach illustrates the concern that products contain bioavailable calcium. While spinach is rich in calcium, it is not an appropriate candidate for a health claim on its label because of its established poor calcium bioavailability (Ref. 70). FDA recognizes the difficulty of assessing mineral bioavailability in humans where inter-individual variation is a significant confounding factor. For this reason, FDA requests comments on how calcium bioavailability can be assessed without bias in products under review for health claim eligibility. More specifically, the agency requests comments that would flag other foods or food components that are good sources of calcium but have poor bioavailability. These solicited comments should also consider products that are processed in such a way that the processing alters the bioavailability. For example, yeast enzymatic cleavage of phytase during the leavening of bread alters calcium bioavailability (Ref. 15). The agency also requests comments on how to address the issue of bioavailability for calcium supplements (Refs. 66, 69, 108 and 122).

D. Proposed Disqualifying Components of Products

Calcium bioavailability means both absorption and tissue utilization of calcium. Therefore, the presence of food or supplement components that cause increased urinary or fecal excretion, or impair the utilization of calcium by bone, would disqualify a product for a calcium-osteoporosis claim. Thus, FDA is proposing in § 101.72(c)(4) to disqualify calcium supplements from a health claim if they fail to meet the United States Pharmacopeia standards for disintegration (Refs. 122, 129 and 130) and dissolution (Refs. 122, 129 and 130). These products should not contain any substance, such as a salt of orotic acid, that is known to be harmful and to have adverse effects on calcium metabolism or on nutrient status (Refs. 42, 61 and 75).

High levels of dietary phosphorus and protein significantly adversely affect the metabolism and obligatory loss of calcium, respectively (Refs. 2, 3 and 17). The agency, however, is not proposing to disqualify high protein products from bearing a calcium claim. Like calcium, protein is not ubiquitously distributed in our food supply and is richest in specific food sources (Refs. 27 and 110). Some of these protein rich foods, such as milk or milk products, contribute more than half the calcium and protein intake of some individuals, notably children. Thus, relatively few foods are sources of calcium and protein, forcing consumers to be selective to meet the nutritional needs for both calcium and protein. It would be misleading to disqualify a product that is both rich in calcium and protein based on the protein's effect on urinary excretion of calcium without knowledge of what contribution this product made to the consumer's total protein intake.

While only a few foods are rich in calcium and protein, nearly all foods contain phosphorus as either a natural component or as an ingredient added during processing (Refs. 17, 31 and 58). Thus, unlike for calcium, consumers do not have to be selective to meet their daily phosphorus needs. In contrast to the low calcium intakes that have been reported for the majority of American women, phosphorus consumption is high for both men and women (Ref. 31). National nutrition surveys indicate that the diets of teenagers and young adults are relatively high in phosphorus and low in calcium (mean daily intake of 500 to 600 mg per day of calcium and greater than 1,000 mg per day of phosphorus) (Ref. 105).

According to NRC's 1989 report "Recommended Daily Allowances," the desired calcium to phosphorus ratio of the United States diet is 1:1, but the ratio of actual food consumption patterns differs with age (Ref. 3). Infant consumption patterns produce a ratio of 2.3:1 for human milk, that decreases with age to 1:1.8 for adults but may be as low as 1:4 for individuals with low intake of dairy foods or green vegetables (Ref. 3). Protein rich foods such as milk, meat, poultry, fish, cheese, and cereal grains contribute the majority of phosphorus in the American diet, but highly processed and convenience foods can contribute 20 to 30 percent of the daily phosphorus as food additives (Ref. 58). Evidence shows that phosphorus intake may be underestimated as much as 15 to 20 percent, because the phosphorus supplied by numerous food additives in processed foods are not always accounted for in tables of food composition (Ref. 106).

FDA is proposing that high levels of phosphorus (naturally occurring or added) in conventional foods or supplements that result in calcium to

phosphorus ratios lower than 1:1 will disqualify the product from bearing a calcium/osteoporosis health claim. FDA's tentative decision to identify phosphorus as a disqualifying nutrient is based on the ubiquitous distribution of this mineral in the food supply, the low ratio of calcium to phosphorus that typifies current intake patterns, and current evidence demonstrating that high levels of dietary phosphorus coupled with low dietary calcium adversely influence hormonal factors that regulate calcium and bone metabolism (Refs. 17, 21, 29, 32, 46, 93, 114, and 116). Recent studies in humans show that high intakes of phosphorus compared to calcium typically observed in the United States diet will produce changes in serum calcium and bone regulating hormones that may adversely affect peak bone mass (Refs. 17, 21, 31, 32, 114, 115 and 116). This evidence is supported by findings from a variety of animal models demonstrating that diets high in phosphorus and relatively low in calcium result in changes in calcium regulating hormones that adversely affect bone formation and stimulate bone resorption, and ultimately bone loss (Ref. 46).

To qualify for the health claim, FDA tentatively proposes in § 101.72(c)(5) that a product should not contain more phosphorus than calcium on a weight per weight basis. For those products that contain just 20 percent of the proposed RDI for calcium (about 180 mg of calcium), the product must contain no more than 20 percent of the RDI for phosphorus (about 180 mg) in a single serving or recommended daily supplement intake to be eligible to bear a health claim. This level is consistent with the 1:1 ratio of calcium to phosphorus set by the RDA for calcium and phosphorus (Ref. 3) and previous nutritional quality guidelines promulgated by FDA. This proposed disqualifying level of phosphorus is consistent with the nutritional guidelines set forth in § 104.47(d)(4): "When technologically practicable, product components and ingredients shall be selected to obtain the desirable calcium to phosphorus ratio of 1:1."

Other nutrients, such as sodium, also have adverse effects on calcium metabolism when high dietary levels are consumed (Refs. 59 and 135). However, sodium and other nutrients in high levels may disqualify a product from the claim because of their association with diseases other than osteoporosis. FDA has proposed disqualifying levels for fat, saturated fat, cholesterol, and sodium in proposed § 101.14. In proposed § 101.72(c)(1), as stated above, FDA proposes that all requirements for health claims as defined in proposed § 101.14 must be met for a product to bear a claim relating calcium intake to osteoporosis. Disqualifying nutrient levels are discussed in the proposal on general principles for health claims published elsewhere in this issue of the **Federal Register**.

Given the proposed conditions and requirements for a product to bear a health claim relating calcium intake to reduced risk of osteoporosis discussed above, some typical foods that would qualify for this claim include servings of: lowfat yogurt, 1 and 2 percent fat milk, skim milk, cultured buttermilk, 2 percent lowfat chocolate milk and tofu (Ref. 44). As discussed in the preamble to the proposal on general principles for health claims, FDA finds no basis to provide an exception to the disqualifying levels to permit a calcium and osteoporosis claim on whole milk.

To assist manufacturers in formulating a health claim, FDA is providing a model message in the proposed regulation.

V. Appendix to the Preamble—Consumer Summary on Dietary Calcium and Osteoporosis

The following appendix is a proposed consumer summary on dietary calcium and osteoporosis. FDA solicits comments on this document as explained in the proposal on general requirements for health claims published elsewhere in this isue of the **Federal Register**.

Appendix—Consumer Summary on Dietary Calcium and Osteoporosis

Dietary Calcium and Osteoporosis

Under the provisions of the recent Nutrition Labeling and Education Act, manufacturers may put clear information on the food label about the relationship between a nutrient, such as calcium, and a disease or health-related condition. To prevent consumers from being misled, the Food and Drug Administration (FDA) allows only truthful label statements about diet and health relationships that are firmly supported by current scientific evidence. There is agreement that the evidence is strong enough to allow a health claim about the relationship between dietary calcium and osteoporosis.

Many consumers have said that health claims on food labels could be useful to them in making improvements in their diets. However, label space is often limited. Therefore, this pamphlet provides information about the diet and health claims that supplements what you may see on food labels.

In addition to dietary calcium and osteoporosis, FDA is allowing health claims about the relationship between sodium and hypertension, saturated fat and cholesterol and cardiovascular disease, fat and cancer, and _____. For information about these other diet and health relationships, write to: [TO BE INSERTED].

What is Osteoporosis?

Osteoporosis is a disease condition in which reduced bone mass causes the bones to fracture easily. The disease occurs in both sexes but is more common among older women.

Why is There Concern About Osteoporosis?

Osteoporosis is a public health concern because from 15 to 20 million Americans are affected. Osteoporosis reduces the mobility and quality of life of the people affected. The disease is responsible for about 50,000 deaths annually, and substantial health care costs are associated with it.

One-third of women 65 years and older have spinal vertebrae fractures, the most common break associated with osteoporosis. Vertebral fractures are often undetected, and few women identify the height loss that results as due to osteoporosis. Many elderly men and women suffer hip fractures as a result of osteoporosis, which few people associate with this disease.

Osteoporosis contributes to some 1.3 million bone fractures per year in persons 45 years and older. Spinal fractures are painful, but hip fractures may have more serious effects and usually result in hospitalization.

What is the Cause of Osteoporosis?

Osteoporosis is a complex disease, and why it develops in some people is not entirely understood at this time. The factors that make a person most at risk for developing the disease are increased age and being a female (particularly when loss of the hormone estrogen occurs) of the Caucasian or Asian race. However, several lifestyle factors over which people have greater control are also believed to be associated with a decreased risk of its development. These include consuming an adequate amount of dietary calcium and getting enough exercise, especially during the bone-forming years; eating a balanced diet; not smoking cigarettes; and either not drinking alcohol or doing so in moderation.

The exact nature of the association between calcium and osteoporosis is under active research. Scientific experts

agree that consuming an adequate amount of calcium in your diet throughout life is important to bone health.

The maximum amount of bone that a person can build is determined by heredity. Bone continues to be added to the skeleton until about 35 years of age, at which time skeletal maturity occurs. Scientists agree that adequate dietary calcium during the bone-forming years is important to building an optimal amount of bone (called "peak" bone mass). Building optimal bone mass through a balanced diet, including adequate calcium, until skeletal maturity occurs may help to delay the onset of or limit the chance of developing osteoporosis later in life.

Bone experts also agree that, for adults in midlife or older years, maintaining adequate dietary calcium is crucial to slowing down the rate of bone loss that naturally occurs at that time. Getting enough dietary calcium is especially important during the first decade following menopause. However, for women at the onset of menopause, dietary calcium alone will not sufficiently slow the rate of bone loss, which is especially rapid early in menopause. At menopause, estrogen replacement therapy is the most effective means to reduce the rate of bone loss, and the risk for fractures.

Low calcium intakes are of greatest concern in adolescent and young women who have high calcium requirements. Young women who do not meet their calcium need during these age periods are most at risk of developing osteoporosis later in life. Postmenopausal women and elderly men also are at special risk of developing osteoporosis.

Do Most People Get Enough Calcium in What They Eat?

Because of concern that some people are consuming too little calcium, the U.S. Public Health Service has set a national health goal for people to eat food sources of calcium regularly. People from 12 to 25 years of age are encouraged to eat 3 or more servings a day of foods that are sources of calcium. This advice is appropriate for pregnant and lactating women because of their higher calcium needs. All adults 25 years and older are encouraged to consume 2 or more servings of calcium-rich foods daily.

How Do You Learn Which Foods Are Sources of Calcium

A good way to learn about food sources of calcium is to read nutrition labels. Most foods now have nutrition information on their labels.

The amount of calcium in a serving of food is listed on the nutrition label as a percentage of the Reference Daily Intake (RDI). The RDI for calcium is 900 milligrams (mg) for adults and children over 4 years of age. The RDI is not an amount recommended for you personally. It is a general reference number to help you determine how the amount of calcium in a serving of food relates to an average amount for a day.

More specific information for individuals comes from the National Academy of Sciences which recommends amounts of calcium for several age groups. For infants and children younger than 11 years, the recommended daily amounts range from 400 to 800 mg. The recommended daily amount of calcium for ages 11 through 24 years for both sexes, when maximum bone growth occurs, is 1,200 mg. The recommended daily amount for 25 years and older is 800 mg. For pregnant or lactating women, 1,200 mg of calcium a day is recommended. These recommended amounts can be reached easily by choosing foods each day that are good sources of calcium.

The richest sources of calcium are milk and other dairy products, which provide much of the calcium in U.S. diets. Some people cannot or only poorly digest the sugar (lactose) in milk, and are said to have "lactose intolerance." Most people with lactose intolerance, however, are able to consume small amounts of milk and other products containing lactose without distress. Also low-lactose and reduced-lactose dairy products are available.

Some foods containing relatively small amounts of calcium but that are eaten frequently during the day, for example, bread, are also good sources of calcium. Other nonfood sources, such as drinking water and some medications, such as antacids containing calcium carbonate, may also contribute to the level of calcium that you consume.

What Do Label Claims About Calcium Mean?

Besides the amount of calcium on the nutrition label, you may see claims about calcium in other places on the package of some products. There are two kinds of these label claims—content claims and health claims.

Content claims are those made about the *amount of calcium* the food contains. For example, a label may say "high in calcium" or "source of calcium." FDA allows a food that contains 20 percent or more of the RDI per serving to be labeled as a "high" in calcium, while a food containing from 10 percent to 20 percent of the RDI per serving can be labeled as a "source" of calcium.

Some foods that are high in or sources of calcium may contain one or more nutrients that increase the risk of a diet-related disease. For example, a high sodium intake is linked to high blood pressure in some people. To alert consumers, a claim about calcium content cannot be made on the label of such foods without indicating the presence of the other nutrient. A label might say, for example, "High in calcium; see nutrition label for information about sodium and other nutrients."

Health claims are those made about the relationship between calcium and osteoporosis. A health claim can be made only on foods that contain 20 percent or more of the RDI of calcium per serving and do not contain another nutrient (or nutrients) that increase the risk of a diet-related disease or health condition. Here are some examples of the kinds of foods on which you may see such claims: low fat milk, skim milk including dry skim milk, buttermilk made from skim milk, chocolate drinks and yogurt made from skim or low fat milk, reduced-calorie chocolate and cocoa dairy drink mixes, orange breakfast drinks, and tofu.

What About Dietary Supplements of Calcium?

The first important approach to getting enough calcium is to choose a healthful diet that has food sources of calcium. If for some reason (such as food intolerance or an increased calcium need during pregnancy or lactation), it's difficult to eat foods with enough calcium, a supplement to the diet may be appropriate. Supplements that exceed the recommended levels are unnecessary, however, and provide no further benefit to bone health. For further guidance, a personal physician or dietitian may be consulted.

Other Risk Factors for Osteoporosis

In addition to eating food sources of calcium regularly, improving some other habits may help to reduce the risk of osteoporosis. Regularly performing moderate weight-bearing exercise, such as walking, can help to increase bone mass during the bone-forming years. In addition, choosing not to smoke and limiting alcoholic beverages are healthful ways to reduce your chances of developing the disease.

Older people benefit from regular exercise that strengthens their muscles and helps lessen the danger of falls that may result in broken bones. A safe environment, such as removal of scatter

rugs, is also important for elderly people.

Facts to Keep in Mind

• It's the total combination of foods that you eat regularly—both the kinds and the amounts—that's important in terms of good nutrition. Eating a particular food or foods isn't a magic key that will assure that you have a more healthful diet.

• Eating a healthful diet, in itself, doesn't guarantee good health. However, a healthful diet is an important part of a healthy lifestyle that includes, for example, regular physical exercise, not smoking, not drinking alcoholic beverages in excess, and not abusing drugs.

• In addition to what you eat, many factors may be related to your own chance of developing a particular disease, for example, your heredity, your environment, and the health care that you get. Our knowledge about most diet-health relationships is incomplete and will improve as scientific knowledge increases. However, enough is known today about some of these relationships to encourage changes in dietary practices believed to be beneficial.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

IX. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

X. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of the Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. Section 101.72 is added to subpart E to read as follows:

§ 101.72 Health claims: calcium and osteoporosis.

(a) *Relationship between calcium and osteoporosis.* An inadequate calcium intake contributes to low peak bone mass and has been identified as one numerous many risk factors in the development of osteoporosis. Peak bone mass is the total quantity of bone present at maturity that experts believe has the greatest bearing on whether or not a person will be at risk of developing osteoporosis and related bone fractures later in life. Another factor that influences total bone mass and susceptibility to osteoporosis is the rate of bone loss after skeletal maturity. An adequate intake of calcium is thought to exert a positive effect during adolescence and early adulthood in optimizing the amount of bone that is laid down. However, the upper limit of peak bone mass is genetically determined. The mechanism through which an adequate calcium intake and optimal peak bone mass are thought to reduce the risk of osteoporosis relates to the fact that all persons lose bone with age, hence those with higher bone mass at maturity take longer to reach the critically reduced mass at which bones can fracture easily. The rate of bone loss after skeletal maturity also influences the amount of bone present at old age and can influence an individual's risk of developing osteoporosis. Maintenance of an adequate intake of calcium later in life is thought to be important in reducing the rate of bone loss particularly in the elderly and in women during the first decade following menopause.

(b) *Significance of calcium.* Calcium intake is not the only recognized risk factor in the development of osteoporosis multifactorial bone disease. Other factors including a person's sex, race, hormonal status, family history, body stature, level of exercise, general diet, and specific life style choices such as smoking and excess alcohol consumption affect the risk of osteoporosis.

(1) Heredity and being female are two key factors identifying those individuals at risk for the development of osteoporosis. Hereditary factors include race, notably Caucasian and possibly Asians are characterized by lower peak bone mass at maturity, and have a significantly higher incidence of bone fracture with increasing age, than African Americans.

(2) Maintenance of an adequate intake of calcium throughout life is particularly important for a subpopulation of individuals at greatest risk of developing osteoporosis and for whom adequate dietary calcium intake may have the most important beneficial effects on bone health. This target subpopulation includes adolescent and young adult Caucasian and possibly Asian American women. In addition, those individuals with known family histories of osteoporosis are also at greater risk of developing this bone disease later in life.

(c) *Health claim conditions.* A food label or labeling may contain a health claim stating that consumption of an adequate calcium intake throughout life helps to optimize peak bone mass during adolescence and early adulthood and to slow the rate of bone loss later in life and, by maximizing the amount of bone present in later years through these mechanisms, may reduce the risk of osteoporosis and related bone fracture provided that the following conditions are met by the product:

(1) All requirements for health claims as defined in § 101.14 are met;

(2) A serving of food or a total daily recommended supplement intake meets or exceeds the requirements for a "high" level of calcium as described in § 101.54;

(3) The calcium content of the product is assimilable;

(4) Dietary supplements shall meet the United States Pharmacopeia standards for disintegration and dissolution; and

(5) A serving or total daily recommended supplement intake does not contain more phosphorus than calcium on a weight per weight basis.

(d) *Health claim requirements.* Health claims relating adequate calcium intake to the possible reduction in the risk of osteoporosis may be used on the label and in the labeling provided that such statements comply with the following requirements:

(1) The claim shall make clear that adequate calcium intake throughout life is not the only recognized risk factor in this multifactorial bone disease by listing the specific factors, including a persons's sex, race, age, and family history, that place them at risk of developing osteoporosis and stating that an adequate level of exercise and a well-balanced diet are also needed;

(2) The claim shall not convey the misconception that the risk of osteoporosis is equally applicable to the general United States population. The claim shall clearly identify the populations at particular risk for the development of osteoporosis. These include white (or the term "Caucasian") women and may include Asian women in their bone forming years (approximately 11 to 35 years of age or the phrase "during teen or early adult years" may be used). These may also include menopausal (or the term "middle-aged") women, persons with a family history of the disease, and elderly (or the term "older") men and women;

(3) The health claim shall state that adequate calcium intake throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The phrase "build and maintain good bone health" may be used to convey the concept of optimizing peak bone mass. When reference is made to persons with a family history of the disease, menopausal women, and elderly men and women, the claim may also state that adequate calcium intake is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss;

(4) The claim shall not quantitate the degree of reduced risk of osteoporosis that may result from maintaining an adequate calcium intake throughout life; and

(5) The health claim shall state that a total dietary intake greater than 200 percent of the recommended daily intake (1,800 milligrams (mg) of calcium) has no further known benefit to bone health.

Sample Health Claim

Osteoporosis affects older persons, especially middle-aged, white women and those whose families tend to have fragile bones in later years. A lifetime of regular exercise and eating a healthful diet that includes enough calcium, expecially during teen and early adult years, builds and maintains good bone health; and may reduce the risk of osteoporosis later in life. Adequate calcium intake is important, but intakes above about 1,800 mg are not likely to provide any additional benefit.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-M

TABLE 1

Calcium and Osteoporosis: Effects of Calcium on Bone Status

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Angus R. M., et al., 1988 (Ref. 18)	Cross-sectional study To determine influence of diet on bone mass in proximal femur, intake of 14 nutrients measured, and bone mineral density quantitated by dual photon absorptiometry (DPA) Bone mineral density also measured in spine and bone mineral content in forearm by single photon absorptiometry	159 White women, aged 23 to 75 years Volunteers, Australia Study Participants asked to record their food and fluid intake for 4 consecutive days by weighing all items on a portable digital scale	None	None	Mean calcium intakes for premenopausal and postmenopausal women were 759 and 717 mg/day, respectively	Usual dietary habits Mean calcium intake calculated from 4-day weighed food record	None	This was a study of multiple nutrients	No significant correlation was found between current calcium intake and bone mass at any site	Results suggested that bone mass is influenced by dietary factors other than calcium Appropriate use of multiple logistic regression
Baran, et al., 1990 (Ref. 25)	Randomized prospective clinical trial Measured: bone density of the lumbar spine by dual photon absorption Blood chemistries measured every 4 weeks included lipid profiles and parathyroid hormone	59 started (37 finished) women (30 to 42 years old premenopausal Control n = 22, Average increase in calcium intake = 610 mg/day	3 years (36 months)	Dairy foods	500 to 600 mg/day as dairy foods	3-day dietary histories repeated Instruction on calcium intake of dairy foods Compliance confirmed with 24-hour urine calcium measure Urged to use low fat dairy products Habitual calcium intake:7 Control = 892 mg/day treatment = 962 mg/day increased to 1300 to 1500 mg/day	All groups were age and weight matched with no difference in habitual calcium intake or initial bone densities Direct questions and HDL-Cholesterol profiles showed no group differences in exercise patterns, thus it was no considered a confounder	None	No change in vertebral bone density over 3-year duration in women consuming the dairy supplemented diet, but the untreated controls showed a significant decline (-2.9%) that differed from the treated group at 30 and 36 months No changes in any parameter of lipid profile or calcium homeostasis other than a significant increase in urinary calcium excretion was observed in the treated group	Unlike earlier studies, this is the first to confirm calcium intakes Suggests that dietary modification via supplementation with dairy products during the period of consolidation could retard vertebral bone loss and decreased the incidence of osteoporosis A very important study, despite high attrition rate of 37%

Table 1 continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Cauley, J. A., et al., 1988 (Ref. 36)	Purpose: To examine the interactions between normal levels and calcium with cortical bone Researchers combined factors for the development of peak skeletal mass (milk consumption during childhood and adolescence) with factors that may be related to the maintenance (serum hormone levels and dietary intakes of calcium) of bone integrity after menopause Hormones studied: Estrone Testosterone Androstenedione Calcium intake in childhood, adolescence, and adulthood was assessed retrospectively from responses to questions concerning frequency of milk consumption at various stages of life	174 postmenopausal women (healthy) All participants were in a 3-year randomized clinical trial designed to evaluate of walking in postmenopausal bone loss	3 years	Habitual and life time calcium intake	None	Calcium intake by food frequency method: 25th percentile: 407 mg/day 50th percentile: 684 mg/day 75th percentile: 942 mg/day Mean daily calcium intake 768 mg/day	None of the participants was receiving estrogen therapy at baseline	Bone measures were assessed with a computed tomographic scanner in the dominant radius at a site three tenths of the distance from the wrist to the elbow approximately one month after the annual clinic visit Current calcium intake was estimated at year 1 and year 3 by a food frequency questionnaire in which women recorded the frequency of consumption of various foods known to be common sources of calcium At year 1, calcium intake was also assessed by 3-day food records that were documented by nutritionist and coded according to the USDA handbook	Little relationship found between androgen hormones and radial bone density Estrone levels were independently related to radial bone density Examination of the relationship of calcium intake to bone revealed a protective effect solely in women who reported high "lifetime" calcium intakes Considering calcium and estrone together revealed an additive relationship between the 2 factors, in that women with high estrone and high calcium levels had significantly greater bone density than women with less calcium and or estrone	Results suggest that a lifetime of adequate calcium intake coupled with adequate levels of serum estrogens could maximize bone density after menopause

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Dawson, Hughes, et al., 1990 (Ref. 44)	Intervention placebo: Controlled Double blind Randomized Measured: Bone mineral density of spine and femoral neck by DPA Biochemical markers of calcium homeostasis	301 healthy postmenopausal women Early postmenopausal n = 67 average = 54.5 years year pm = 3.2 Sub-Groups High Calcium, n = 124 Low Calcium, n = 112 Late postmenopausal n = 169 average = 59.9 years	24 months	Placebo micro crystalline cellulose calcium carbonate Calcium citratemalate (CCM) Depending on habitual calcium intake, women were randomized to 3 treatments Thus, 6 treatment groups total	500 mg/day 500 mg elemental calcium 500 mg elemental calcium all tablets	Assessed by questionnaire initially and every 6 months By design half selected had habitual calcium intakes of: (1) < 400 mg/day (2) 400 to 650 mg/day	None	Effectiveness of calcium supplementation was affected by years since menopause Therefore data analyzed separately for: (1) Menopause in last 5 or fewer years (accelerated rate of a bone loss). (2) Menopause more than 5 years ago Time of day of supplementing (before bedtime) may have produce different effects between calcium carbonate and CCM, since calcium carbonate is absorbed better when consumed with a meal	Women in early menopause lost bone from spine and this rapid rate of loss was not affected by calcium supplementation (500 mg calcium) from any source Women in late menopause, the rate of bone loss was less rapid in those with higher habitual calcium intakes and there were no differences in bone density among treatment groups at any site All late postmenopausal women had significant bone loss from the spine, except those with a lower habitual calcium intake who received CCM For those on a low dietary calcium diet, CCM significantly decreased the rate of bone mineral loss from the spine, femoral neck, and radius Calcium carbonate decreased bone loss only at femoral neck and radius.	Study presents strong evidence that bone loss in early postmenopausal is unresponsive to calcium supplementation Women in late menopause, whose habitual calcium intake is less than 400 mg may reduce their bone loss by increasing their calcium intake to 800 mg/day

Table 1 continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Desai, S., et al., 1987 (Ref. 48)	Cross-sectional Measured: Bone mineral density by DPA of the lumbar vertebrae Estimates of calcium intake made from 3-day diet histories via computer software package	60 normal premenopausal 30 to 40 years of age Average age = 35	None	Habitual calcium intake assessed from 3-day diet history Average = 868 mg/day Range: 278 to 2064 mg calcium/day	None	None	Subjects had no other factors known to alter calcium or bone metabolism	None	Bone density at any site did not correlate with calcium intake, age or calorie intake	Dietary data from a 3-day record is not sufficient estimate of habitual calcium intake No measurement of physical activity which may have been an important confounder in this age group
Fujita, T., et al., 1990 (Ref. 55)	Clinical trial: Non placebo Controlled Not blinded Not randomized Japanese study Measured: Radial bone mineral density by single photon absorptiometry and spinal trabecular bone density by quantitative computed tomography	12 test subjects Asian female > 70 year age, normal except for osteopenia expected for age 20 controls age matched All subjects in geriatric hospital All subjects in late menopause	24 months	Oyster shell electrolysate (OSE)	900 g of calcium as OSE	Hospital diet consumed by all subjects Contained about 600 mg/day calcium	No record control of physical activity	Differences in physical activity may have confounded the results It remains unclear	Radial bone mineral density increased significantly in subjects consuming the OSE calcium and decreased significantly in the untreated controls No change in spinal bone density in either calcium treated or untreated controls Concluded that in late menopause had positive response of cortical but not cancellous bone to calcium supplementation	Study flawed by large percentage of attrition attributed to their age (>70)

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Halioua, et al., 1989 (Ref. 60)	Cross-sectional Measured: bone mineral content and bone mineral density of the nondominant arm at the distal and mid (2/3) radius by single-photon absorptiometry	181 premenopausal women aged 20 to 50 mean age, 3 to 5 years All Caucasian	None	Habitual diet Calcium intakes for current, past, and lifetime classified as; Low, (L500 mg/day) Intermediate (>500 mg and <800 mg/day) High (>800 mg/day)	Diet assessment included current, past and lifetime calcium intake Used a quantitative food frequency questionnaire based on a 1 week intake Validated on a subset of 20 women on a 3-day dietary intake record (r = 0.52 Between the 3 methods) Similar quantitative food frequency questionnaire used to determine past and both current and past intakes were used to estimate lifetime calcium intake Appears to be a carefully conducted procedure conducted by a trained professional		Physical activity assessment, used a questionnaire to establish: Current activity Past activity Lifetime activity with each classified as: sedentary, moderate or active	All menopausal women, or women with abnormal menstrual cycle excluded	An intermediate or high lifetime calcium intake was associated with significantly higher bone mineral density and content at both distal and midradius when data was adjusted for physical activity Similar findings were observed when data was adjusted for calcium intake Thus, lifetime high calcium, and active level of exercise was associated with highest radial bone density	Any estimate of past or lifetime calcium intake is inherently weak, but effort was made to validate against current intake estimate Findings suggest that both adequate calcium intake and regular exercise during adolescence enhance peak bone mass

able --cont'inued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Holbrook T., et al., 1988 (Ref. 72)	Prospective cohort	957 white upper middle class subjects, aged 50 to 79 years (416 men, 531 women) sub-sample of cohort of 6,155 including all hyperlipidem (a 15% random sample)	14 years	Dietary calcium usual intake estimated from 24-hour diet recall taken in 1973 to 1975 and quantified in 1985	Range of estimated calcium intake: not given	Use 24-hour recall, weak method for estimate of calcium intake	Alcohol, age, obesity, sex, smoking, exercise, estrogen replacement	None	Hip fractures were usually proportional to calcium intake in both sexes therefore positive effect associated with calcium 33 hip fractures (male 15 and female 18) mean calcium intake: mg/day Men with fracture = 305.9 Men without fracture = 384.9 Females with fracture = 319.8 Females without fracture = 401.3	Weakest point of study was method of estimating calcium intake from 24-hour recall, particularly since the data were collected 10 years prior to analysis Study was weakened by small sample size Unresolved issue as to whether calcium effect is preventive after 50 years of age or is the therapeutic end result of habitual higher calcium intake, thus affecting peak bone mass

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Kanders, B., et al., 1988 (Ref. 78)	Non randomized Cross-sectional Measured: Bone mineral mass by SPA 1/3 radius site Bone mineral density of the lumbar spine by DPA Physical activity measurement via Minnesota Leisure Time Activity Questionnaire Daily walking by a 7-day pedometer recording Nutritional assessment by 24-hour dietary recall with food models and a prospective 6-day record to yield a weighted 1-day intake All women were within 20% of ideal body weight	60 women eumenorrheic, healthy normal age 25 to 34 years old	None	Lifestyle variation with regard to habitual calcium intake	None	Mean calcium: 871 mg/day Range: 286 to 2,128 Only one subject avoided dairy products 17 were taking calcium supplement users for 3 years	Exercise monitored: Energy Expended: Average Kcal/day = 960 Range: 286 to 2,128 Examined statistically as: <970 kcal/day >970 kcal/day	None	Highly significant correlation between bone mineral density of the lumber spine and overall level of physical activity Radial bone density showed no correlation to physical activity and only a modest relations to calcium intake which was statistically significant Statistical comparison made after the group was divided at the RDA for calcium of 800 mg/day both vertebral and radial mineral were significantly greater in those with high calcium intake The mean spinal bone mineral density was highly significantly different between women with the highest calcium intake and physical activity level, relative to those who were relatively inactive and on a lower calcium intake. -Bone mineral density of the spine did not increase with calcium intakes above 800 - 1000 mg/day, implying a calcium threshold effect.	General conclusion that Bone mineral density of the spine can be influenced by both mechanical stress of physical activity and optimal calcium nutrition during the period of skeletal maturation (consolidation) Data implied an optimal calcium intake between 800 to 1000 mg of calcium

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Kelly, P. J., et al., 1990 (Ref. 82)	Cross-sectional Measured: Bone mineral density of radius by single photon absorptiometry and lumbar spine and hip by DPA to assess relation between bone mineral density and: Dietary calcium intake Anthropometric features Age Serum sex hormone level	48 normal men (age 21 to 79, median 44)	None	Dietary calcium assessed from questionnaire validated against 4-day dietary record	Range: 0.3 to 1.7 g/day (from figure 1)	Not specified	None	None	Dietary calcium intake was significant predictor of bone mineral density of axial bones, explaining 24% and 42% of the variance at the lumbar spine and femoral neck, respectively This effect was independent of weight In contrast with the axial skeleton, bone mineral density at each forearm site was predicted by weight and an index of free testosterone but not dietary calcium intake	Strengths: Appropriate application of stepwise logistic regression Limitations: Specific diet of study participants not described Level of physical exertion not discussed, may present as confounder
Lacey, M., et al., 1991 (Ref. 86)	Cross-sectional Measured: Mid-radial bone mineral content and bone density by single photon densitometry	178 Japanese women living in Japan 89 premenopausal women (35 to 40 years) 89 postmenopausal women (55 to 60 years)	None	Habitual dietary intake	None	Habitual diet assessment carried out on 3-day food diary interpreted by American interviewer using Japanese computerized nutrient data base A quantitated food frequency questionnaire was used to assess calcium intake between 14 to 22 years of age	None	Physical activity Medical history and anthropometric measurements were taken to determine influence on bone status	Current calcium intake was not associated with bone indices on either pre- or postmenopausal women Vegetable intake and current milk intake were positively correlated with mid-radial indices An important finding since both are calcium rich foods	Assessment of past calcium intake in these very elderly ladies was confounded by probate food restrictions imposed during WWII when many of these women would have faced food restriction

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Lutz, J., et al., 1990 (Ref. 94)	Cross-sectional Measured: Bone mineral content of the lumbar spine and right proximal femur (femoral neck and trochanter) by dual-photon absorptiometry	37 with mother-daughter pairs aged 52 + 7 years and 25 + 4 years Mothers premenopausal n = 20 postmenopausal n = 17	None	3-day dietary intakes assessed dietary contribution notably calcium Mean calcium intakes: mother-= 1102 mg/day daughters = 818 mg/day 13 mother had <800 mg/day 7 daughters had <800 mg/day	None	None	Supplemental calcium intake by mothers (n = 21) averaged 580 mg/day by daughters (n = 13) averaged 340 mg/day This may have confounded the study Another confounder may be the heterogeneity of the subjects with respect to their age and menopausal status Exclusion criteria in selecting pairs included estrogen use or other factors that would affect bone	23 mothers and 19 daughters were taking vitamin/mineral supplements	Total calcium intake was significantly correlated with 3 bone mineral density sites for the daughters, but not for the mothers	3-day dietary records are not sufficient to get an accurate estimate of calcium intake Study may be flawed by over interpretation of the findings concerning calcium intake The method used was not competent to estimate habitual calcium intake
Matkovic, et al., 1990 (Ref. 97)	Calcium intervention Longitudinal trial Measured: Calcium balance Radiogrammetry of the hand Single photon absorptiometry of distal radius DPA of the lumbar spine	30 adolescent females healthy 14 years old at onset eumenorrheic 18 of these participated in the balance study	2 year	Habitual dietary calcium or-- Supplemental calcium from either milk or calcium carbonate	Subjects stratified into 2 groups: Control n = 9 <850 mg calcium/day initially with a continued average intake of 750 mg calcium/day Calcium supplemented Milk group n = 10 <10,900 ml of milk/day Calcium carbonate group n = 12 took 4, 250 mg calcium tablets/day average calcium/day = 1640 mg Stratification was based on prestudy calcium intake	Determined from 3-day food record initially and at 6, 12, 18 and 24 weeks	None	For statistical analysis the high calcium groups were pooled since baseline values, bone mass, nutrition etc. were the same	While trend toward an increase in bone density in those girls consuming the higher calcium intake was observed over 2 years in the distal forearm and spine, this difference did not reach statistical significance Both groups showed a significant increase in bone mass and more significantly bone density Girls retained 200 to 500 mg calcium/day suggesting that inadequate calcium intake may translate into inadequate retention and a reduction in peak bone mass	No adjustment was made for physical activity differences between the two groups which may have a confounding effect Very difficult study design to follow--too convoluted Due to the small "n" in this study of 9 for the control and 20 for the calcium supplement group a type II error is possible

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Mazess, R., et al., 1991 (Ref. 98)	Longitudinal observation over a 2-year period Dual-photon absorptiometry of lumbar spine and Single-photon absorptiometry of the standard one-third radius and distal radius sites	200 to 300 White premenopausal women aged 20 to 39 All were ambulatory and free of current or previous chronic disease or medications known to affect bone	2 years	Normal diet, content assessed from several; 24-hour reporting periods over the two years using precoded Nutrient Adequacy Reporting System	Dietary calcium intake 909 + 351 mg/day	Normal diet	No specific treatments	Study of effects of age, dietary intake, physical activity, smoking and birth-control pills on bone mineral density	There was no association of calcium intake with bone mineral density or changes in bone mineral density Current calcium intake was not a significant influence on bone and mineral density in this age group No apparent additive interaction of activity and calcium intake on bone mineral density Body weight was a better predictor of bone mineral density than was any other factor No association of bone mineral density or bone mineral density changes with calcium	Appropriate analysis of data using linear and multiple regression Calcium intake and methods were weak, used less reliable method of 24-hour recall

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
McCulloch R., et al., 1990 (Ref. 99)	Cross-sectional Random selection Measured: Cancellous bone density of the os calcis using computed tomography	101 healthy normal females 20 to 35 years old	None	Childhood milk consumption Current dietary calcium intake Avocational Physical activity Various Lifestyle variables, e.g., smoking Range of Current Calcium Intake: 150 to 1560 mg/day	None	Dietary information determined from a questionnaire as was assessment of childhood physical activity Questionnaire was readministered 10 weeks later and discrepancies resolved Current levels of physical activity and calcium intake also evaluated by a 2-week and 1-week recall check test Limited explanation given for this check test	Exclusion criteria included: menstrual disfunction, kidney disease, etc.	None	There was a nonsignificant correlation between calcium intake and bone density of the os calcis There was no significant difference in bone density of the os calcis of subjects grouped according to self classifications high, moderate or low childhood milk consumers	Questionable competency of the dietary calcium intake validation estimate--not offered Diet and calcium intake analysis, a very weak point of this study

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Nelson, M., et al., 1991 (Ref. 102)	Prospective clinical trial, Double-blind, placebo controlled, Randomized for dietary, variable, Assigned according to preference to exercise training or sedentary Measured: Trabecular bone density of lumbar spine (L1-L3) by computed tomography (QCT) Femoral-neck (nondominant) and Lumbar spine (L2-L4) bone mineral density by DPA Bone mineral density of the shaft of the nondominant radius (1/3 distance) by single photon absorptiometry Total body calcium by delayed gamma neutron-activation Various measurements of muscle strength, aerobic capacity and body fluid analysis for hormones electrolytes.	36 postmenopausal Caucasian women All > 2 y postmenopause Average = 10.8 year Average age = 60.2 All < 130% ideal body weight	12 months	Milk with high calcium content 831 mg calcium/day Moderate calcium milk drink-placebo artificial milk 41 mg calcium/day	None	Usual diet, instructed all subjects to consume 800 mg calcium/day through inclusion of 4 servings of dairy products per day	Exercise which included walking 1 mile per day 4 times/week for 52 weeks or Sedentary no scheduled routine exercise but were allowed weekend recreation 4 Groups designated as: Exercise, moderate dietary calcium n = 9 Sedentary, moderate dietary calcium n = 9 Sedentary, high dietary calcium n = 9	Possible differences in dietary content of Vitamin D, protein and phosphorus Groups differed initially only by parity: Exercise group = 4.3 Sedentary = 2.4	Bone mineral density of the spine, measured by QAT decreased 7% in sedentary group and increased in exercise group by 0.5% (p = 0.028) but calcium intake had no significant effect Femoral neck bone mineral density measured by DPA decreased 1.1% in moderate calcium group and increased 2% in high calcium group (p = 0.014) and no significant effect of exercise No change in hormone or urinary metabolism observed with any treatment	Well controlled and well designed study examining more than usual endpoints Important finding was that due to varying proportion and rates of bone turnover of cancellous and cortical bone at various skeletal sites, exercise and dietary calcium may preferentially modify bone mineral at these different sites Findings confirm previous studies showing calcium to affect cortical bone but not cancellous bone Limit power of study since each group contained only 9 subjects

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Picard, D., et al., 1988 (Ref. 111)	Cross-sectional Observational Measured: Bone mineral content of the spine by DPA and of the forearm by single photon absorptiometry	183 women, aged 40 to 50 average age = 43.8 years all normal healthy with regular menses	None	Range of historical intake: High > 1000 mg/day n = 38 Medium 500 to 1000 mg/day n = 75 Low < 500 mg/day n = 70	Historic and habitual calcium intake: Average calcium intake at age 20 = 576 mg/day	Diet history taken to determine intake at age 20 3-day food recall to verify calcium intake	Estimates of caffeine, alcohol intake, cigarette smoking, exercise, estrogen use, and parity were also made	Homogeneous population of French Canadian women, geographic and racial differences were minimized	Significant positive correlations were noted between the bone mass measurement at the spine and forearm and weight, height and calcium intake at age 20 Significant differences were observed between the low and high calcium intake groups for the mean adjusted bone mineral content at both sites Concluded: Chronic calcium intake has a significant effect on lumbar bone mass indices in premenopausal women	Study did not indicate whether the effect of calcium intake was on the formation of maximal peak bone mass or on slowing the rate of bone loss at midlife Has all the predicted limitations inherent to a cross-sectional study examining historical dietary intake

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Polley, K. J., et al., 1987 (Ref 113)	Prospective intervention with consecutive and concurrent controls Random assignment to treatment Measured forearm mineral content by single photon absorptiometry	Postmenopausal women <65 years old 3 treatment groups 210 completed 52 strict controls, 122 not able to take supplements, 136 treated	Initial 9-month control period 9-months of the treatment (total duration 18 months)	Group 1: Reduced sodium Group 2: Increased dairy foods 1250 mg/day Group 3: diet + 1000 mg calcium as sandolcal total diet content: 1700 mg Untreated controls None	Group 1: None Group 2: 450 mg calcium, dairy Group 3: 1000 mg effervescent tablets of calcium gluconate, lactate and carbonate Untreated controls None	Group 1: 709 mg calcium Group 2: 711 mg calcium Group 3: 714 mg calcium Average for treated 711 mg calcium Untreated controls 717 mg calcium	Group 2: Subdivided into dairy products + salt restriction Dairy products only	Diet Sodium Content Group 1: 1827 mg/day Group 2: Restricted 1803 mg/day 2103 Group 3: (+ calcium) 2422 mg/day	Bone mineral content No significant differences in forearm mineral content for any treatment or subgroup, initially Rate of Bone Loss The difference between pretreatment and after 9-months of calcium was significantly reduced Calcium treated women had a greater reduction in the rate of bone loss, but it was not statistically different from the untreated strict controls Comparison of women within 10 year of menopause showed a significantly different (reduced) rate of bone loss in both the calcium supplement and dairy product only group, relative to untreated control.	Poor or questionable compliance, especially in control group Confusing design with too many variables Unexplained significant reduction in rate of bone loss in strict controls between period 1 and 2 Questionable inclusion of noncompliant subjects in control groups

Table 1--continued

Reference* (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Smith, E. L., et al., 1989 (Ref. 123)	Double blind study of effects of calcium carbonate supplement on bone loss Random assignment to treatment or control groups Bone mineral content and width measured bilaterally on the radius, ulna and humerus Single-photon absorptiometry used	169 women aged 35 to 65 years Subjects recruited from general population of Madison, WI	4 years	OS-Cal 500 (Marion Labs) Each tablet contained 500 mg elemental calcium in form of calcium carbonate	1500 mg calcium/day was desired goal Less was actually achieved	Usual diet for each participant	None	Subjects excluded from study if they had a history or current diagnosis of osteoporosis, malignancy, and any other condition known to have major effects on calcium metabolism	Bone mineral content and bone content/width loss rates were consistently lower in treatment than in control subjects Loss was significantly reduced in the left and right humerus and right radius In premenopausal women, only left humerus bone mineral content loss was significantly reduced by calcium supplementation In postmenopausal women, bone mineral content and bone mineral content/width bone loss was reduced in all 12 of the bone variables measured, 5 at $p<0.01$, and 2 at $p< 0.05$	Calcium supplementation counteracted a large portion of the additional bone loss attributable to menopause in this population

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Stevenson J. C., et al., 1988 (Ref. 124)	Cross-sectional 16 women placebo group applied inactive gel 5 grams daily throughout the study to the skin of the abdomen and upper thighs and took 3 inactive tablets daily for the first 12 days of each calendar month 38 women in treatment group took either synthetic human calcitonin or percutaneous estradiol together with oral progesterone for 12 days each month, or both	59 healthy postmenopausal women most of whom were within 5 years of menopause Volunteers Median age 55 years (37 to 64)	12 months	Calcitonin: Ciba-Geigy Estradiol: Basins-Iscovesco	Synthetic human calciton-20 IU 3 times/week by s.c. injection Estradiol 5 grams daily Progesterone 300 mg/day	Dietary intake of calcium assessed by questionnaire and interview Dietary intake of calcium before treatment 530 mg (lower quaritle) and 1564 mg (upper quaritle)	See study design	None of the women taking any other drug known to affect calcium metabolism	No correlation was found between current intake of calcium and either total calcium in the body or the density of trabecular of cortical bone in the forearm or vertebral trabecular bone Dietary intake of calcium did not influence the rate of postmenopausal bone loss in the 54 women who completed 12 months of active or placebo treatment Even when extremes of calcium intake were examined, no difference was found in bone measurements between the women with the highest and lowest intake	Results of this sturty suggest that the bone density of women in the early menopause is not influenced by current dietary intake of calcium Weak dietary data, determining calcium intake

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Stevenson J. C., et al., 1989 (Ref. 125)	Cross-sectional study of bone density measurements of vertebral and proximal femur using DPA Possible predictors and risk factors for bone density were assessed in study participants	284 White healthy women-volunteers ages 21 to 68 Included 112 premenopausal women	Cross-sectional study	Dietary calcium intake assessed	Dietary calcium estimated mean calcium intake for premenopausal women was 598 g/day, while for postmenopausal women it was 619 g/day	An estimate of dietary calcium intake was derived form the current consumption of diary products	None	None of study participants was taking any drugs known to influence bone or calcium metabolism	Peak adult bone density had been attained soon after the end of linear skeletal growth Thereafter, there was some decline with age in the proximal, femur, but the major fall in bone density in all sites was related to the menopause Other factors decreasing bone density, and thus increasing risk for osteoporosis (low body weight, alcohol and cigarette consumption, nulliparity, lack of previous use of oral contraceptives, and lack of regular exercise) seemed to be important None, however could predict satisfactorily women at future risk for osteoporosis.	Values obtained for bone density were similar to those obtained from equivalent studies performed in women in the United States In agreement with others, no evidence obtained of skeletal consolidation in the third or fourth decade Weak assessment of dietary calcium intake; no validation

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Tylavsky F., et al., 1988 (Ref. 128)	Cross-sectional Used multiple regression model to assess effects of current calcium, P, and protein intake on bone indices Measured: Bone mineral content and bone density at the mid and distal radius using single photon densitometry	287 omnivorous postmenopausal women 88 lacto-ovo-vegetarian postmenopausal women All Caucasians	None	Habitual intake from omnivorous and lacto-ovo vegetarians (16-year minimum duration of lacto-ovo-vegetarian diet)	Quantitive food frequency questionnaire used to estimate usual and past calcium intakes Administered by a trained interviewer Validated against 3-day food record	Current calcium intake: Average omnivores: 902 + 21 mg calcium/day Lacto-ovo-vegetarian: 823 + 48 mg calcium/day	Factors known to affect bone density excluded subjects from study, e.g., long-term immobilization, hyperparathyroidism etc.	Smoking, alcohol use, parity and lactational experience was also determined and differed between the omnivorous and lacto-ovo-vegetarians The 2 groups also varied significantly by their age, weight, body mass in diet, lean body mass and parity Groups did not differ in number of subjects using estrogen, aluminum antacids or magnesium Omnivorous women had a greater use of thiazide diuretics that conserve calcium which may have masked true differences in bone densities	Bone indices were in general positively influenced by body mass index, and dietary protein intake and negatively influenced by age and dietary phosphorus Current calcium intake had no positive effects on bone indices	Question the accuracy of the quantitative food frequency questionnaire, however, authors did validate it against a 3-day food record for 20 adult women

Table 1--Continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Van Beresteijn, E., et al., 1990 (Ref. 132)	Longitudinal study Measured: Bone mineral content of distal third nondominant radius Serum electrolytes and calcitropic hormone levels	154 perimenopausal women 60 pre- and 94 post-menopausal After the 5th year, all women were postmenopause	8 year followup study	Habitual calcium intake 3 Groups: < 800 mg/day (n = 28) 800 to 135 mg/day (n = 95) 1350 mg/day (n = 31)	Dietary calcium intake determined by cross-check dietary history method	Habitual calcium intake was estimated from the mean of 7 annual histories	None	No estimates of physical activity were made which may serve as a confounding factor Women with significantly lower habitual calcium intakes also had significantly lower intakes of total protein energy and phosphorus, a potential confounder	Cortical bone mineral content/bone width decreased over time in all groups The rate of bone loss did not differ significantly between groups Bone mineral content/Bone width or bone loss correlated with age or habitual dietary calcium intake Concluded: Habitual calcium intake exceeding 800 mg/day was not effective in preventing cortical bone loss in early menopause	Weak estimate of annual calcium intake

Table 1--continued

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Van Beresteijn, E., et al., 1990 (Ref. 131)	Complicated: Longitudinal Nonrandomized Cross-sectional Observational Measured: Bone loss at the radius determined by single photon absorptiometry One-time measurement of bone mineral content of spine and femoral neck by DPA Rate of bone loss at radius extrapolated to spine and femoral neck	60 normal healthy postmenopausal women 3 to 10 years post menopause average = 7.7 years average age = 61	Longitudinal component, 8 years	Habitual calcium intake	Range of calcium intake: 560 to 2,580 mg/day average calcium intake = 1132 ± 401 mg/day	Habitual calcium intake estimated as a mean of 8 annual dietary intake estimates, 75% diary derived in Dutch population Used Cross-check dietary history method	None	No activity assessment, may be a confounding factor	With Univariate analysis, neither cortical bone (radius or femoral neck) or cancellous (spine) was correlated to habitual calcium intake Body mass index had a protective effect on cortical bone but not trabecular bone Concluded: In early postmenopause, bone mineral content of the appendicular and axial skeleton are not related to calcium intake Longitudinal measurements of cortical bone mass are of limited value in predicting bone density of spine	Study results do not rule out possibility that high calcium intake in early postmenopausal phase may decrease the rate of loss of cancellous bone mass Question the appropriateness of combining longitudinal and cross-sectional data and extrapolating from one data set to another Weak dietary calcium estimates

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21 CFR Part 101

[Docket No. 91N-0096]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Lipids and Cardiovascular Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to authorize the use on foods and food labeling of health claims relating to the association between reduction in dietary intake of lipids (particularly saturated fats and cholesterol), decreased blood cholesterol, and decreased risk of cardiovascular disease, particularly coronary heart disease. The agency reviewed this topic under provisions of the Nutrition Labeling and Education Act of 1990. The agency's conclusion is based on its review of the available scientific literature and on its review of conclusions and recommendations provided by the Federal government and other documents from recognized scientific bodies. The agency concludes that the strength and consistency of the extensive publicly available scientific evidence supports such claims, and that there is significant scientific agreement, among experts qualified by scientific training and experience, to evaluate such claims, about such support.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Paddy Wiesenfeld, Center for Food Safety and Applied Nutrition (HFF-268), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1492.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorize the Secretary of Health and Human Services (the Secretary) to issue regulations authorizing nutrient content and health claims on the label or labeling of foods. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under the act (21 U.S.C. 343(r)(1)(B)).

Published elsewhere in this issue of the **Federal Register** is a proposed rulemaking to establish general requirements pertaining to the use on food labels and in labeling of health claims that characterize the relationship of nutrients, including vitamins and minerals, herbs, or other nutritional substances (referred to generally as "substances"), to a disease or health-related condition (proposed in "General Principles for Health Claims"). In the proposal on general requirements for health claims, FDA, following the provisions of the 1990 amendments, has tentatively determined that for foods that qualify for claims, such claims would only be justified for substances in dietary supplements as well as in conventional foods if the agency determines based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The 1990 amendments also require (section 3(b)(1)(A)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x) that within 12 months of their enactment, the Secretary shall issue proposed regulations to implement section 403(r) of the act, and that such regulations shall determine, among other things, whether claims respecting 10 topic areas, including lipids and cardiovascular disease, meet the requirements of the act. In this document, the agency will consider whether a claim on food or food products, including conventional foods and dietary supplements, on the relationship between lipids and cardiovascular disease would be justified under the standard proposed in "Food Labeling: General Requirements for Health Claims for Food."

B. Public Health Aspects: Basis for Considering a Health Claim Relating Lipids and Cardiovascular Disease

1. Cardiovascular Disease

The specific disease or health related condition identified in the 1990 amendments is cardiovascular disease, diseases of the heart and blood vessels. Cardiovascular disease is a major public health problem in the United States. Coronary heart disease (CHD) is the most common, most frequently reported, and most serious form of cardiovascular disease. Despite the dramatic decline over the past 15 years in the death rate from cardiovascular disease: 35 percent for all cardiovascular disease, 40 percent for CHD, and more than 50 percent for stroke (Ref. 36), CHD and stroke kill nearly as many Americans as all other diseases combined. Cardiovascular disease, primarily CHD, is also among the leading causes of disability. Changes in lifestyles, risk factor reduction, and medical intervention were major contributors to this decline (Ref. 36).

In order to be consistent with the magnitude of the public health problem and with the conclusions of the Federal government and other reports from recognized scientific bodies, such as the National Research Council (Ref. 20) and the Life Sciences Research Office (LSRO) (Ref. 78), the focus of this document is CHD rather than the broader problem of cardiovascular disease. CHD is the most common, most serious, and earliest form of cardiovascular disease, frequently producing symptoms and health problems in middle-aged adults (Ref. 20). Despite a declining death rate from CHD since the mid 1960's, CHD still accounts for more deaths than any other disease or group of diseases (Ref. 35). More than 1.25 million heart attacks occur each year (two-thirds occur in men), and more than 500,000 people die as a result (Ref. 35). In the United States, it is very common for significant pathogenesis of CHD to occur without easily detectable symptoms (Refs. 31 through 34). Thus, the total affected population is considerably larger than the statistics on death and illness would indicate. In addition to its impact on the nation's health, CHD costs the U.S. economy over $50 billion annually (Ref. 35).

2. Dietary Lipids

Food sources of dietary lipids commonly consumed in the United States include fats and oils (e.g., butter, margarine, vegetable oils, and shortenings), salad dressings, meats, and whole dairy products and egg yolk.

Digestion of food fats liberates fatty acids and other lipid components, including cholesterol, that are then absorbed for use in the body.

Fatty acids may be classified by length: short-chain (less than 6 carbons), medium-chain (6 to 10 carbons), or long-chain (12 or more carbons). Fatty acids may also be classified as saturated fatty acids (lacking double bonds), as monounsaturated fatty acids (containing one double bond), or as polyunsaturated fatty acids (containing two or more double bonds). The polyunsaturated fatty acids are subdivided into those whose first double bond occurs either three carbon atoms from the methyl end (omega-6-fatty acids) or six carbon atoms from the methyl end (omega-3-fatty acids) of the molecule. Dietary lipids and fatty acids are commonly referred to as "fat," e.g., as "total dietary fat" and as "saturated fat or saturated fatty acid" or "polyunsaturated fat or polyunsaturated fatty acid."

Dietary fats serve several major physiological functions. Small amounts (1 to 2 percent of total calories) of linoleic and linoleic acids, two polyunsaturated fatty acids, are essential in the diet as precursors of other essential lipids. Fats facilitate the intestinal absorption of fat-soluble vitamins. Cholesterol and other lipids are major components of all cell membranes. In addition, cholesterol is the precursor for synthesis of steroid hormones and bile acids.

Fat is the most concentrated source of dietary energy of all the nutrients, supplying 9 calories per gram (g) as compared to 4 calories per g from either carbohydrate or protein. More than one-third of the calories consumed by most people in the United States are provided by fat. In 1985, the estimated average intake of total fat ranged from 34 percent of caloric intake for children 1 to 5 years of age to 37 percent of calories for adults 19 to 50 years of age (Ref. 107). On average, saturated fat intakes were between 13 to 14 percent of calories. The major dietary sources of both total and saturated fats were dairy and meat products and baked goods.

Dietary cholesterol is also a type of dietary lipid, but it has different chemical and physiological properties from fatty acids. Cholesterol is derived either from the diet or from synthesis in the body. Only about 40 percent of ingested cholesterol is absorbed, the remaining 60 percent passes out in the stool. Average daily intakes of dietary cholesterol in the United States are estimated to be 304 milligrams (mg) and 435 mg for women and men, respectively (Refs. 20 and 33).

3. Relationship of Dietary Lipid (Saturated Fats and Cholesterol) and CHD

Because of the importance of CHD as a public health problem, identification of "modifiable" risk factors has received considerable research and public health policy attention since the early part of this century. Fatty streaks and cholesterol were identified many years ago as prominent components of the blood vessel (arterial) lesions whose buildup caused a narrowing or blockage of the blood flow to the heart (Refs. 20, 33, and 35). Following these early observations, a large body of scientific evidence has accumulated on the relationship of different types and amounts of dietary fats to risk of CHD. Based on the weight of the scientific evidence now available, virtually all recent dietary guidelines for Americans, whether from the Federal government or from the community of health professionals, have noted the high intake of dietary fat by the U.S. population and also the strong association of diets high in fat, particularly saturated fat and cholesterol, with increased risk of CHD (Refs. 20, 29, 31, 32, 33, 34, 35, and 36).

Many risk factors contribute to development of CHD. There is general agreement that elevated blood cholesterol levels are one of the major "modifiable" risk factors in the development of CHD (Refs. 31, 32, 35, and 36). Federal government and other reviews (Refs. 20, 31, and 33 through 36) concluded that there is substantial epidemiologic and clinical evidence that high blood levels of total cholesterol and low density lipoprotein cholesterol (LDL-cholesterol; LDL–C) are a cause of atherosclerosis (inadequate circulation of blood to the heart due to narrowing of the arteries), and represent major contributors to CHD (Refs. 20, and 31 through 36). Factors that decrease total blood cholesterol and LDL-cholesterol will also decrease the risk of CHD. High intakes of saturated fat, and to a lesser degree, of dietary cholesterol are consistently associated with elevated blood cholesterol levels. Thus, it is generally accepted that blood total and LDL-cholesterol levels are major risk factors for CHD, and that dietary factors affecting blood cholesterol levels affect the risk of CHD (Refs. 20, 31, and 33 through 35).

FDA has limited this review to those aspects of the dietary lipid and cardiovascular disease relationship for which the strongest scientific evidence and agreement already exists. This limitation was necessary because of the extremely large volume of literature available on the broader topic. Even with the narrow focus on dietary intakes of saturated fat and cholesterol, blood cholesterol levels, and risk of CHD, the volume of available scientific literature was large. Moreover, the focus that FDA has chosen is most consistent with current dietary guidelines for the U.S. population.

C. Regulatory History

1. Fat, Fatty Acids, and Cholesterol Labeling

The regulatory history of nutrient content and descriptive labeling for fat and related lipids reflects the changing nature of the scientific evidence over the years and also the increasing acceptance of research results by the general scientific community. Early emphasis was on dietary cholesterol. Later, as more research results became available, saturated fats were recognized as the primary dietary factor related to elevated blood cholesterol and to risk of CHD. At one time, it was felt that dietary modifications should be undertaken only under a physician's care. More recently, dietary recommendations for the general population have become the norm.

A detailed history of FDA policies on labeling of fat, fatty acids, and cholesterol is provided elsewhere in this issue of the **Federal Register** in the document on the use of nutrient content claims for these nutrients. Because of the availability of that history, FDA believes that it is not necessary to repeat it in detail here.

2. Health Claims

For many years, FDA has permitted firms to label foods with truthful, nonmisleading information about nutrient content. In the past, however, the agency did not permit firms to provide consumers with information in the label or labeling concerning how the food may be used to affect a disease or health-related condition because such claims could make the food a drug. A complete description of FDA's regulatory history in the area of health messages (subsequently, in this proposal, the term "health claim" is used in place of "health message" for consistency with terminology used in the 1990 amendments) is published elsewhere in this issue of the **Federal Register**, § 101.14. A brief summary is presented here.

In the **Federal Register** of March 14, 1973 (38 FR 6951), FDA promulgated regulations that provided, in part, that a food shall be deemed to be misbranded if its labeling represents, suggests, or

implies that the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom (see current 21 CFR 101.9(i) (1)).

In the **Federal Register** of August 4, 1987 (52 FR 28843), FDA proposed to change its policy to permit the appropriate use on food labeling of health claims. That document proposed to amend nutrition labeling regulations in § 101.9 to permit health claims when (1) they are truthful and not misleading; (2) they are supported by valid, reliable, and publicly available scientific evidence derived from well-designed and conducted studies consistent with generally accepted scientific procedures and principles performed and evaluated by persons qualified by expertise and training in the appropriate disciplines; (3) they are consistent with generally recognized medical and nutritional principles for a sound total dietary pattern; and (4) the food bears nutrition information in accordance with the requirements of § 101.9. There were wide differences in opinion and numerous adverse comments were received in response to the proposal.

In the **Federal Register** of August 8, 1989 (54 FR 32610), FDA published a request for comments on a wide range of food labeling issues, including health claims. On December 7, 1989, FDA convened a public hearing in Seattle. The topic of health claims was the prime focus.

Based on comments received, FDA withdrew the August 1987 proposal and published a reproposal in the **Federal Register** of February 13, 1990 (55 FR 5176). The 1990 reproposal proposed to more narrowly define appropriate health claims. As part of this reproposal, the agency stated that six topic areas would be evaluated for their appropriateness for health claims including lipids and cardiovascular disease.

D. Evidence Considered in Reaching the Decision

The agency has reviewed all relevant scientific evidence on saturated fat and cholesterol and their relationships to blood cholesterol levels (specifically total cholesterol and LDL-cholesterol) and risk of CHD. The scientific evidence reviewed included all conclusions reached in: "The Surgeon General's Report on Nutrition and Health" (Ref. 35); "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 29); "The Lipid Research Clinics Population Studies Data Book," Volume II, "The Prevalence Study—Nutrient Intake," (Ref. 149); "Population Strategies for Blood Cholesterol Reduction" (Ref. 33); "High Blood Cholesterol in Adults, Detection, Evaluation, and Treatment" (Ref. 31); "Hypertension and High Blood Cholesterol, Working Report on Management of Patients With" (Ref. 32); "The Relationship Between Dietary Cholesterol and Blood Cholesterol and Human Health and Nutrition" (Ref. 150); "Nutrition Monitoring in the United States, an Update Report on Nutrition Monitoring" (Ref. 30); and "Healthy People 2000: National Health Promotion and Disease Prevention Objectives" (Ref. 36).

The agency also considered the reports of recognized non-U.S. Government scientific bodies that bear on this topic. FDA reviewed the National Research Council's (NRC's) "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 20); "Recommended Dietary Allowances" (Ref. 136); "Lipids and Cardiovascular Disease" (Ref. 78); and "Diet, Nutrition, and the Prevention of Chronic Diseases" (Ref. 151).

To ensure that its review of the scientific evidence was complete, in the **Federal Register** of March 28, 1991, FDA published a notice (56 FR 12932) requesting scientific data and information relevant to the 10 specific topic areas identified in section 3(b)(1)(A) of the 1990 amendments, including dietary lipids and cardiovascular disease.

The agency reviewed and considered all comments submitted in response to the **Federal Register** notice in developing this document. Furthermore, the agency updated the conclusions reached in these documents by reviewing all human studies that have appeared in the literature since the publication of the documents listed above and all review articles. The agency also considered the results of nonhuman primate studies to the extent that they clarified human studies or suggested possible mechanisms of action.

E. Comments Received in Response to FDA Request for Scientific Data and Information

In response, to the FDA's request (56 FR 12932), FDA received 23 comments from food manufacturers, nutrient or dietary supplement manufacturers, national organizations of nutritionists and public health professionals, trade associations of nutrient supplement manufacturers, private physicians and health foundations, faculty of medical schools, and the Government of Canada. The comments dealt with the issue of lipids and cardiovascular disease as well as with the provisions and requirements of the 1990 amendments in general. FDA reviewed all of the documents, including books, abstracts, review articles, and scientific articles that were submitted. When appropriate, FDA included data submitted in scientific articles or books in its scientific literature review.

The majority of the comments, with one exception, expressed the view that the link between dietary fat and cholesterol intake and risk for cardiovascular disease was very strong. Many comments raised issues concerning the safety of polyunsaturated fatty acids in foods and supplements. Comments suggested that safety issues related to polyunsaturated fatty acids included increased risk of cancer and coronary thrombosis in humans, effects on immune function, and a role in osteoporosis. Comments recommended that consumption of foods (i.e., those high in salt) that alter other risk factors for CHD (i.e., hypertension) be included in the risk factor assessment of CHD.

The Director General, Food Directorate, Health and Welfare, of Canada submitted information on the regulatory status of health claims in that country which it considered helpful in the context of increased harmonization of regulations or standards affecting trade in specific products. Canadian law prohibits health claims on labels or in advertising when a nutrient is described for treatment, prevention, or cure of 46 diseases and disorders, including heart disease. On the relationship of the nutrient to the disease, the Canadian document stated:

> * * * the evidence linking saturated fatty acid intake with elevated blood cholesterol and the risk of heart disease is among the most persuasive of all diet-disease relationships. * * * Dietary cholesterol, though not as influential in affecting levels of blood cholesterol, is not without importance.

The Director General also stated that food label health claims regarding the role of fats in CHD risk would likely result in a food product being classified as a drug because the Food and Drug Act in Canada prohibits the advertising and sale to the general public of a food that is represented either by label or in advertising as a treatment, preventative, or cure for some 46 diseases, disorders, or abnormal physical states. Heart disease is among the major diseases for which such claims are prohibited.

Comments from national organizations of nutritionists and public health professionals advised that the agency should take a cautious approach to the use of health claims on foods and supplements with particular attention to avenues by which such claims might be abused or misinterpreted by the general

public. The comments recommended that scientific agreement should be the cornerstone for the use of health claims and that FDA should consider the data submitted in the context of meeting dietary requirements through intake of food. The comments asserted that only about 25 percent of the population may be responsive to reduction in dietary cholesterol and saturated fat, and thus the majority of the population at risk of cardiovascular disease may require medical advice and guidance and may need medication or a combination of medication and diet to achieve satisfactory lowering of serum cholesterol.

One comment recommended use of a formula that would indicate the cholesterol and saturated fat concentration in food. The term "cholesterol-saturated fat index" (CSI) was suggested. A low CSI index would indicate a low saturated fatty acid and cholesterol content. The use of such an index in planning low fat diets or in identifying potentially atherogenic foods was suggested. Comments from food manufacturers identified a number of modifiable risk factors for cardiovascular disease including dietary intake of saturated fat and cholesterol, sodium, fiber, and antioxidant vitamins. The manufacturers noted that both lifestyle and diet can have significant impacts on the risk of cardiovascular disease. One manufacturer submitted model health claims and examples of labeling. Another manufacturer suggested that the agency identify threshold levels of fats (saturated fatty acids, monounsaturated fatty acids, polyunsaturated fatty acids, total fat), and threshold levels of other dietary nutrients in relationship to fats. The comments expressed concern that deficiencies might be produced by significantly decreased fat intake. A manufacturer noted that a low fat food should contain the usual levels of all other important nutrients commonly found in that food. A manufacturer commented that low fat foods containing high concentrations of salt and sugar may lead to increased risk of cardiovascular disease by increasing hypertension and obesity, respectively.

One manufacturer expressed concern about varying nutrient densities of foods and how best to express nutrient content of foods. One food manufacturer suggested a need for further research in the area of trans fatty acids and serum cholesterol levels.

An association of medical professionals provided a number of references that suggest serum cholesterol goals for patients with noninsulin-dependent diabetes mellitus and patients with hyperlipidemia.

Trade organizations of supplement manufacturers provided a number of comments on the value and safety of dietary supplements and suggested categories under which health claims on dietary supplements might be classified. Comments also expressed concern about the amount of saturated fatty acids and total fat contained in the 2,350 calories per day reference diet proposed by FDA as the basis for nutrition labeling for the general food supply. The comments stated that this level of calories may represent excess calories, saturated fat, and total fat for a significant proportion of the population (i.e., women).

Comments from professional medical associations and members of university medical faculties suggested that the emphasis of health claims regarding fat and cardiovascular disease should be on reduction of both saturated fatty acids and total fat, and that complex carbohydrates are recommended as the major replacement for calories from fat.

Comments were submitted regarding definitions for saturated fatty acids and polyunsaturated fatty acids. One comment suggested that saturated fatty acids be subdivided in a manner analogous to the subdivision of omega-3 and omega-6 polyunsaturated fatty acids. The comment noted that fatty acids of less than 12 carbons in length (for example, lauric acid) are metabolized by the liver, while saturated fatty acids of more than 12 carbons in length are metabolized through the lymphatic system.

One comment dealt with the Keys equation (Ref. 20) and noted that the equation does not have a term for the amount of monounsaturated fatty acids.

As appropriate, comments will be responded to in this document in the review of the scientific literature or in the discussion of the proposed regulation.

II. Review of the Scientific Evidence

A. Federal Government Documents

In 1982, a monograph derived from the population studies of the Lipid Research Clinics Program (Ref. 149) provided extensive information on the prevalence of hyperlipidemia (elevated blood lipids) in the United States. The data from 17 Lipid Research Clinics throughout the United States were derived from a series of epidemiologic surveys aimed at identifying the distribution, causes, and consequences of hyperlipoproteinemia (elevated levels of lipid transport particles in the blood).

A report to Congress pursuant to the Food Security Act of 1985 (Ref. 150) prepared by the Department of Health and Human Services and U.S. Department of Agriculture (DHHS/USDA) concluded that carefully controlled studies under metabolic ward conditions leave little doubt that increasing dietary cholesterol will induce a rise in plasma total cholesterol in most people. The report stated that when all data are taken together, the increase in plasma cholesterol resulting from ingestion of dietary cholesterol averages about 10 mg cholesterol per 100 milliliters (decaliters (dL)) for every 100 mg dietary cholesterol per 1,000 calories consumed. Thus, the report stated, increasing dietary cholesterol from 300 to 500 mg per day for a person consuming 2,000 calories per day will cause an increase in the plasma cholesterol of about 10 mg per dL. The report found that the major effect of dietary cholesterol is to raise the LDL-cholesterol fraction of total blood cholesterol.

Comprehensive reviews of the relationship of dietary fats and CHD are included in recent Federal government reports. In 1988, the "Surgeon General's Report on Nutrition and Health" (Ref. 35) reviewed studies of associations between dietary factors and risk of chronic disease. The Surgeon General's report found that results of epidemiologic, clinical, and animal studies provided strong and consistent evidence for a relationship between high intakes of saturated fat, high blood cholesterol, and increased risk of CHD. Conversely, reductions in blood cholesterol levels reduce the risk of death from CHD. The report noted that excessive dietary saturated fat is the major contributor to total blood cholesterol levels. The report also noted: (1) The effect of dietary cholesterol on blood cholesterol levels is less consistent than that for saturated fats (Ref. 35); (2) the roles of other dietary fats such as monounsaturated fatty acids and polyunsaturated fatty acids were not well defined. The Surgeon General's report concluded that the disproportionate consumption of foods high in fats was of primary concern for Americans. The Surgeon General's report recommended reduction in intake of fats (especially saturated fats and cholesterol). Although the relationship of CHD and lipids was primarily attributable to saturated fats and cholesterol, the recommendation for changes in American dietary patterns included a reduction in consumption of total fat because of the possible association of total fat with risk of other

diseases (cancer and diabetes), because of the likely role of high dietary fat intakes in increased risk of obesity (another risk factor for CHD), and because a decrease in total fat consumption facilitates a reduction in saturated fatty acids.

DHHS and USDA in "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 29) state that the lipids in American diets most often and most strongly associated with increased risk of atherosclerotic CHD are saturated fat and cholesterol. CHD rates and population risk were most strongly related to average serum cholesterol levels, particularly LDL-cholesterol levels. According to this report, other factors strongly linked with increased risk of CHD are high blood pressure, smoking, and diabetes. The relationship between obesity and CHD risk was more variable. Among the recommendations from the DHHS/USDA report to Congress relating to decreasing the risk of CHD include: decreasing the total amount of fat in the diet to less than 30 percent of calories; decreasing the amount of saturated fat in the diet to less than 10 percent of calories; eating less animal fat (the source of all dietary cholesterol) to aid in reducing serum cholesterol; and restricting intake of salt to aid in decreasing blood pressure (Ref. 150).

Reports from the National Cholesterol Education Program (NCEP); National Heart, Lung, and Blood Institute, National Institutes of Health, 1988 to 1990) reached similar conclusions regarding relationships among intake of dietary saturated fats and cholesterol, elevated blood cholesterol levels, and CHD (Refs. 31 through 34). The reports noted that approximately 55 percent of adult Americans have cholesterol levels at or above a desirable level. The reports also emphasize the important roles of genetic and environmental factors in blood cholesterol levels. The reports concluded that excessive intake of saturated fat, total fat and dietary cholesterol, together with excessive body weight, all contribute to elevated blood cholesterol levels. The reports stated that the role of total fat intake is not direct, but reduced fat intake aids in decreasing intakes of saturated fat and cholesterol and may facilitate maintenance of ideal healthy body weight. The National Cholesterol Education Program (NCEP) (Refs. 31, 33, and 34) recommended the following pattern of nutrient intake for healthy Americans:

(1) Consume less than 10 percent of total calories from saturated fatty acids;

(2) Consume an average 30 percent of total calories or less from all fat;

(3) Consume dietary energy in amounts needed to reach or maintain a desirable body weight; and

(4) Consume less than 300 mg of cholesterol per day.

The NCEP panel, noted compelling evidence that the atherosclerotic process (and hypertension) begins in childhood and progresses into adulthood. Toddlers over 2 years of age may safely make the transition to recommended eating patterns as they begin to eat with the family (Ref. 34). The NCEP recommendations are not intended for infants from birth to 2 years of age (Ref. 34).

The Public Health Services (PHS) DHHS report "Healthy People 2000: National Health Promotion and Disease Prevention Objectives," (Ref. 36) noted that cardiovascular disease, primarily CHD and stroke, kill nearly as many Americans as all other diseases combined, and that a casual relationship between high blood cholesterol and CHD has been demonstrated (Ref. 36). As noted in other Federal government documents, the report stated that the key modifiable factors that influence risk of CHD include: cigarette smoking, high blood cholesterol, high blood pressure, excessive body weight, and sedentary lifestyle. Reducing death from heart disease and stroke, and reducing mean serum cholesterol level among adults to no more than 200 mg per dL, are among the major public health goals identified in the Healthy People 2000, report. The Healthy People 2000 report recommended that Americans should reduce dietary fat intake to an average of 30 percent of calories or less and average saturated fat intake to less than 10 percent of calories in order to help achieve these goals.

B. Reviews From Recognized Scientific Bodies

The National Research Council's 1989 report, "*Diet and Health:* Implications for Reducing Chronic Disease Risk" (Ref. 20) reviewed the role of dietary fats and risk of chronic disease. The report concluded that there is clear evidence that the total amount and types of fats and other lipids in the diet influence the risk of cardiovascular disease (Ref. 20), and that evidence that intake of saturated fatty acids and cholesterol are causally related to CHD (CHD) is especially strong and convincing. The report recommended that persons in the general population limit their intake of total fat to 30 percent of calories and reduce their intake of saturated fatty acids to 10 percent or less of total calories. The report stated that individual responses to dietary cholesterol vary, but noted that, on average, intakes exceeding 100 mg of dietary cholesterol per 1,000 calories elevates LDL-cholesterol by 8 to 10 mg per dL. They recommended limiting dietary cholesterol intake to 300 mg per day or less.

LSRO/Federation of American Societies for Experimental Biology (FASEB) (Ref. 78) prepared an evaluation of the scientific literature on the relationships between dietary lipids and cardiovascular disease, particularly CHD (Ref. 78). The LSRO's conclusions support the major conclusions of the Federal government and other reports from recognized scientific bodies on the role of dietary lipids (saturated fats, other fats, and cholesterol) in the risk of CHD.

With respect to cholesterol, the LSRO report concluded that: (1) Dietary cholesterol may be a greater dietary risk factor than generally realized; (2) almost all individuals respond to dietary cholesterol with at least some rise in serum cholesterol; (3) the danger of high dietary intakes of cholesterol for certain individuals who are high responders to dietary cholesterol may be even greater than the average; and (4) the average increase in serum cholesterol ranges from 6 to 10 mg per dL for each 100 mg cholesterol consumed per 1,000 calories. More recent analysis of epidemiologic data suggests that an increase of 1 mg serum cholesterol per dL, sustained for many years, increases risk of CHD by 1.5 percent. LSRO (Ref. 78) concluded that a strong case, based on circumstantial evidence, implicates dietary cholesterol in atherogenesis, and therefore supports current dietary recommendations to limit dietary cholesterol consumption to less than 300 mg per day.

C. Review of the Scientific Literature

1. Background

CHD is the most common and most serious form of cardiovascular disease. Atherosclerosis is the underlying pathogenic cause in the development of CHD. A relationship between dietary lipids, deposition of cholesterol esters in arterial walls, and CHD was hypothesized early in this century (Ref. 20). Animal studies provided the first direct evidence linking diets high in saturated fat and cholesterol to cholesterol accumulation in atherosclerotic lesions. In this document, the agency reviews pertinent studies relating high intakes of dietary lipids (particularly saturated fats and cholesterol) to elevated serum cholesterol levels and to risk of CHD.

2. Criteria

The criteria used to select pertinent studies required them to be publicly available in English, to present primary data, to include direct measurements or quantitative estimates of dietary lipids, and to include measurements of risk of CHD (incidence and prevalence rates, mortality, or clinical measures of blood total or LDL-cholesterol levels).

In the agency's evaluation of the scientific literature on the relationship of dietary lipids (saturated fat and cholesterol), blood cholesterol levels, and risk of CHD, FDA gave more weight to human studies than to studies in animal models. Because the conclusions of the Federal government and other review documents most consistently identified saturated fat and cholesterol as causally related to CHD risk, a review of studies on other than nonhuman primates and on aspects of cardiovascular disease other than CHD published subsequent to the most recent Federal government reviews, and other reviews by recognized scientific bodies, was not included in this review. Similarly, study results for end points other than CHD or the clinical intermediates of blood total and LDL-cholesterol were also not reviewed due to time constraints and because of the strong focus on these measures in the reports of government and others.

FDA reviewed several types of epidemiologic studies. The strengths and weaknesses of different types of epidemiologic studies and the methodologies for assessment of dietary intakes are reviewed elsewhere (Ref. 20).

FDA generally gave the greatest weight to randomized, double-blind, controlled (placebo or self) clinical trials. Dietary intervention studies conducted for shorter periods of time with fewer subjects were used to support conclusions of large clinical trials. FDA looked for repeated and consistent findings across different types of studies and different population groups. Data were evaluated against general criteria for good experimental design, execution, and analysis. FDA evaluated the weaknesses and strengths of individual studies; then looked at the strength of the overall combined evidence, taking into account the strength of the association, the consistency of findings, specificity of the association, biological plausibility, and dose response. Because of general scientific agreement prior to this review, FDA also looked for consistency or inconsistency with prior conclusions.

The relationships among dietary fats, including saturated fats, cholesterol, and risk of CHD are complex. For this reason, common measures or elements of diet and assessment of risk of CHD were sought in all studies. These measures or elements include the following:

(a) Identification of level of dietary lipids most consistently related to raising levels of blood cholesterol. As a minimum, information on intakes of saturated fat and cholesterol was required;

(b) Identification of commonly used clinical measurements in the assessment of development or progression or risk of CHD. As a minimum, studies were required to have measurements of total cholesterol. Measurements of low density lipoprotein cholesterol (LDL-cholesterol) were deemed desirable;

(c) Observation of clinically manifest CHD including, for example, myocardial infarction, angiographically demonstrated lesions, CHD mortality, and total mortality, were deemed desirable when measures of blood cholesterol were available. These measures were essential in the absence of blood cholesterol data.

3. Dietary Lipids and Risk of CHD

a. *Epidemiologic studies*—i. *Background.* Epidemiologic studies describing the relationship between dietary fats, their effect on blood cholesterol levels, and risk of CHD were described and reviewed extensively in Federal government reports (Refs. 33, 35, and 36), other documents (Ref. 20), and in many reviews cited in these documents. The Federal government and other reviews by recognized scientific bodies concluded that there was strong and consistent evidence that blood total cholesterol and LDL-cholesterol levels are a cause of CHD (Refs. 20, 31, 33, and 36); they estimated that on average, a 1 percent reduction in serum cholesterol is associated with a 1.5 to 2 percent reduction in risk of CHD (Refs. 20, 31, 33, 63, 79, 80, and 147).

FDA reviewed a number of studies and reviews (including meta-analysis of epidemiological and clinical trials) published subsequent to 1987 (Refs. 1, 17, 27, 62, 63, 74, 75, 77, 80, 98, 108, 109, 112, 113, 114, 117, 120, 128, 129, 130, 132, 137, 141, 147) on the relationship of blood cholesterol and CHD and confirmed that more recent studies confirmed and strengthened the previous conclusion.

This section (II. D.) begins with a brief description of two epidemiologic studies reviewed by the Federal government and other reviews by recognized scientific bodies (Refs. 20 and 35) and which describe the relationships between dietary lipids (saturated fat, total fat, and cholesterol) and blood cholesterol levels. The design, results, and conclusions of epidemiologic studies subsequent to the above conclusions are contained in Table I of this document.

In the seven countries study, which was conducted in the United States and six other countries, and included 11,579 men 45 to 49 years of age, 7-day food records and duplicate meals were collected and analyzed to determine the relationship of intake of specific dietary lipids to serum cholesterol (Ref. 35). The results demonstrated a positive correlation between calories consumed from total fat and serum cholesterol levels ($r=0.67$). Correlations between intake of saturated fat and dietary cholesterol and between dietary cholesterol and serum cholesterol were stronger (0.87 and 0.90, respectively). The results of the study showed that there were substantial variations in the amounts and types of fats consumed by different populations. Average blood cholesterol levels and rates of CHD were highly correlated with the percent of calories derived from saturated fatty acids and less strongly correlated with total dietary fat intake. Furthermore, the study provided strong evidence that the risk of CHD is continuous across a wide range of serum cholesterol levels (Ref. 20). The NCEP Expert Panel (Refs. 31 and 33) concluded that this study provided strong epidemiologic support for the relationship between diets high in saturated fat and increased risk of CHD.

The Ireland-Boston Diet-Heart Study (Refs. 20, 35, and 73) was a prospective study of middle-aged Irish men residing in Ireland and brothers who had migrated to Boston. Each group consumed diets typical of their places of residence. Brothers living in Ireland or in Boston who consumed low-fat, low cholesterol diets had similar age-adjusted serum cholesterol levels. The Irish immigrants who adopted the high-fat diet of Boston (16 to 18 percent of calories as saturated fat; 2 to 3 percent of calories as polyunsaturated fat; and 233 to 273 mg cholesterol per 1000 calories) had higher serum cholesterol levels and higher risk of CHD than brothers consuming diets lower in fat and cholesterol. Thus, a positive association was found between dietary intakes of saturated fat and cholesterol and elevated serum cholesterol and risk of CHD among men with similar genetic backgrounds but whose dietary patterns and lifestyles differed.

Based on these and similar results from numerous other studies, the Federal government and other reviews

concluded that an extensive amount of evidence (derived from a variety of types of epidemiologic studies and reinforced by other kinds of research) demonstrated that dietary lipids, particularly saturated fat and cholesterol, are highly correlated with blood cholesterol and rates of CHD (Refs. 17, 27, 108, 109, and 131). Current intake of saturated fat in the U.S. American diet has been estimated to average about 13 percent to 14 percent of total calories (Refs. 20 and 29).

ii. *Update.* FDA reviewed all human studies subsequent to 1987 to determine whether conclusions reached in the Federal government and other reviews by recognized scientific bodies needed to be modified based on the results of more recent findings. In the short review below, studies dealing with omega-3-fatty acids are not considered because the relationship of omega-3-fatty acids and heart disease is the subject of another health claims proposal published elsewhere in this issue of the **Federal Register.** For reasons discussed previously, reporting of results is limited to dietary intakes of saturated fat and cholesterol relative to blood total cholesterol, LDL-cholesterol, or risk or occurrence of CHD.

In a cross-sectional analysis of 976 African men and women of color aged 15 to 64 years, there was a significant independent correlation between blood total cholesterol and dietary intakes of specific types of fat and cholesterol (Ref. 134). Consumption of diets high in fat and saturated fat (37 and 12.3 percent of calories, respectively) and cholesterol (greater than 310 mg per day) were positively correlated with increased blood cholesterol levels (7.5 millimole (mmol) per l or 290 mg per dL) compared to 4.5 mmol per l (174 mg per dL) in the group that consumed less fat (35.8 percent), saturated fat (10.8 percent) and cholesterol (284 mg per day) (Ref. 134).

The relationship between composition of foods and CHD risk factors, including serum cholesterol, was analyzed in the study by Trevisan et al. (Ref. 139). This cross-sectional study of 10,800 middle-aged men and women in 9 Italian communities (dietary data obtained by questionnaire) showed that higher serum cholesterol levels (5.65 mmol/L; 218 mg/dL) (5.65 mmal/L; 218 mg/dL) were strongly associated with diets high in butter (relatively high in saturated fat and low in other types of fatty acids) (Ref. 139). Additionally, lower levels of blood cholesterol (5.45 mmal/L; 210 mg/dL) were associated with dietary patterns characterized by higher intakes of olive oil and vegetable oil (relatively low in saturated fat and high in polyunsaturated fat and monounsaturated fat) (Ref. 139).

A Belgian study of 5,485 men and 5,456 women showed that in both sexes, higher saturated fat (17.3 percent of calories) and dietary cholesterol (435 mg/day) intakes were associated with higher total cholesterol levels (235 mg per dL) after adjustments were made for lifestyle and physiologic variables using multiple regression-analysis (Ref. 68). Lowik et al. (Ref. 83) studied 199 elderly men and 180 elderly women (65 to 79 years of age) and found a positive correlation between intake of saturated fat (assessed by dietary history) and blood total cholesterol in women but not in men.

Dietary and cross-checked lifestyle questionnaires were used to determine the relationship of diet to serum lipids in 315 free-living Dutch males between 28 and 29 years of age (Ref. 5). The typical Dutch diet contained 39 percent fat, 43 percent carbohydrate and 3282 calories per day. Consumption of a diet high in saturated fat (15.5 percent of calories) and cholesterol (128 mg per 1,000 calories) showed a weak but significant positive association with total serum cholesterol and LDL-cholesterol. Many other epidemiological studies are described in Table 1 which relate diet intakes of dietary fat, especially fatty acid and to blood cholesterol levels (Refs. 28, 40, 51, 70, 83, and 143).

Results of a reanalysis of data collected in the Israeli survey of 8,829 men (40 to 60 years of age) showed a highly significant positive relationship between intake of dietary saturated fat and elevated serum cholesterol. Data were adjusted for intra-individual variability by use of a regression model (Ref. 70).

A prospective study in Japan involving two cohorts of men and women with greater than 2,250 subjects in each cohort monitored dietary animal fat intake and serum cholesterol levels for 7 to 11 years (Ref. 121). At baseline, each cohort was 40 to 69 years of age in 1963 to 1966 or in 1972 to 1975. At initiation of the study, animal fat intake (as determined by random food collection, interviews, and 24-hour dietary recalls) was 4.5 percent of daily calories in the 1963 to 1965 cohort and 9.6 percent of daily calories in the 1972 to 1975 cohort. Serum cholesterol increased 22 mg/dL in men and 29 mg/dL in women which was highly correlated with high intakes of animal fat in every age group and for both genders, but there was no significant change in CHD during the two decades. Serum cholesterol was inversely associated with cerebral hemorrhage in the early cohort.

FDA reviewed meta-analyses and primary data from epidemiologic and clinical studies which analyzed the relationship of lowering of serum cholesterol to risk of CHD (Refs. 12, 14, 16, 17, 42, 63, 76, 85, 86, 106, 130, 137, 141, 146, and 147). Meta-analysis combines data collected with differing methodologies. This complicates data analysis and assessment.

Bush et al. (Ref. 17), in a meta-analysis of nine prospective studies, found that in women a diet low in saturated fat and cholesterol was associated with lower levels of blood total cholesterol and LDL-cholesterol (Ref. 17). Women with total blood cholesterol values greater than 265 mg per dL were at three times greater risk of CHD than women with blood cholesterol below 220 mg per dL.

Shekelle and Stamler (Refs. 120 and 130) reviewed and reanalyzed published epidemiologic studies to evaluate the strength of the effect of dietary cholesterol intakes on serum cholesterol and risk of CHD. The authors evaluated whether dietary cholesterol alone had an independent effect on blood cholesterol. They evaluated four prospective studies (Western Electric study, Ireland Boston Diet-Heart Study, the Zutphen study, and the Honolulu Heart Program) published since 1981. Dietary cholesterol intake in individuals was found to be significantly and positively related to their long-term risk of CHD, independent of, and in addition to, serum cholesterol, blood pressure, and tobacco use. On average, a dietary intake of 300 mg cholesterol per 1,000 calories was associated with a blood cholesterol that was increased approximately 6 to 7 percent. On average, a 200 mg per 1,000 calorie higher intake of cholesterol at baseline was associated with a 30 percent higher CHD rate (95 percent confidence interval).

In summary, recent epidemiological studies evaluated the relationships of dietary fat intakes and blood cholesterol levels. In general, these studies reported significant independent positive correlations between serum total cholesterol and dietary intakes of saturated fat and cholesterol.

There are several detailed recent reviews of this area (Refs. 48, 62, 63, 74, 75, 117, 129, 130, 148). These reports also concluded that there was substantial epidemiologic evidence showing that consumption of dietary fats, especially saturated fatty acids and cholesterol, was highly positively correlated with elevated blood cholesterol and risk of CHD.

b. *Clinical studies*—i. *Background.* Even in very large epidemiologic studies, it is difficult to identify a relationship between dietary intake of a specific nutrient and a disease. One problem is that diets consumed by study participants are not homogeneous, and it is difficult to accurately quantify dietary intakes from dietary recall records. Clinical studies, however, are able to estimate the effects of particular foods or food components with respect to a specific disease process. Clinical trials provide more specific, definitive, and quantitative information on the relationship of dietary components (for example, saturated fat or cholesterol) and to risk factors related to CHD (for example, levels of serum cholesterol).

Federal government reports and other reviews by recognized scientific bodies described and extensively reviewed a wide variety of clinical trials and concluded that the results of clinical trials support epidemiologic studies and show that diets high in saturated fat and cholesterol are strongly correlated with high levels of serum cholesterol (Refs. 20, 31, 33, and 35). These reports also note that some research has also been directed toward identification of specific fatty acids which alter serum cholesterol levels. For example, saturated fatty acids, such as palmitic (C–16), myristic (C–14), and lauric acid (C–12), are more cholesterol-raising than other saturated fatty acids (Ref. 20). However, the reports varied considerably in the emphasis placed on these findings and none of the reviews specifically targeted these three saturated fatty acids when making recommendation for dietary changes by the U.S. population.

The Federal government and other reviews concluded that possible roles of other fatty acids (i.e., monounsaturated fats, polyunsaturated fats) modulating blood cholesterol levels and or CHD risk have been suggested by human studies, but that the evidence is weaker than those roles described for saturated fats and dietary cholesterol.

ii. *Update*—(1) *Dietary intervention to reduce serum.* Dietary intervention trials are reviewed in Table II. The effect of a low fat, low cholesterol diet on serum cholesterol levels, myocardial infarction, and mortality from CHD was assessed in the Minnesota Coronary Survey, a double blind, randomized, open enrollment, dietary trial that included 4,393 men and 4,664 women. The study was conducted in six state mental hospitals and one nursing home (Ref. 42). The patients consumed institution-provided diets for an average of 384 days. Two diets containing 39 percent of total calories as fat were compared. The control diet (a high saturated fat diet) provided 18 percent saturated fat, 5 percent polyunsaturated fat, 16 percent monounsaturated fat, and 446 mg cholesterol per day. The experimental diet (a low saturated fat diet) had less saturated fat (9 percent) and cholesterol (166 mg) and more polyunsaturated fat (15 percent) than did the control diet. Consumption of the low saturated fat diet was associated with a reduction in serum total cholesterol from 207 mg per dL to 175 mg per dL. Serum cholesterol levels in the control group remained at 203 mg per dL. Four and one-half years after starting the diet, however, no differences were observed in the population studied in myocardial infarctions, deaths from CHD, or total mortality. Eighty-one percent of the patients stayed in the hospital less than 1 year. There was, however, a decrease in numbers of deaths and myocardial infarctions in men and women in the 45 to 55 year old subgroup who consumed low saturated fat diets for more than 2 years. A similar change was not observed in the 35 to 39 year old group.

Women, as previously reported in men, with the highest basal serum cholesterol levels achieve the greatest reductions in serum cholesterol upon dietary intervention. In a recent study by Boyd et al. (Ref. 9) of 206 women over 30 years old with monographic dysplasia (breast cancer), half were placed on a low fat (total fat 21 percent, saturated fat 7 percent of total calories, respectively; cholesterol 244 mg per day), high carbohydrate (52 percent of calories) diet for 1 year. Total fat and saturated fat was 37 and 14 percent of total calories, respectively, and cholesterol 344 mg per day in the control diet. In women who consumed the low saturated fat diet, total serum cholesterol levels were significantly reduced by 8 percent at 4 months and serum cholesterol was most effectively reduced in women with the highest basal serum cholesterol levels. No significant changes in serum cholesterol were observed in the control group. The group that received dietary counseling had a significant decrease in body weight and low density lipoprotein cholesterol as well, which was not observed in the group that did not receive counseling.

The effectiveness of dietary instruction on the control of serum cholesterol levels was related in the following study. Curzio (Ref. 26) demonstrated that low fat, low saturated fat, and low cholesterol dietary counseling by trained dietitians' changes in dietary patterns are effective means of reducing serum cholesterol and risk of CHD. Half of 124 hypercholesterolemic and hypertensive patients received dietary counseling regarding low-fat, low-cholesterol diets and half did not (Ref. 26). At baseline the average serum cholesterol for all subjects was 6.5 mmol per 1 (250 mg per dL). Serum total cholesterol, measured two years later, significantly decreased in both groups compared to initial serum cholesterol levels. The group that received dietary counseling had a greater decrease in body weight, total cholesterol (12 percent compared to 8 percent in the control group), and LDL-cholesterol than did the group which did not receive counseling.

(2) *Multifactorial clinical intervention.* The corner stone of multifactorial clinical intervention for reduction in serum cholesterol is low saturated fat and low cholesterol diets as a part of larger lifestyle changes. These multifactorial clinical trials often include several concomitant changes including: the use of a combination of interventions diets low in fat, saturated fat, cholesterol, and sodium, control of high blood pressure, reduction in smoking; stress management; and moderate exercise programs. A 10.5 y. followup of the Multiple Risk Factor Intervention Trial (MRFIT), which involved 12,866 men at risk of CHD was recently reported. Half (n=6,428) of the subjects were assigned to special intervention and the other half 6,438 to usual care. A significant decrease (24 percent) in mortality due to acute myocardial infarction and a 7.7 percent decrease in death from all causes (Ref. 101) was observed. This study demonstrates in subjects at risk of developing CHD that multifactorial dietary and lifestyle changes reduce risk. These data can also be cautiously applied to the general population who possess more than two risk factors for CHD.

A small multifactorial intervention trial (71 subjects, 55 who were at high risk of developing CHD) used a low fat-vegetarian diet (6.8 percent of calories) and reported significant regression of coronary lesions (Ref. 106). There was no regression of the disease in control subjects who consumed higher fat diet (29.5 percent of total calories.

(3) *Metabolic studies.* "Metabolic ward" studies are conducted under tightly controlled conditions. Such studies, however, due to their short duration (usually less than 2 months) and small numbers of subjects (usually less than 50 subjects) have less predictive value for determining risk of CHD than do clinical trials. Metabolic ward studies do provide important

information regarding possible specificity, dose-response relationships, short-term effects and possible mechanisms by which dietary fats and cholesterol affect serum cholesterol and risk of CHD. These studies allow for cautious conclusions to be made on the effects of dietary lipids on serum lipids and can be used to confirm inferences derived from clinical studies.

Review of the extensive number clinical trials and clinical trials and metabolic ward studies which have been reported since the publication of the reports by the Federal government and by recognized scientific bodies (Refs. 2, 4, 6, 9, 20, 26, 31, 33, 35, 36, 42 through 45, 53, 54, 57, 69, 82, 88, 89, 92 through 94, 103, 105, 144) are not discussed in detail in the text of this document. Major features and results of a number of these studies are included in Table II, however.

In summary, these studies generally have shown that dietary fat affects blood cholesterol levels in most individuals. Not all dietary fats affect blood cholesterol levels to the same degree or in the same direction. In the majority of studies, dietary intakes in which saturated fat and cholesterol were low relative to basal or control diet showed an association with lower blood cholesterol levels and CHD risk. The nature of most of the studies did not permit conclusions as to links between intakes of specific types of fat (specific saturated fatty acids, monounsaturated, and polyunsaturated fatty acids) and effects on serum cholesterol. Results are, however, consistent with earlier conclusions in the reports by the Federal government and other recognized scientific bodies that diets low in saturated fats are associated with lower total blood cholesterol and LDL-cholesterol.

(4) *Dietary cholesterol and serum cholesterol.* In addition to linking diets high in saturated fat to increases in serum cholesterol levels, the Federal government and other reviews by recognized scientific bodies also concluded that high intakes of dietary cholesterol are associated with higher blood cholesterol levels. Several recent studies have examined this association. Current American intake of dietary cholesterol is approximately 425 mg per day for men and lower for women and children.

Healthy (n=10), free-living, normo-lipidemic men (average age 27 years) participated in a blinded crossover study designed to determine the effects of dietary cholesterol and exercise on serum cholesterol levels. Subjects who consumed low-fat diets (30 percent of calories with a polyunsaturated to saturated fatty acid constant value of 1.5), exercised aerobically 25 minutes per day, and were supplemented with 600 mg per day of cholesterol for 4 weeks showed increases in LDL-cholesterol compared to subjects fed diets supplemented with 200 mg per day cholesterol (Ref. 66). Individual responses were highly variable but there were significant increases in LDL-cholesterol. Three out of 10 subjects showed an increase in LDL-cholesterol of greater than 2-percent and two showed increases in LDL-cholesterol between 10 and 25 percent.

In a dietary intervention study, 58 free-living subjects previously identified by the authors as "hypo"- or "hyper"-responders to dietary cholesterol were placed on low fat diets (total fat was 29 percent, and monounsaturated fat was 7.5 percent of total calories and polyunsaturated fat to saturated fat content was held constant at a ratio of 1.5). The subjects were challenged with increased dietary cholesterol levels (ranging from 90 to 410 mg cholesterol per day) in a cross-over design (Ref. 41). Those subjects who were responders to saturated fats (blood cholesterol increased more than 8 percent) also showed a small increase in serum total cholesterol and LDL-cholesterol when challenged with increased dietary cholesterol while on 29 percent fat diets. Thus response to dietary cholesterol was not totally dependent on saturated fat intakes. Other dietary cholesterol studies (Ref. 93) are described in Table II.

Segal (Ref. 118), using data from epidemiological and clinical studies, estimated that if individuals reduced consumption of dietary cholesterol from 300 mg per 1000 calories per day to 150 mg of cholesterol per 1000 calories per day without making any dietary change in fat or in total calories, they would experience in a 7.6 mg per dL decrease in blood cholesterol.

In summary, the limited number of dietary cholesterol intervention studies published subsequent to the reports by the Federal government and other recognized scientific bodies show results consistent with those reports, i.e., that dietary cholesterol has an independent effect on serum cholesterol level.

(5) *Individual differences in response to dietary lipids.* The variability in individual responses to dietary lipids is well-recognized (Refs. 20 and 35). Connor (Ref. 21) and Gotto (Ref. 50) reviewed possible mechanisms that may explain variations in individual response to lipids. These authors postulated that each individual may have a threshold amount of saturated fat or cholesterol that when consumed, will increase serum lipid levels (i.e., LDL-cholesterol), and a ceiling amount beyond which further dietary consumption of foods that elevate blood cholesterol will have no effect. The average threshold amount for most people would be 100 mg of cholesterol per day. An average ceiling amount would be approximately 300 to 400 mg per day.

D. Safety Considerations

Reductions in dietary intakes of saturated fat and cholesterol would presumably result in higher intakes of other dietary components (monounsaturated and polyunsaturated fats, carbohydrates, and commercially generated fats) since calories lost from decreased intake of saturated fats must be "made up" by other components. Increased intakes of other types of fats is a possible result. Some of these fats are not metabolized in a manner analogous to common dietary fats and are not generally found in diets to a significant degree.

It is possible that the amount and type of fats available for consumption by the public may change. The agency in its review of the recent scientific literature and comments received by the agency, has identified several areas of possible concern regarding changing American dietary patterns.

1. Trans-Fatty Acids

One area of potential concern is the increasing availability for consumption of trans-fatty acids. Trans-fatty acids (generally isomers of cis monounsaturated fatty acids) are primarily constituents of commercially hydrogenated or hardened natural vegetable oils used in the formulation of margarine, shortenings, salad and cooking oils. Trans-fatty acids may also be found in some meat and dairy products since they are synthesized in the rumen of cattle. Hydrogenation of vegetable oils high in unsaturated fatty acids is used to make oils more palatable or to meet functional needs in food processing. It has been estimated that from 2 percent to 7 percent of beef fat and butterfat, and from 10 to 30 percent of margarine, shortenings and salad oils consist of trans-fatty acids. This is equivalent to approximately 6 percent of total fat consumed in the US or 8.1 g of trans-fatty acids per person per day (Refs. 20 and 65).

The reports of the Federal government and other recognized scientific bodies concluded that most of the evidence indicates that trans-fatty acids, in the quantities currently consumed in the

U.S. diet, do not adversely influence serum cholesterol concentration, and that when substituted for saturated fatty acids, the trans-fatty acids may be associated with a decrease in serum cholesterol (Ref. 20). Studies that examine the effects of trans-fatty acids on serum cholesterol levels are limited, however, and often report conflicting results and conclusions. In addition, there may be other effects unrelated to lipid and lipoprotein metabolism, that deserve careful attention and additional investigation.

LSRO prepared a report on health effects of dietary trans-fatty acids for the agency in 1985 (Ref. 77). In 1885, the estimated average trans-fatty acid content in the U.S. food supply was about 5.5 percent. This level of trans-fatty acids was consistent with that found in human adipose tissue. The data suggested an association rather than a casual relationship.

Studies with individuals fed diets of similar fatty acid composition, except for the replacement of cis isomer (i.e., oleic acid) with the trans isomer (i.e., elaidic acid) of partially hydrogenated vegetable oils, showed that the trans oils were no more cholesterolemic than were the cis isomers (Ref. 77). Similar studies in which elaidic and oleic acid were fed to different experimental groups were not definitive and differences between groups in elevation in serum cholesterol were not significant. Short term studies in animals showed that dietary elaidic acid or partially hydrogenated vegetable are cholesterolemic but not atherogenic (Ref. 77).

In one recent study, the gluteal adipose tissue fat biopsies were removed from 76 free living U.S. males, average age 46.8 years, and analyzed for cis and trans-fatty acids (Ref. 64). No strong correlation was found between concentrations of trans-fatty acids and 10 cardiovascular risk factors, including clinical lipid profiles. The total level of trans-fatty acids in adipose triglyceride was 4.14 percent or equivalent to the proportion consumed in the diet. One isomer 7c–16 carbons:1 double bond (small c represents cis isomer) which is formed from a fatty acid found in hydrogenated shortening (9c–18 carbons:1 double bond) was positively correlated with four risk factors: body mass index, total cholesterol, LDL-cholesterol and systolic blood pressure.

Recently Mensink (Ref. 95) conducted a randomized cross-over design study which included 34 women and 25 men to assess the effect of trans-fatty acids on serum lipids. The average age of the subjects was 25.5 years and all were healthy. The isocaloric diets fat (39 percent of calories, mean calories 2,700 differed in that 10 percent of the total energy was provided as either oleic acid (cis), elaidic acid (the trans form of oleic) or saturated fat (lauric and palmitic acid). Each diet was fed for 3 weeks. The trans-fatty acid diet (saturated fatty acid 10 percent of calories, plus 11 percent additional from trans-fatty acid) increased LDL-cholesterol by 14 mg per dL compared to the oleic acid diet. The diet high in saturated fat (19.4 percent of calories) increased LDL-cholesterol by 18 mg per dL compared to the oleic acid diet (saturated fat 9.5 percent of calories). Trans-fatty acid also produced a small, but significant increase in triglycerides compared to the oleic acid enriched diet. Since the trans-fatty acids increased LDL-cholesterol this could conceivably increase the risk of CHD. The concentration of trans-fatty acid used in the diet was higher than current U.S. consumption. More studies are needed to confirm these results, to determine dose response levels, and to identify populations most sensitive to trans-fatty acids. The issue of the biological effects of hydrogenation of polyunsaturated fatty acid vegetable oils is unresolved.

In its recent evaluation, LSRO concluded on the basis of several reports both prior to 1987 and one major study subsequent to 1987, that there is a strong possibility that trans-monounsaturated fatty acid (i.e., elaidic acid), may raise blood LDL-cholesterol and thus may have atherogenic potential (Ref. 78).

2. Other Safety Considerations

a. *Cholesterol gallstones.* The reports of the Federal government and other recognized scientific bodies conclude that being female and being obese are the factors most consistently associated with gallstones (accumulation of bile supersaturated with cholesterol) (Ref. 20)). There is conflicting and inconsistent evidence regarding a possible effect of diets high in polyunsaturated fats on gallstones (Ref. 20). There is no evidence that intakes of polyunsaturated fats up to 10 percent of total calories affect susceptibility to or induces gallstones in humans.

The relationship of diet and gallstones is reported in the update of the scientific literature. Chileans and some North American Indians commonly consume diets low in both total and saturated fat, but high in complex carbohydrates, and have one of the highest incidence of cholesterol gallstones in the world (Ref. 102). In a study that included twenty healthy 18 to 22 year old Chilean men (described in Table II) consumption of a diet (3219 calories) that contained 120 g per day of legumes reduced LDL-cholesterol (16 percent). Biliary cholesterol saturation increased significantly in 19 of 20 subjects receiving the legume-enriched diet. The authors suggest that the results are consistent with the hypothesis that legumes, (possibly due to nondigestible, saponins) are a potential risk factor for cholesterol gallstone diseases.

b. *Polyunsaturated fats.* Safety concerns associated with consumption of diets enriched in polyunsaturated fats include the following: Long term and increased consumption of polyunsaturated fats may alter membrane fluidity, which in turn, could alter cell membrane function with as yet, undefined results; may decrease levels of high density lipoprotein (a lipoprotein associated with decreased CHD risk) and increase in serum triglycerides (also as yet no firm conclusions); and may increase predisposition to or frequency of certain types of cancer. (In a companion document published elsewhere in this issue of the **Federal Register**, the relationship of dietary lipids, including unsaturated fatty acid such as polyunsaturated fatty acid, and cancer is reviewed relative to health claims.)

It has been suggested that polyunsaturated fats increase formation of lipid hydroperoxides, which in turn could alter or damage cell membranes. Both native and oxidized LDL-cholesterol are hypothesized to cause endothelial cell membrane injury, thus initiating atherogenesis by potentially increasing platelet adherence to blood vessel walls (Ref. 20 and 132). Other dietary components may influence cell membranes also.

In a review article, Steinberg (Ref. 132), pointed out that in vitro studies have demonstrated that oxidized LDL-cholesterol, perhaps resulting from increased hydroperoxides from polyunsaturated fats, is taken up 10 times faster by macrophages [large cells that engulf foreign particles] than unoxidized or native LDL-lipid. Furthermore, antioxidants such as vitamin E inhibited the peroxidation of polyunsaturated fat-LDL-cholesterol in vitro.

Berry (Ref. 6) reported the effects of diets enriched in either monounsaturated fat (oleic acid) or as polyunsaturated fat (linoleic acid) in 26 healthy male college students on blood cholesterol levels and concentration of oxidized LDL-cholesterol. The fat and saturated fat content of both diets was 32 and 8 percent of total calories, respectively. Approximately 17 percent of calories were from monounsaturated

of polyunsaturated fats. Each dietary treatment period lasted for 12 weeks and a 4-week Yeshiva diet was eaten during a 4-week cross-over period between diets. Compliance to the diets was assessed by measurement of fatty acid composition of red blood cell membranes. On the positive side, compared to baseline levels, total cholesterol was significantly reduced by 10 percent consumption of the monounsaturated diet and by 16 percent from consumption of polyunsaturated enriched diet. On the negative side, thiobarbituric acid-reactive substances (i.e., lipid peroxides) in blood increased significantly in the blood (LDL-cholesterol) of subjects who consumed the diet enriched in polyunsaturated fat. The authors suggested that monounsaturated fatty acids may be preferable because they are a poorer substrate for lipid peroxidation than polyunsaturated fatty acids. Other studies reviewed, which examined the effect of dietary polyunsaturated fats on serum lipids including HDL-cholesterol, are found in Table II.

c. *Persons with hypertriglyceridemia.* Although high blood cholesterol levels of lipids known as triglycerides (hypertriglyceridemia) has often been associated with increased risk of cardiovascular disease, the significance of this observation remains controversial (Ref. 20). Dietary changes including increased intakes of simple carbohydrates when fat intakes are decreased may unfavorably alter this condition (Ref. 20).

E. Conclusions

The conclusions of the reviews by the Federal government and by recognized scientific bodies that high blood levels of blood cholesterol and LDL-cholesterol are a cause have been confirmed and strengthened by recently published reports (Refs. 12, 14, 16, 17, 27, 38, 42, 76, 85, 86, 87, 106, 108, 109, 128, 131, 137, and 146). Additionally, earlier conclusions that lower levels in blood cholesterol are associated with the decreased risk of CHD have also been confirmed by recent reports including those of Sprakfa et al. (Ref. 128) and others (Refs. 12, 14, 16, 42, 76, 85, 86, 106, 128, 137, and 146). Estimates from new analysis of epidemiologic data suggest that a one mg per ml increase in serum cholesterol sustained for many years increases CHD risk by about 1.5 percent (Ref. 78). Significant reduction in serum cholesterol (greater than 5 mg per dL) decreases CHD mortality in men and women.

The conclusions of the Federal government and other reviews by recognized scientific bodies that substantial evidence from animal and human studies shows that consumption of dietary fats, especially saturated fats and cholesterol, are highly correlated with elevated blood total and LDL-cholesterol levels and increased risk of CHD were recon firmed and strengthened by research published subsequent to those reports. Recent cross-sectional and prospective studies confirm these conclusions by reporting significant correlations between dietary intakes of saturated fat and cholesterol and increased serum cholesterol (Refs. 5, 17, 28, 68, 134, and 139).

The Federal government reports and other reviews prepared by recognized scientific bodies noted the multifactorial nature of CHD. Factors included high serum cholesterol and LDL-cholesterol, high blood pressure, family history of CHD, cigarette smoking, obesity, sedentary lifestyle, and diabetes were identified as major risk factors.

Diets rich in total fat, saturated fat, and cholesterol increase total serum cholesterol and LDL-cholesterol (Refs. 17, 18, 19, 44, 51, 53, 54, 67, 103, 121, 139, and 140). Estimates from clinical trials and metabolic ward studies suggest that lowering intake of saturated fatty acids by 7 percent of total calories and accompanied by declines in blood cholesterol of 10 to 14 percent should decrease the risk of premature CHD over a decade by about 20 percent, or over a lifetime of 30 percent (Ref. 78).

Potential safety issues relate to possible changes in the relative composition of and amount of fats in the U.S. food supply. Because of lack of long-term safety data on increased consumption of polyunsaturated fats and trans-fatty acids, the Federal government and other reviews by recognized scientific bodies recommend that dietary consumption of polyunsaturated fatty acids remain at current intake levels of 7 percent of calories and should not exceed 10 percent of total calories (Refs. 20, 35, and 78). Intakes of trans-fatty acids were also recommended not to exceed current levels (Ref. 78).

The diet-CHD relationship is very strong and consistent for saturated fat and less so for cholesterol. Diets high in saturated fat and cholesterol are associated with elevated levels of blood total and LDL-cholesterol and consequently of risk of CHD. Diets low in total fat and cholesterol facilitate a reduction in saturated fat and cholesterol intakes and thus are also recommended as useful for lower blood cholesterol levels and for reducing the risk of CHD. A general population approach to reduce total dietary saturated fat, total fat, and cholesterol has been recommended as a practical goal for reducing blood cholesterol and risk of CHD as an achievable goal.

F. Tentative Decision To Authorize Health Claim and Label Statements: Dietary Lipids and Cardiovascular Disease

The agency reviewed the conclusions reached by the Federal government and other reviews by recognized scientific bodies, recent review articles, and the pertinent human and nonhuman primate studies published since 1988. The agency also considered all comments received in response to the request for data and information on the topic of lipids and cardiovascular disease. The totality of the scientific evidence provides strong and consistent support that diets high in saturated fat and cholesterol are associated with elevated levels of blood cholesterol and LDL-cholesterol and with risk of CHD. The general public health support of this concept, as evidenced by all recent dietary guidelines from both the government and other recognized scientific bodies, demonstrates that there is clear, significant agreement among experts qualified by training and experience to evaluate such evidence that the relationship between saturated fat and cholesterol, to blood cholesterol levels and, thus to decreased risk of CHD is particularly strong.

The prevalence of CHD is high in the U.S., and the associated medical and other costs are also high. About 27 percent of adults (male and female; black and white) aged 20 to 74 years of age have blood cholesterol levels in the "high risk" category (total cholesterol greater than 240 mg per dL and LDL-cholesterol greater than 160 mg per dL) (Ref. 119). Another 14 percent have "borderline high" cholesterol levels (total cholesterol between 200 to 239 mg per dL and LDL-cholesterol between 130 to 159 mg/dL) in combination with two or more risk factors. The majority of the American population would benefit from decreased consumption of dietary fat and cholesterol. Extrapolating from the 1986 population data, these observations suggest that 64 million Americans over 20 years of age are candidates for medical advice and intervention. For individuals who have high blood lipid levels, estimates of benefits to be derived from decreased serum lipids include an 8 percent reduction in total cholesterol resulting in a 19 percent reduction in myocardial infarction; and a 7 percent reduction in all cause mortality (Ref. 141).

Dietary fat intakes by the U.S. population are generally considered to be higher than desirable (Refs. 20, 29, 31, 33, and 35). Dietary estimates for American adults show, that average that saturated fat intakes of American adults are about 13 percent of calories, total fat intakes are about 37 percent of calories, and average cholesterol intakes range from 300 to over 40 mg daily for adult women and men. The current intakes of saturated fat and total fat are currently well in excess of recommended goals of less than 10 percent and 30 percent of calories, respectively. Current cholesterol intakes of adult men also exceed recommended goals. The feasibility of meeting recommended fat intakes by the general population was evaluated by a health survey which included 10,348 American men aged 18 and older (Ref. 116). The study results suggested that American adults can successfully follow a low saturated fat, low cholesterol diet without formal consultation with health professionals.

Browner et al. (Ref. 13) made statistical estimates on CHD mortality and total mortality if all Americans (across all ages, sex and race subgroups) reduced total fat intake to 30 percent of total calories as proposed by the Federal government guidelines and health care professionals. The estimates assumed optimal dietary compliance, without allowing for other risk factors or medical intervention. Under these limitations, Browner et al. (Ref. 13) estimated that serum cholesterol levels would decrease by 20 mg per dL. The estimated reduction in risk of CHD mortality was reported to be 5 percent in the elderly and up to 20 percent in younger people. This reduction was projected to result in a 2 percent decrease in all cause mortality. Each individual, based on a 1986 census data, would increase his or her life expectancy by 3 to 4 months. For other individuals, the increase in life expectancy and quality of life would be much greater.

Thus, FDA believes health claims conforming to the proposed regulation will assist those of the general population who wish to select foods reduced in saturated fats, total fats, and cholesterol for reduction in serum cholesterol level and therefore, the risk of CHD.

No deficiency of essential fatty acids or cholesterol or other adverse effects is anticipated from the decreased consumption of dietary lipids (saturated fat, cholesterol and total dietary fat) to levels proposed by the Federal government and other reviews recognized by scientific bodies.

III. Proposed Regulation

A. Scope of Regulation

Based on the totality of the evidence, FDA has tentatively determined that there is and significant scientific agreement among experts qualified by training and experience to evaluate such claims, that consumption of diets high in saturated fats and cholesterol increases total and LDL-cholesterol levels and thus the risk of developing CHD.

The specific health claim topic, as contained in section 3(b)(1)(A)(vi) of the 1990 amendments, is "dietary lipids and cardiovascular disease". FDA, however, limited its review to saturated fats and cholesterol, and to CHD. The agency considered these limitations necessary because of the extremely large volume of research available on the broad topic of dietary lipids and cardiovascular disease, because the scientific data most explicitly supports the lipid nutrient relationship to blood cholesterol levels and thus CHD and finally because CHD is the most serious, primary, and earliest form of cardiovascular disease. In addition, FDA based its selection of saturated fats and cholesterol among the dietary lipids on the conclusions of a number of comprehensive reports by the Federal government and the National Academy of Sciences which identified high levels of these dietary lipids with high blood cholesterol, which is as causally related to CHD. FDA recognizes that considerable research is being conducted on possible roles of other dietary lipids than saturated fats and cholesterol and the risk of CHD. However, time constraints precluded thorough review of these other lipids. Petitions, in accordance with proposed requirements for health claims petitions prohibited elsewhere in this issue of the **Federal Register**, may be submitted to the agency to request that the relationship of other dietary lipid components to CHD, and that other aspects of cardiovascular disease,

B. Relationship Between Dietary Lipids and Cardiovascular Disease and the Significance of the Relationship

Proposed § 101.73(a)(1) describes the relationship between dietary lipids and cardiovascular disease. Proposed § 101.73(a)(2) describes the significance of the nutrient-disease relationship for the U.S. population.

Cardiovascular disease, of which CHD is the most frequently reported manifestation, caused nearly one of every two deaths in the United States in 1987. More than 1 million individuals suffer heart attacks each year, and more than 500,000 die from complications associated with CHD. In contrast, it is estimated that for every 1 percent drop in serum cholesterol levels, there will be, on average, a 1.5 to 2 percent drop in incidence in CHD.

Current dietary guidelines recommend that saturated fat intakes be at or below 10 percent of calories and preferably at 7 percent of calories, and that cholesterol intakes be at or below 300 mg per day. Adults in the U.S. consume, on average, 13 percent of calories as saturated fats. Presently, intakes of dietary cholesterol by American women are at the goal of 300 mg per day but are higher (approximately 400 mg per day) for American adult men.

CHD is associated with a number of risk factors: high blood cholesterol levels, obesity, high blood pressure, cigarette smoking, a family history of heart disease, and physical inactivity. Currently, average serum cholesterol levels in the U.S. are 213 mg per dL for adults. Approximately 25 to 30 percent of the adult U.S. population have serum cholesterol levels above 200 mg per dL.

The significant public health benefits to be derived from decreased consumption of foods high in saturated fats and cholesterol with respect to decreased morbidity and mortality from CHD are based on conclusions reached by Federal government documents such as "The Surgeon General's Report on Nutrition and Health" (Ref. 35) and other reviews by recognized scientific bodies including the National Academy of Sciences' "Diet and Health" (Ref. 20) and reports from the NCEP (Refs. 31, 32, 33, and 34) and supported by FDA's review of the more recent evidence.

C. General Requirements

1. Conformity With 21 CFR 101.14 (General Requirements for Health Claims on Food)

In § 101.73(a)(3)(i), FDA is proposing that health claims relating to an association between dietary lipids (specifically saturated fats and cholesterol) and CHD may be made on the label or in the labeling of a food so long as all the general requirements set forth in § 101.14, proposed elsewhere in this **Federal Register** document, are met. Proposed § 101.14 sets forth such matters as the levels of fat, saturated fat, cholesterol and sodium that would disqualify a food from bearing a health claim and the manner in which a claim must be presented.

2. Qualifying Nutrients: Saturated Fat and Cholesterol

In § 101.73(a)(3)(ii), FDA is proposing that a health claim relating diets low in saturated fats and cholesterol to

reduced risk of CHD would be prohibited unless the food that is to bear a claim meets the requirements of the definitions for "low saturated fat," and "low cholesterol." These requirements are set forth in proposed § 101.62.

The evidence for the association between intake of dietary lipids and blood cholesterol levels, and ultimately to the risk of developing CHD, is strongest for dietary saturated fats and cholesterol. In the proposed "General Requirements for Health Claims for Food" (published elsewhere in this issue of the **Federal Register**), FDA is proposing that for a substance, such as dietary saturated fat or cholesterol, for which decreased levels are needed to achieve dietary goals, the substance be at a low enough level in a food that is a candidate for a claim to justify the claim. It is further proposed that a level that meets the proposed levels for the term "low" be the deciding criteria. In a companion document on "Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Foods," FDA is proposing that the food contain 1 g or less of saturated fatty acids per label serving size and per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids. In that same document, FDA is also proposing that a food can qualify for a "low cholesterol" claim if it contains 20 mg or less of cholesterol per label serving size, per reference amount customarily consumed, and per 100 g of food.

The linkage of dietary saturated fat to blood cholesterol, however, raises questions as to the definition of saturated fats. In another document published elsewhere in this issue of the **Federal Register** ("Supplementary Mandatory Nutrition Labeling"), FDA is proposing to retain the current definitions of saturated fats for nutrition labeling purposes. Saturated fats are defined as the sum of lauric, myristic, palmitic, and stearic acids (C12–C18). Several recent reviews by recognized scientific bodies (Ref. 20) and more recent studies (Refs. 54 and 56) have suggested that the serum cholesterol-raising properties of saturated fats are limited primarily to C12 through C16, and that C18 does not have an appreciable effect on serum cholesterol levels. In response to early agency proposals on content claims for cholesterol and saturated fat (Ref.), and in response to FDA's request for scientific data and information relating to health claims (Ref.), FDA received numerous comments from the food industry requesting that declaration of saturated fat for nutrition labeling purposes be limited to the sum of the three saturated fats most clearly related to serum cholesterol-raising effects (i.e., lauric, myristic, and palmitic).

FDA is aware of this rapidly evolving research area but is proposing not to limit the definition of saturated fats to those most related to adverse effects on serum cholesterol. As noted previously, elevated blood cholesterol is not the only risk factor related to CHD and ultimately to cardiovascular disease. Other saturated fats have also been implicated to increase risk for cardiovascular disease, particularly relative to thrombogenic effects (blood clotting) and related effects which affect blood flow (Ref. 20). For this reason, FDA is proposing not to limit declaration of saturated fats to those related to blood cholesterol.

3. Additional Requirements for Saturated Fats

In proposed § 101.73(a)(3)(iii), FDA is proposing that health claims relating diets low in saturated fat and cholesterol to decreased risk of CHD must also contain saturated fat at levels less than 1 g per 100 g or food.

FDA, as noted above, is proposing to allow the use of the term "low saturated fat" if the food contains 1 g or less of saturated fat per label serving size and per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids (see document "Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Foods" published elsewhere in this use of the **Federal Register**). FDA is proposing the latter criterion in lieu of one based on one tied into the amount of saturated fat per 100 g of food. FDA has explained that it is doing so because the calorie density criterion will allow consumers to make comparisons among fats and oils and thus to aid them in choosing those products lowest in saturated fats when selecting from a category of products whose composition is essentially 100 percent fat. However, for health claims, FDA is concerned that a health claim linking saturated fat and reduced risk of CHD might inappropriately encourage increased consumption of fats and oils with the expectation that they have added health benefit. This is contrary to the recommendations of most current dietary guidelines which unanimously recommend reductions in total fat as well as saturated fat. Thus, FDA is proposing to require in § 101.72(a)(3)(iii) that a food must contain saturated fat at a level of less than 1 g per 100 g of food to bear a health claim.

4. Other Qualifying Nutrients: Low Total Fat

In § 101.73(a)(3)(ii), FDA is also proposing that health claims relating diets low in saturated fat or cholesterol to lower blood cholesterol levels and reduced risk of CHD are prohibited unless the food also meets requirements for a "low" claim relative to total fat content as proposed in the document "Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Foods" published elsewhere in this issue of the **Federal Register**). In that document, FDA is proposing to define "low total fat" as 3 g or less of fat per label serving size, per reference amount customarily consumed, and per 100 g.

While total fat is not directly linked to increased risk of CHD, it may have significant indirect effects. Low total fat diets facilitate reductions in intakes of saturated fat and cholesterol to recommended levels. Furthermore, obesity is a major risk factor for CHD, and dietary fats, which have more than twice as many calories as proteins and carbohydrates, are major contributors to total calorie intakes. For many adults, maintenance of desirable body weight is more readily achieved with moderation of intake of total fat. The issue of dietary fat and risk of cancer is addressed elsewhere in this issue of the **Federal Register**. This approach is also most consistent with the U.S. Dietary Guidelines and other dietary guidance that recommends diets low in saturated fat, total fat, and cholesterol.

5. Examples of Qualifying Foods

FDA used the criteria for dietary lipids content and sodium to identify foods that would likely be able to bear health claims about the relationship of saturated fat and cholesterol to effects on blood cholesterol, and thus, to risk of CHD. Examples of foods qualifying for a health claim include most fruits and vegetables; skim milk products; sherbets; most flours, grains, meals and pastas (except for egg pastas); and many breakfast cereals. FDA believes that many of these foods are appropriate foods for health claims. However, the agency is concerned that some foods with no apparent nutritive value other than calories (such as candies) would also qualify. FDA solicits comments and suggestions on how to restrict the use of fat/CHD health claims to foods that are generally recognized as part of healthy diets.

D. Specific Requirements for Health Claims

1. Health Claims: Requirements

In § 101.73(a)(4)(i), FDA is proposing that health claims relating dietary lipids to blood cholesterol and CHD must make clear diets low in saturated fat and cholesterol, will reduce blood cholesterol levels which in turn will reduce the risk of developing CHD.

This requirement is based on the effect, as well as the strength, of the scientific evidence regarding the relationship of dietary lipids, especially saturated fatty acids and cholesterol, to risk of CHD. This relationship is extensively documented and summarized in Federal government reports, in other reviews by recognized scientific bodies, and in the science review presented in this document. It shows the intermediate effect of the dietary lipids on blood cholesterol levels and of the blood levels on the risk of CHD. This intermediate effect must clear in any health claim.

2. Variability in Response to Dietary Modification

In § 101.73(a)(4)(ii), FDA is proposing to require that health claims relating diets low in saturated fats and cholesterol to reduced risk of CHD state that most but not all people will reduce blood cholesterol levels with a decreased intake of saturated fatty acids and cholesterol. These responses are variable between, among, and even within individuals, and the variability is greater with respect to dietary cholesterol than to saturated fats.

3. Interchangeable Terms

The scientific evidence most strongly supports a link between dietary saturated fats and cholesterol and CHD. In proposed § 101.73(a)(4)(iii), the agency is proposing to allow manufacturers to use the terms of "CHD" or "heart disease" to name the disease. These terms are terms most commonly used to describe the disease and therefore are expected to be the most understandable for the consumer. Fewer terms are also expected to minimize consumer confusion.

Similarly, to reduce confusion and misleading declarations, the agency is proposing to require the use of the terms "blood cholesterol" or "total blood cholesterol" rather than the more technically correct terms "serum," "plasma cholesterol," or "LDL-cholesterol." The term "blood cholesterol" is more commonly used by consumers and is consistent with terminology in most dietary guidelines. FDA is also proposing to require the use of the dietary terms "saturated fat" and "cholesterol" because these terms are consistent with the terminology on the nutrition label and, therefore, should be less confusing to consumers.

4. Multifactorial Nature of the Disease

In § 101.73 (a)(4)(iv), the agency is proposing to require that health claims identify other risk factors (in addition to elevated blood cholesterol) for CHD. Other modifiable risk factors include high blood pressure, cigarette smoking, physical inactivity, and obesity. These various risk factors appear to act in concert to increase risk. Their effects are at best additive and may in some cases be multiplicative. The agency believes that this additional information provides a basis for the nutrient-disease relationship and will increase consumer understanding of the numerous factors that contribute to risk of CHD.

E. Optional Requirements

In § 101.73(a)(5)(iii), the agency is proposing to allow manufacturers to provide accurate, up-to-date, factual information about the incidence, prevalence or frequency of, morbidity, mortality, cost of health care, etc. data including socio-economic status or educational level, age, sex, or race relating to risk of the CHD. The intent is to provide consumers with such information as will help them understand the seriousness of CHD in the U.S. The source of such information should be the most current and commonly used data from the National Center for Health Statistics. Use of such data will maintain consistency in estimates or statistical data used in the health claim. The source of the data used in the health claim must be identified.

F. Model Health Claims

In proposed § 101.72, FDA is providing four model health messages to help manufacturers to understand the requirements of proposed § 101.72(a) and to help them understand the type of message that FDA considers to be necessary and appropriate.

IV. Appendix to the Preamble—Consumer Summary on Dietary Lipids and Cancer and Dietary Lipids and Coronary Heart Disease

The following appendix is a proposed consumer summary to provide factual information in an easily understandable manner, to assist the consumer in understanding the seriousness of the diet (dietary lipids)/disease (cardiovascular disease) relationship. The role or relationship of dietary lipids (particularly saturated fats and cholesterol) to cardiovascular disease (particularly CHD) is discussed. FDA solicits comments on this document as explained in the proposal on general requirements for health claims published elsewhere in this issue of the **Federal Register.**

Appendix—Dietary Lipids and Cancer and Dietary Lipids and Coronary Heart Disease

Under the provisions of the recent Nutrition Labeling and Education Act, manufacturers may put clear information on the food label about the relationship between a nutrient, such as fat or cholesterol, and a disease or health-related condition. To prevent consumers from being misled, the Food and Drug Administration (FDA) allows only truthful label statements about diet and health relationships that are firmly supported by the current scientific evidence. There is agreement that the scientific evidence is strong enough to allow health claims about the association between total dietary fat and the risk of some types of cancer and the association between dietary saturated fat and cholesterol and the risk of CHD.

Many consumers have said that health claims on food labels could be useful to them in making improvements in their diets. However, label space is often limited. Therefore, this pamphlet provides information about diet and health claims that supplements what you may see on food labels.

In addition to the association between fat and cancer and between saturated fat, cholesterol and heart disease, FDA is allowing health claims about calcium and osteoporosis and sodium and hypertension. For information about these other diet and health relationships, write to: to be inserted.

What is Coronary Heart Disease?

A common usage term for coronary heart disease is heart disease. Coronary heart disease encompasses the heart muscle and its supporting blood vessels. Complications from heart disease results from narrowing of blood vessels (medically called atherosclerosis) and decreased flow of blood to various parts of the body. Myocardial infarction or MI is a medical term used to describe a heart attack.

Atherosclerosis occurs because of raised fatty or fibrous deposits (plaque) that develop in the walls of blood vessels in the affected area. The process of plaque development is gradual, and often begins in childhood.

What is Cancer?

Cancer is not one disease, but more than 100 different diseases. In each of these diseases, cells begin to grow out-of-control at one site in the body, and these abnormal cells spread to other parts of the body.

Why Are Heart Disease and Cancer Major Public Health Concerns?

Coronary heart disease and cancer are public health concerns because they are the two leading causes of death in this country. Illness and death from these diseases cost billions of dollars in health care costs and in lost work. Moreover, early deaths from these two diseases cheat many victims of valuable years of life.

Despite the recent sharp decline in the death rate from this condition, coronary heart disease still accounts for the largest number of deaths in the U.S. Cancer is the second leading cause of death in this country. The leading causes of cancer death are lung cancer, colorectal cancer, breast cancer, and prostate cancer.

What Causes Cancer and Coronary Heart Disease?

Both of these diseases are caused by a combination and interaction of multiple environmental, behavioral, social, and hereditary factors. It is clear that diet, one of the environmental factors, plays an important role in the development of these diseases.

Heredity and other factors, including elevated blood serum cholesterol, cigarette smoking, high blood pressure, obesity and inactive life style, are known to increase a person's risk of developing coronary heart disease. Elevated blood cholesterol, one of the major risk factors for coronary heart disease, is associated with excess fat, especially saturated fat, and cholesterol in the diet.

Many studies have established a strong association between consuming a diet high in saturated fat and cholesterol and increased risk of coronary heart disease. High saturated fat and cholesterol diets are estimated to be associated with one-third of the cases of coronary heart disease reported in this country.

The way diet affects blood cholesterol varies among individuals. However, blood cholesterol does increase in most people when they eat a diet high in saturated fat and cholesterol and excessive in calories. Of these, saturated fat has the greatest effect; dietary cholesterol has less.

Cancer has many causes and several stages in its development. The risk factors for developing cancer include a family history of a specific type of cancer (such as breast, prostate or colon cancer), cigarette smoking, alcohol consumption, radiation, and dietary factors.

Currently, the strongest scientific evidence relating diet to cancer is that the amount of total fat in the diet may have a relationship with cancer. In particular, many experts agree that a high fat diet may influence the risk for developing breast, colon, and prostate cancers.

Not enough is known currently for scientists to decide whether different kinds of fats (animal or vegetable; saturated or unsaturated) may be responsible for an increased risk of developing cancer.

Because of scientific agreement that reducing total fat and saturated fat is likely to lower the rates of these two major chronic diseases, it is recommended that Americans 2 years of age and older choose a diet low in total fat and saturated fat. Animal products are the source of all dietary cholesterol. Eating less fat from animal sources will help to lower the cholesterol as well as the saturated fat in your diet.

Do Most People Get Too Much Fat, Saturated Fat and Cholesterol in What They Eat?

The average U.S. diet, it's estimated, contains about 37 percent of calories from total fat, 13 percent of calories from saturated fat, and 360 mg of cholesterol per day. Health experts recommend diets that contain 30 percent or less of calories from total fat, 10 per cent or less of calories from saturated fat, and 300 mg or less of cholesterol a day. The U.S. Public Health Service has set a national health goal that all persons who are 2 years of age and older consume these levels of fat and cholesterol by the end of this decade.

How Do You Learn How Much Fat and Cholesterol Foods Contain?

You may or may not be able to tell that there's fat in a food by looking at it. Butter, margarines, shortenings, and oils are the more obvious sources of fat. In other foods, such as cheese, baked goods, nuts, and salad dressings, the fat isn't as easily detected. Cholesterol content is not obvious at all in foods.

A good way to learn about fat and cholesterol content is to read nutrition labels. Most foods now have nutrition information on their labels.

The amounts of total fat and saturated fat in a serving of food are listed in grams (g) on the nutrition label. Cholesterol is listed in milligrams (mg).

"Daily values" for fat, saturated and cholesterol also appear on food labels. These numbers have been established by FDA for several nutrients that are important in diet and health relationships. The daily values are to help you learn how the amount of a nutrient in a serving of food relates to a reasonable amount for the day.

The daily value for total fat is 75 g, and for saturated fat is 25 g. That means total fat for a day of 75 g, of which no more than 25 g should be from saturated fat. These numbers are based on a 2350-calorie diet that has 30 percent of calories from fat and 10 percent from saturated fat. A 2350-calorie diet is about the calories recommended for an adult woman.

If you consume a different number of calories a day, it's not hard to figure out your own daily values for total fat and saturated fat. First, multiply the number of calories you consume by 30 percent (for example, $2000 \times .30 = 600$). Then divide that number by nine, which is the number of calories each g of fat provides (600 divided by $9 = 67$ g of fat a day). Repeat for saturated fat ($2000 \times .10 = 200$; 200 divided by $9 = 22$ g of saturated fat a day).

The daily value for cholesterol is 300 milligrams, which is an upper limit that's generally recommended for healthy people. A food that contains 150 milligrams of cholesterol per serving, therefore, would provide about half of the daily value for cholesterol.

What Do Label Claims About Fat and Cholesterol Mean?

In addition to the amount of fat and cholesterol listed on the nutrition label, you may see other claims about fat and cholesterol content on some food packages. There are two types of these claims—nutrient content claims and health claims.

Nutrient content claims describe the amount of fat, saturated fat or cholesterol a food contains. These types of claims can be used on a label only if a food meets several definitions established by FDA.

Cholesterol claims

- A "cholesterol free" food has less than 2 milligrams of cholesterol and 2 grams or less of saturated fat in a serving.
- A "low cholesterol" food has 20 milligrams or less of cholesterol in a serving and in 100 grams of food and 2 grams or less of saturated fat in a serving.
- A "reduced cholesterol" food has its cholesterol content reduced by 50 percent or more compared to the regular

food product and contains 2 g or less of saturated fat in a serving.

Cholesterol claims may be made only on foods that contain a limited amount of fat (no more than 11.5 g per serving and per 100 g) unless the claim also tells the total amount of fat, for example, "cholesterol free, contains 12 g of fat per serving."

Fat claims

- A "fat free" food has less than a half g of fat in a serving and no added fat or oil.
- A "low fat" food has 3 g or less of fat in a serving.
- A "reduced fat" food has a 50 percent or more reduction in fat with at least a 3 g reduction in fat content.
- A "low saturated fat" food has 1 g or less of saturated fat in a serving and no more than 15 percent of its calories from saturated fat.
- A "reduced saturated fat" food has its saturated fat content reduced by 50 percent or more compared to the regular food product with at least a 1 g reduction in fat.

Also, the labels of some foods in which fat or cholesterol has been significantly reduced, but not enough to meet the definitions above, may have a statement that tells how much less fat or cholesterol the product contains than a comparable product; for example, "This pound cake contains 40 percent less fat than our regular pound cake."

Foods such as fruits and vegetables that meet the definitions for fat or cholesterol without special processing may have claims on them. However, the label must say that fat or cholesterol isn't usually present in the food, for example, "broccoli, a fat-free food," "frozen perch, a low fat food," or "raspberries, a low saturated fat food."

Health claims are those made about the relationship between the amount of a nutrient you eat and the risk of a disease, for example, between total fat and cancer or between saturated fat and cholesterol and heart disease.

Health claims about the relationship between fat and cholesterol and heart disease can only be made on products that are low in saturated fat and cholesterol, and have 15 percent or less of their calories from fat. To make a health claim, the product also cannot contain another nutrient that increases the risk of a diet-related disease other than atherosclerosis, for example, a high amount of sodium which has a relationship to high blood pressure.

Health claims about the relationship between fat and cancer can be made only on foods that are low in fat and do not contain another nutrient that increases the risk of a diet-related disease other than cancer.

These are some of the kinds of foods on which you may see health claims about nutrients related to cancer and heart disease: fruits, fruit juices, vegetables, breakfast cereals, dried peas and beans, skim milk, pasta products, and diet salad dressings.

Other Risk Factors for Cancer and Heart Disease

Coronary heart diseases and cancer are complex diseases with multiple causes, and they (usually) develop over a long period of life. Hereditary as well as environmental factors contribute to the risk for developing these diseases. In addition to practicing good nutrition, several other controllable factors are part of a healthy lifestyle and may help to decrease your chances of cardiovascular disease and cancer. These include maintaining a healthy body weight and good physical fitness, not smoking cigarettes, drinking only in moderation if at all, and not abusing drugs.

Facts to Keep in Mind

- It's the total combination of foods that you eat regularly—both the kinds and the amounts—that's important in terms of good nutrition. Eating a particular food or a specific food isn't a magic key that will assure you have a more healthful diet.
- Eating a healthy diet, in itself, doesn't guarantee good health. A healthy diet, however, is an important part of a healthy lifestyle.
- In addition to what you eat, many factors may be related to your own chance of developing a particular disease, for example, your heredity, your environment, and the health care that you get. Our knowledge about most diet-health relationships is incomplete, and will improve as scientific knowledge increases. However, enough is known today about some of these relationships to encourage specific dietary practices that are believed to be beneficial.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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VI. Environmental Impact

The agency determined under provisions found in 21 CFR 25.24(a)(11) that this action by the agency is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environment impact statement is required.

VII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

VIII. Effective Date

FDA notes, however, that in section 10(a)(3)(B) of the 1990 amendments, Congress provides that if the Secretary, and by delegation FDA, finds that requiring compliance with section 403(q) of the act, on mandatory nutrition labeling, or with section 403(r)(2) of the act, on nutrient content claims, 6 months after publication of the final rules in the **Federal Register** would cause undue economic hardship, the Secretary may delay the application of these sections for no more than 1 year. In light of the agency's tentative findings in its RIA that compliance with the 1990 amendments by May 8, 1993, will cost $1.5 billion, and that 6 month and 1 year extensions of that compliance date will result in savings that arguably outweigh the lost benefits, FDA believes that the question of whether it can and should provide for an extension of the effective date of sections 403(q) and (r)(2) of the act is squarely raised.

FDA has carefully studied the language of section 10(a)(3)(B) of the 1990 amendments and sees a number of questions that need to be addressed. The first question is the meaning of "undue economic hardship." FDA recognizes that the costs of compliance with the new law are high, but those costs derive in large measure from the great number of labels and firms involved. The agency questions whether the costs reflected in the aggregate number represent "undue economic hardship."

Therefore, FDA requests comments on how it should assess "undue economic hardship." Should it assess this question on a firm-by-firm basis, as was provided in the bill that passed the House Committee on Energy and Commerce (H. Rept. 101–538, 101st Cong., 2d sess., 24 (1990)), an industry-by-industry basis, or should it assess this question on an aggregate basis? If the agency should take the latter approach, comments should provide evidence that would permit the agency to make a determination that there is "undue economic hardship" for most companies. FDA also points out that assessing hardship on a firm-by-firm basis would likely be extremely burdensome because of the likely number of requests.

FDA will consider the question of the meaning and appropriate application of section 10(a)(3)(B) of the 1990 amendments as soon as possible after the comment period closes. The agency intends to publish a notice in advance of any final rule announcing how it will implement this section to assist firms in planning how they will comply with the act. The early publication of this notice is to assist firms in avoiding any unnecessary expenses that could be incurred by trying to comply with a compliance date that may cause "undue economic hardship."

IX. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. to 4 p.m., Monday through Friday.

In accordance with section 3(b)(1)(B) of the 1990 amendments, FDA must issue by November 8, 1992, final regulations for mandatory nutrition labeling. If the agency does not promulgate final regulations by November 8, 1992, the 1990 amendments provide that the regulations proposed in this document shall be considered as the final regulations. The agency has determined that 90 days is the maximum time that it can provide for the submission of comments and still meet this statutory timeframe for the issuance of final regulations. Thus, the agency is advising that it will not consider any requests under 21 CFR 10.40(b) for extension of the comment period beyond February 25, 1992. The agency must limit the comment period to no more than 90 days to assure sufficient time to develop a final rule based on this proposal and the comments it receives.

List of Subjects in 21 CFR Part 101

Food Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Sec. 4, 5, 6, of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. New § 101.73 is added to subpart E to read as follows:

§ 101.73 Health claims: lipids and cardiovascular disease and lipids and cancer.

(a) *Coronary heart disease*—(1) *Relationship between dietary lipids (primarily saturated fat and cholesterol) and coronary heart disease:* Diets high in the lipid components, saturated fat and cholesterol are associated with increased levels of blood cholesterol and, thus, increased risk of developing coronary heart disease. Reductions in intake of saturated fats and cholesterol are associated with decreased levels of blood cholesterol and lower risk of developing coronary heart disease.

(2) *Significance of the relationship between saturated fat and cholesterol and risk of coronary heart disease.* The cost of coronary heart disease in the United States is considerable in terms of morbidity, mortality, direct health care expenditure and loss in productivity. Substantial improvements in the quality of life and significant reductions in health care costs can result from reducing the morbidity and mortality associated with coronary heart disease. Early management of risk factors for

coronary heart disease can aid in achieving this major public health goal for which national, population based recommendations to reduce risk of coronary heart disease and other forms of cardiovascular disease have been made. One of the major recommendations is to decrease consumption of dietary fat, especially saturated fat and cholesterol.

(3) *General requirements.* A health claim associating a diet low in saturated fat and cholesterol with decreased risk of coronary heart disease may be made on the label or labeling of a food provided that:

(i) All requirements set forth in § 101.14 are met;

(ii) A serving of the food meets the requirements of § 101.62 for:

(A) "Low saturated fat,"

(B) "Low cholesterol," and

(C) "Low fat."

(iii) The food contains 1 gram or less of saturated fat per 100 grams.

(4) *Specific requirements.* The health claim would be prohibited unless the following requirements are met:

(i) The health claim shall state that a diet low in saturated fat and cholesterol will reduce high blood cholesterol and, thus, reduce the risk of coronary heart disease.

(ii) The health claim shall state that a diet low in saturated fat and cholesterol will reduce high blood cholesterol in some individuals but not in all;

(iii) The health claim shall use the following terms:

(A) For the disease: coronary heart disease or heart disease;

(B) For lipid levels: Blood cholesterol or total blood cholesterol; and

(C) For dietary terms, saturated fat(s); or cholesterol.

(iv) The health claim may indicate that coronary heart disease is a multifactorial disease. It may identify major risk factors:

(A) A family history of coronary heart disease;

(B) Those who have elevated blood cholesterol levels;

(C) High blood pressure;

(D) Those who smoke cigarettes

(E) Those who are obese (greater than 30 percent above ideal body weight);

(F) Those who have diabetes; and

(G) Those who are physically inactive.

(5) *Optional information.* The health claim may provide the following information.

(i) The health claim may state that individuals with elevated blood cholesterol, a family history of coronary heart disease, or those with multiple risk factors for coronary heart disease should seek medical advice and guidance; and

(ii) The health claim may include information on the number of people in the United States who are at risk or who have been diagnosed as having coronary heart disease or may include information on morbidity and mortality associated with coronary heart disease. The sources of such information must be identified, and be current (as found in information from the National Center for Health Statistics).

(6) The following are four sample health claims that may be used in food labeling to describe the relationship between dietary lipids and cardiovascular disease:

Four Sample Health Claims

1. Diets low in saturated fat and cholesterol, as part of well balanced diets and healthy lifestyles, will reduce elevated blood cholesterol and lower the risk of developing heart disease in most individuals. Individuals at highest risk include those with a medical history of heart disease, hypertension, or who have blood cholesterol levels greater than 200 mg per dL. Other risk factors include: inheritance of premature coronary heart disease, smoking, obesity, diabetes mellitus, and sedentary lifestyle.

2. Heart disease is associated with many risk factors including: a family history of premature heart disease, high blood cholesterol, hypertension, cigarette smoking, obesity and consumption of diets high in saturated fat and cholesterol. A healthful diet low in saturated fat, total fat, and cholesterol will lower blood cholesterol and reduce the risk of heart disease in most people.

3. Developing heart disease depends upon many factors, including a family history of the disease, high blood cholesterol, high blood pressure, being overweight, cigarette smoking, lack of exercise, and diets high in some types of fat. A healthful diet low in saturated fat, total fat, and cholesterol and a healthy lifestyle will lower blood cholesterol levels and reduce the risk of heart disease in most people.

4. High blood cholesterol is a major cause of coronary heart disease. Other important factors are a family history of heart disease, being overweight, high blood pressure, and cigarette smoking. A healthy diet low in saturated fat, total fat, and cholesterol will lower blood cholesterol levels and reduce the risk of heart disease in most people.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

TABLE 1.—LIPIDS AND CARDIOVASCULAR DISEASE: EPIDEMIOLOGICAL STUDIES (SCIENCE SUMMARY UPDATE)

Reference	Study design	Study population	Duration	Test/Methods	Results	Comments and assessment
Abbot 1988 (Ref 1).	Prospective, Framingham Study.	2425 men and women; 50 to 79 years; Multiple risk factors: BP, Wt, smoking, HDL-C, TC, estrogen.	12 year	N/A	Importance of HDL-C; possible to have high TC of which HDL-C make it high and have decreased risk of CHD; (men HDL-C 53 to 129 mg/dl or women 47 to 55 mg/dl reduce risk of CHD); HDL-C protect women who are above 50 years old HDL-C less than 46 mg/dl 6 times increased risk women of CHD for men less than 53 mg/dl results in 60 to 70% chance of MI.	Protective effect of HDL-C in men and women varies with age estimates relative risk reduction.

TABLE 1.—LIPIDS AND CARDIOVASCULAR DISEASE: EPIDEMIOLOGICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Test/Methods	Results	Comments and assessment
Burke 1991 (Ref. 15).	Cross-sectional	Minnesota residents 25 to 74 years old, both sexes; first survey in 1980 to 82 had a population of 3365; second survey in 1985 to 87 consisted of a population of 4545.	N/A	Part of the Minnesota Heart Survey. This survey is more focused upon examining concurrent community trends in awareness of heart disease and preventive factors Dietary survey methods are not discussed in this paper.	In both men and women, the distribution of cholesterol levels decreased from 1980 to 1982 to 1985 to 1987. The greatest decline in serum total cholesterol was observed in the 65 to 74 year olds.	The survey is not applicable to the questions of dietary causes of heart disease.
Bush 1988 (Ref. 17).	Prospective re-analysis of the relationship of diet to serum cholesterol in women.	Analysis of data for women from 9 prospective studies: (Framingham, Tel Aviv, NHANES) with emphasis on HDL-C.	variable	N/A	Women with greater than 265 mg/dl TC are at 3X greater risk of MI; HDL-C is strongly negatively correlated and is an independent predictor of CHD in women. For each 10 mg/dl reduction in HDL, there is a 50% decrease in MI; low cholesterol diet or high P/S diets in women decrease TC, LDL-C, and HDL-C; obese women have high TC, LDL-C and low HDL-C.	HANES survey showed no association between dietary and serum cholesterol
Dagenais 1990 (Ref. 27).	Prospective	4576 men, 35 to 64 years; Multi-factors; end points first event CHD, angina, MI, CHD death. Subjects free of heart disease at beginning of study.	12 year	Baseline history through questionnaire, complete medical evaluation to rule out CVD. Cardiologist diagnosed angina, enzyme levels, EKG, MI, autopsy data.	Adjusted data for age High serum cholesterol was positively correlated with the first coronary event, but not CHD mortality. Two-thirds of CHD incidence is due to elevated blood pressure, smoking and high serum cholesterol.	Since elevated BP is a risk factor in CHD, antihypertensive medications may be a confounding risk factor. Well-controlled.
Dyerberg 1989 (Ref. 40).	Cross-sectional study of dietary fats and serum lipids in two population groups (in Greenland and Denmark).	45 to 64 year old Danish men and Greenland Inuit men.	25 years of data.	Laboratory analysis of blood; morbidity data, which the author admits is not as good among the Inuits as the Danes.	Inuits: Fat energy, 39%; P/S ratio, .84; n-3 PUFA 14g/day Danes: Fat energy, 42%; P/S ratio, .24; n-3 PUFA, 3g/1 day. Although the Inuits have higher fat intake than Danes, Danes have a 13:1 incidence of acute MI, compared to Greenlanders. There is a highly significant difference (<.005) between the Danes and Inuits in all of the following parameters: cholesterol, triglycerides, LDL, VLDL, and HDL.	Uncontrolled for other risk factors, such as genetic and lifestyle differences.
Gramenzi 1990 (Ref. 51).	Case-control study of impact of diet on CHD.	Cases: 287 Italian women, with history of acute MI; average age 49; 649 Controls: patients from 30 hospitals.	5 years	Food frequency and lifestyle questionnaire.	Acute MI was strongly associated with frequency of consumption of meat, ham, salami, butter, total fat added to food and coffee. A slight inverse relationship was observed between consumption of fish, carrots, green vegetables and fresh fruit.	Questionnaire was verified by telephone in only 10% of cases. Insensitive dietary collection (Food frequency reported as low, medium, or high).

TABLE 1.—LIPIDS AND CARDIOVASCULAR DISEASE: EPIDEMIOLOGICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Test/Methods	Results	Comments and assessment
Kesteloot 1989 (Ref. 68).	Cross-sectional	Stratified random sampling in 42 counties of Belgium which yielded 5485 men and 4856 women.	Cross-sectional	Data on nutrition were obtained by a 24 hour food record method.	In both sexes, saturated fat intake increased both total cholesterol and HDL-cholesterol. Also, in both sexes, there is an inverse relationship between polyunsaturated fat intake and HDL-cholesterol. Dietary cholesterol makes no independent contribution to total serum cholesterol but increases HDL-cholesterol in women.	Adjustment through multiple regression analysis for age, height, weight, alcohol and cigarettes. Other lifestyle variables and other food components should be included in the model.
Keys 1988 (Ref. 70).	Cross-sectional re-analysis.	8829 Israeli men, 40 to 60 years.	N/A	In the original study, Israeli men were divided into 6 groups, based on region of birth. The serum cholesterol was measured only once. Keys redid the analysis of the original Israeli study, using a regression model he developed with schizophrenics.	When intra-individual variation is corrected, a highly significant relationship between mean dietary fatty acid consumption and mean serum cholesterol appears.	Keys' point that the relationship between serum cholesterol and dietary fat can not be understood by a one-time serum cholesterol measurement is well-taken. His model, which was developed in schizophrenics, has questionable representativeness. The authors from the original study have not responded.
Lowik 1991 (Ref. 83).	Cross-sectional study of dietary fats and serum cholesterol.	539 healthy elderly (aged 65 to 79y) Dutch individuals; after exclusion of those using cholesterol-lowering drugs, antidiabetic medication, and those on a dietary regimen, 199 men and 180 women remained.	N/A	Nutritional survey within the Dutch Nutrition Surveillance System; food consumption data.	Among men, intake of monounsaturated fat was positively and consistently associated with serum total cholesterol. Among women, intake of saturated fat was positively associated with serum total cholesterol.	This is a correlational study, and therefore does not look at individual outcomes. Since elderly people on a diet were excluded, those responsive to high-cholesterol diets may have been underrepresented. Confounding was well-controlled.
Mitchell 1989 (Ref. 97).	Prospective study	3301 Mexican-Americans (1393 men, 1908 women); 1877 non-Hispanic whites (835 men, 1042 women), 25 to 64 years of age.	9 years	Mean levels of cardiovascular risk factors were computed, and each subgroup was given a cardiovascular risk score. ECG's have been obtained on all subjects, and coding according to the Minnesota criteria has now been completed on all diabetic subjects.	In both men and women, triglyceride, and HDL-C was lower in Mexican-Americans than in non-Hispanic whites after controlling for age and sex, non-Hispanic white diabetics were 2.3 times as likely (no CI reported) as Mexican-American diabetics to have ECG evidence of MI.	The current risk factors might not fully capture lifetime exposure to risk factors. Current risk factors might not account for all the variance in CV outcome. Currently, only detailed information on diabetics has been compiled and analyzed; would like to see completed study on healthy individuals.

TABLE 1.—LIPIDS AND CARDIOVASCULAR DISEASE: EPIDEMIOLOGICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Test/Methods	Results	Comments and assessment
Pekkanen 1990 (Ref. 108).	Prospective study of serum lipids and CHD mortality.	2541 white men, ages 40 to 69; both free of and with a history of CVD.	10.1 years follow-up.	Baseline measurements obtained as part of the Lipids Research Clinics Program Prevalence Study, annual follow-up for mortality, not intervention. Vital status is currently known for over 99.6% of participants.	Among those with CVD at baseline, those with high TC levels (>6.19mmol/l), had a risk of death from CVD (including CHD) 3.45 times higher (95% CI 1.63 to 7.33) than those with desirable total cholesterol(TC) (<5.16 mml/l) For LDL-C: a RR of 5.92 (95% CI 2.59 to 13.51) for >4.13 mmol/l compared to <3.35 mmol/l. For HDL: a RR of 6.02 (95% CI 2.73 to 13.28) for <.90 mmol/l compared to 1.16 mmol/l. TC and LDL-C levels were also sign. predictor of death from CVD in men without preexisting CVD, but at a lower level of absolute risk of death. 10 year.	Well-controlled study. Measurements were complete; dropout rate extremely low.
Pocock 1989 (Ref. 109).	Prospective study of relationship of werum lipids to ischemic heart disease. British Regional.	7725 British men, age 40 to 59 years.	7.5 years	Blood samples, standardized for hr of day; morbidity and mortality documented elsewhere.	An increase in TC is associated with a significant increase in the risk of ischemic heart disease. A decrease in HDL is associated with a significant increase in the risk of ischemic heart disease. Triglycerides are not a predictor of ischemic heart disease once other factors are controlled.	Study is well-controlled
Reed 1990 (Ref. 110).	Prospective study of serum choleseterol and CHD.	514 sets twins, male, age 42 to 55 family history of CHD, TC, HDL-C, physicians records, death certificates.	14 to 18 year	Used 2 way analysis of variance.	Family history of ischemic heart disease is significantly and independently correlated with ischemic heart disease. Family history is a better predictor of heart disease than blood lipids.	Well-controlled study. Data collected and analysis carried out very precisely.
Shimamoto 1989 (Ref 121).	Prospective study of the relationship of animal fat intake to CHD.	2 cohorts: 1. 2257 men and women, ages 40 to 69 at baseline, followed from 1963 to 1966 to 1973. 2. 2711 men and women, ages 40 to 69 at baseline, followed from 1972 to 1975 to 1983.	7 to 11 years	Surveillance through investigation all hospitalized cases plus six other ascertainment sources: national insurance claims, reports by local physicians, ambulance records, death certificates, reports by public health nurses and health volunteers, and risk factor surveys.	Animal fat intake doubled in men ages 40 to 59 from 4.5% of daily calories in 1969 to 9.6% in 1980 to 1983; significant upward shifts occurred in the means and distribution of serum total cholesterol and serum total protein in every age and sex group. Age-adjusted incidence from CHD shows no significant change overall during the 2 decades. For men and women ages 70 and older, there was no significant trend for CHD incidence except sudden death and all CHD in women, which increased significantly.	This study examines many risk factors and many outcomes (all CHD, and hemorhhagic stroke, and cerebral infarct). The nutrition survey were administered to a sample of the men. Nutritional intake was calculated by a standard Japan Food Tables. The portion of the study that relates diet to outcome uses ecologic data, which suffers from ecologic fallacy.

TABLE 1.—LIPIDS AND CARDIOVASCULAR DISEASE: EPIDEMIOLOGICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Test/Methods	Results	Comments and assessment
Slattery 1988 (Ref. 123).	Ecological comparison: CHD mortality and food consumption trends Fat content (SA) used.	Individuals who died of CHD and dietary data during the same period.	1909 to 1989 (71 years).	Dietary data: 1. Food balance sheets. 2. Food disappearance data. 3. Household surveys from Food Agriculture Organization, Economic Research Service USDA Population data vital statistics publication.	Up to 1950 increase in CHD mortality in 45 to 54 year old and 55 to 64 year age groups. Mid 1960's to 1978 decline in CHD mortality in same age groups. Percent of total calories from fat increase from 1090 to 1960. Fats and oils contributed to 40% of total dietary fat.	Limitation on availability of accurate dietary data Ecological data does not prove causal relationship. Latency period between change in diet and change in risk of CHD (10 to 20 year). Data did suggest a trend toward decrease in SFA and cholesterol preceded national decline in CHD.
Sprafka 1990 (Ref. 128).	Cross-sectional study of serum cholesterol and CHD mortality.	A set of Minnesota residents age 25 to 74 in 1980 to 82, and another set age 25 to 74 in 1985 to 1987.	N/A	Analysis of covariant means and frequency distributions.	Between 1980 to 1982 and 1985 to 1987, serum total cholesterol declined significantly by 5.2mg/dl in men and 5.8 mg/dl in women. HDL decreased 1.6 mg/dl in men and 0.9 mg/dl in women. The mortality from CHD declined 20.1% in men and 12.9% in women from the 1981 survey to the 1985 one.	Multiple confounders not adjusted.
Stephen 1990 (Ref. 133).	Cross-sectional	Total US population studies included 8 to 20,000 subjects all ages, both sexes.	64 years	Results were compiled from all the studies carried out in the United States in which assessment of individual dietary intake had been carried out and where information on fat intake had been reported.	Fat intakes rise from 34% energy in the 1930's to 41% in 1960, then falling steadily to 36% energy in 1984. This trend was seen for all age and sex groups. These results differ markedly from food supply trends and indicate a fall in U.S. fat intake, which preceded the decline in heart disease mortality.	The data here is consistent with fat intake being a factor in heart disease. This study is of value to show that data gathered from food balance figures are misleading, by not allowing for waste or spoilage and includes food used for purposes other than human consumption.
Steyn 1990 (Ref. 134).	Cross-sectional study of dietary intake and serum lipids.	976 racially-mixed subjects aged 15 to 64.	Cross-sectional	Food intake was calculated from a dietary questionnaire, which included a 24-hour dietary recall. Multiple linear regression was carried out from men and women separately.	There was a significant independent correlation between serum total cholesterol and the following: dietary intake of saturated fat, intake of polyunsaturated fat, the P/S ratio, and the intake of cholesterol.	This study uses within-population data, rather than international comparison. Although this reduces the effect from genetic and environmental differences, there are still many unknown factors, which may impact upon the relationship between nutrients and total serum cholesterol.
Sytkowski 1990 (Ref. 137).	Prospective study of serum lipids and CHD.	3 male cohorts, who were 50 to 59 year old in 1950, 1960, 1970. No. subjects in each: 485, 464, 514.	Each cohort was followed for 10 year.	Risk factor assessment TC, BP, smoking, stress management.	43% reduction in 10 year risk of death from CVD in 1970 compared to 1950 group; and a 60% reduction in 10 year mortality rate in those who were free of CVD at base line. Risk factors status in 1970 and 1950 groups; from base line TC dropped 22 vs 12 mg/dl; smoking decreased 56% vs 34% and hypertension decreased from 36% vs 20%.	Well-controlled study. A decline in incidence of CVD and improved medical interventions can not be ruled out as contributing to the decline in mortality.

TABLE 1.—LIPIDS AND CARDIOVASCULAR DISEASE: EPIDEMIOLOGICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Test/Methods	Results	Comments and assessment
Trevisan 1990a (Ref. 139).	Cross-sectional study of dietary fats and serum lipids.	4903 Italian men and women, age 20 to 59 year; part of the Italian Nine Communities Study.	N/A	Interview administered PUFA and CHD risk, food frequency.	Increase in frequency of consumption of butter correlated with increase in serum cholesterol and glucose in men and with glucose in women. Olive oil and vegetable oil intake is inversely associated with serum cholesterol, glucose and systolic blood pressure	Data was adjusted for many confounders. The Italian population does not consume very much corn, or sunflower oil. This study grouped corn, soybean and sunflower oil all as PUFAs. Frequency of consumption of 53 food items, then selected top 14 of the 35 to use to calculate atherogenic index and amount (small, medium or large).
Trevisan 1990b (Ref. 140).	Cross-sectional study of diet and serum cholesterol.	10,800 men and women, ages 20 to 59, randomly selected from each of nine communities throughout Italy.	Cross-sectional	Interview-administered food frequency questionnaire.	In both sexes, serum cholesterol increased with higher consumption of foods with high fat content. These findings were independent of any possible confounding effect of age, adiposity, alcohol intake and cigarette smoking.	The detail of the food questionnaire was not sufficient to conclude that fat as a specific nutrient is responsible for the increase in the individual risk.
Van Horn 1990 (Ref. 143).	Multicenter cross-sectional study of the relation of diet to serum lipids.	5111 free-living men and women, black and white, 18 to 30 years old during the period 1985 to 1986.	1 year	Assessment interviews clinical lipids psychosocial anthropometric.	Part of CARDIA Study, fat consumption significantly correlated with serum cholesterol in white men and women age 28 to 30 BMI was positively, significantly correlated with TC, LDL-C in all race and sex groups Education was positively associated with HDL-C in black and white men and women. HDL was negatively associated with carbohydrate regardless of race and sex in 25 to 30 year old group BMI was significantly, and negatively correlated with HDL in black and white men and in black women	Method of assessment of diet validated and reliable for white men and women, but not for blacks Multiple factor analysis across subgroups results in inconsistent and erroneous findings in subgroups.

TABLE 1.—LIPIDS AND CARDIOVASCULAR DISEASE: EPIDEMIOLOGICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Test/Methods	Results	Comments and assessment
Yamori 1989 (Ref. 146).	Cross sectional multicenter cardiac study of the relation of diet to serum lipids.	40 centers 20 countries 100 males and 100 females 50 to 54 year.	1 year	BP, clinical dietary factors CVD risk factors. Dietary: Potassium, calcium, protein.	Preliminary report of Cardia Study; specific regions in China have high BP, high salt intake (13 to 16 g/day), K and Ca intake low in China and Japan. Together high Na low K and Ca result in high BP and therefore increased risk for CVD Caucasia in USSR have low TC (172 mg/dl), high protein Cultural habits to boil meat which reduced fat and cholesterol, have low incidence of CVD in 7 community centers in Japan in which Na consumption in high have increased incidence of stroke and stomach cancer.	Lack of sufficient detail of dietary fat assessment; difficult to draw conclusions regarding dietary fat and heart disease.

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
Abbott 1990 (Ref. 2).	Diet Intervention, (lipoprotein metabolism, self controlled.	7 NonDiabetic (ND) 7 NIDDM, Pima Indians age ND 32 yr, 1 female age. NIDDM 39 (3 female cross over).	5–7 weeks diet 1: high fat, 5 wks. diet 2: low fat, high carbohydrate, 5 to 7 wks.	Solid food 1. High fat 42% of calories. 2. High Carbohydrate (65%), low fat (21%) of calories.	Consumption of high carbohydrate diet, by both ND/NIDDM groups, reduced LDL-C levels. Fractional clearance and total VLDL, LDL-C, and apoprotein B unchanged. Plasma VLDL TG increased by carbohydrate diet.	Since LDL-C was decreased in both ND/DIDDM by high carbohydrate, low fat diet; gives support for a general population strategy to lower serum cholesterol. Small number of subjects. Well designed study.
Baggio 1988 (Ref. 4).	Metabolic study of impact of impact of dietary fats on serum lipids (Controlled).	11 males, 20.9 aver yr. Metabolic ward	6 week 5 week/diet	Low fat diet High fat olive oil	Found decrease in TC (−9.5%), LDL-C (−12.2%) TG (−25/5%) in olive oil enriched diet; HDL unchanged; Olive oil rich in oleic acid (C18:1). Diet compliance measured: Fatty acid; profiles of RBC membranes before and after diet; olive oil used in food. High fat diets in Mediterranean countries but low CHD death rates.	Small number of subjects, well designed and well controlled for compliance.
Berns 1990 (Ref. 5).	Dietary intervention and lifestyle study. Evaluation of diet by questionaire and diet records. Subjects divided into cohorts.	315 Dutch males 28–29 yr, free-living, selected based on BMI.	2 weeks	Representative of Dutch population; fat: 39% of calories; carbohydrate: 43% of calories, cholesterol: 128 mg/kcal.	BMI, body fat, waist/hip ratio, intra-abdominal fat and alcohol positively associated with, TC, TG Alcohol (%) strongly and independently associated with TC and HDL-C.	TC levels within population very large. Actual TC range much larger within population than predicted by Keys equation.

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
Berry 1991 (Ref. 6).	Randomized dietary intervention (cross-over). Evaluation of diet by diet records.	26 healthy males	12 week/diet, 32 wk study.	High MUFA diet high PUFA diet (each 32% of total calories); solid foods.	Total serum cholesterol reduced by MUFA and PUFA diets: (MUFA: 9-10%; PUFA: 16%). TG and HDL unchanged by the diets. Lipid peroxidation (measured by thiobarbituric acid reactive substance activity) increased on PUFA enriched diet. Suggested that PUFA diet could cause oxidative stress. Compliance measured by RBC membrane fatty acid composition.	Well designed and conducted study. Short duration, small number of subjects, one gender. Authors suggest MUFA not only lowers TC but may reduce atherogenic potential from oxidized LDL.
Boyd 1990 (Ref. 9).	Randomized dietary intervention.	206 women >30 yrs of which >50% had mammographic dysplasia. Free-living	1 year	Test diet: Low fat diet decreased from 37% down to 21% of calories; carbohydrates increases from 44% up to 52% of total calories. Control diet: habitual diet.	Low fat, high carbohydrate diet reduced serum cholesterol levels most in women who had the highest basal cholesterol levels. Results suggest that women and men respond similarly to low-fat diet.	Analyzed only one sample/interval. Suggested the use of serum cholesterol levels as a monitor for dietary compliance compared to estimates from food records. Results suggest women and men respond similarly to low fat diet.
Brinton 1990 (Ref. 11).	Self-controlled metabolic ward study of the effect of dietary lipids on lipoprotein and apoprotein metabolism.	13 (5 male & 8 female); Mean age: 24 yr; BMI: 22.9.	4 wk run-in; 2 diets; 4 wk per diet.	2 Diets 1. HSFA fat 42% of calories P/S 0.1. 2. LSFA fat 9% of calories P/S 1. Solid food diets, intake adjusted to maintain individual energy requirements.	Used radiolabeled apo I and II to measure FCR (fractional catabolic rate and TR (transport rate). Switch from HSFA to LSFA diet decreased HDL-C by 29% while apo AII did not change. FCR of APO I increased 11% and TR decreased 14%. FCR apo AII increased 5%. LPL decreased 23% HL decreased 17%. Increase in clearance of HDL and decrease in synthesis. Within each diet group HLD-C was inversely related to apo AI FCR but not apo AI TR. Diet influence apo AI TR which may account for decrease in HLD-C.	Diets were at extremes (42%) vs a very low fat diet (9%); diets were short term (2 wk); highly variable results; TR not measured direct but by formula which could lead to statistical artifact. Composition of baseline diet not specified.
Brown 1990 (Ref. 12).	Drug/diet intervention study, randomized, double blind.	120 men 62 year high risk CVD.	2.4 yr	1. Lovasatin (40 mg/d)+Colestipol (30 mg/d). 2. Niacin (4 mg/d)+Colestipol (30 mg/d). 3. Placebo or Colestipol. All subjects on low-fat diet.	Serum lipid profiles and arteriographic analysis used to evaluate drug treatment-diet. Lovastatin+colestipol reduced LDL 46%, increased HDL 13%, progression of lesion limited to 21%, regression increased 32%. Niacin+colestipol reduced LDL 32%, increaed HDL 43% decreased progression 25%, regression increased to 39%. Diet reduced LDL 7% and increased HDL 5%. Aggressive drug intervention reduced incidence and frequency of MI by 73%.	Well designed study. Change in CHD assessed visually and quantitatively by 2 experienced blinded observers.

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
Buchwald 1990 (Ref. 14).	Surgical Intervention..... Randomized trial of illeal bypass surgery and serum lipids and CHD risk.	838 men/women 51 year old, high risk, MI survivors 90% men.	9.7 years.....	Ileal bypass 417 control 421 surgery.	Surgical intervention decreased TC 23%, LDL 37% and increased HDL 14.3%, decreased morbidity due to CHD (44 vs 32), reduced recurrent MI events (39 vs 24), reduced death all causes (62 vs 49). Both groups were on AHA Phase II diet.	Can not ethically have control which does not receive drug or diet to lower serum cholesterol. Good study.
Burr 1989 (Ref. 16).	Dietary intervention ..... Randomized ..... Evaluation of diet by diet questionaires.	2033 male survivors of MI; mean age 56; Wales. 4 groups; 1. reduce fat intake; 2. increase P/S ratio; 3. increase fish intake; 4. increase fibre intake	2 year.....	Experimental diets plus control. 1. Low fat (30%)..... 2. P/S of 1.0..... 3. Fish (200–400 g) per wk. 4. Fiber (cereal) 18 g/day.	No significant differences in fat or fiber group with respect to MI death, total mortality or reinfarction. Total mortality lower in fish group (29%) at 2 years, no difference in IHD events. Fiber group had slightly lower survival rate.	Differences between compliance to diets on fat and control group very small: both at about 32% fat ad 0.78 P/S ratio. TC fell 0.14 mmol/1 in low fat group (3 to 5%). Fiber compliance better: 19 g/day vs 9 g/day control group Difficult to control dietary intake.
Cobb 1991 (Ref. 18).	Drug and diet intervention. Randomized, double blind, crossover. Evaluation of diet by diet records. Metabolic ward.....	70 men/women, high risk hereditary and environmental factors.	3 wk/diet 10 day wash out.	High Fat diet vs Low Fat diet Lovastatin (40 mg/day) (drug).	Found no diet-drug synergism in reduction of blood cholesterol. Lovastatin reduced blood cholesterol on both low and high fat diets.	Did not do cross-overs, many patients were in advanced disease state, more patients (80%) had reduced cholesterol levels on low fat diet but had smaller reduction.
Cohen 1988 (Ref. 19).	Dietary intervention, effect of dietary fat on serum lipids, controlled.	12 healthy males, 20–25 yr old, exercised, non-smokers, normal glucose tolerance, non-obese.	3 days, nonfasted subjects.	Intake response: fat and blood lipids—test fat was cream [11% C14:0; 30% C16:0; 14% C18:0 and 27% C18:1]. Fat intake: 1. 40 g..... 2. 80 g..... 3. 120 g.....	Measured the effect of fat consumption on serum TG. In response: 40 g cream=251 mg/dl; 80 g cream=503 mg/dl; 120 g cream=712 mg/dl. In normal healthy males the serum TG levels were proportional to the amount of fat consumed. Maximum response to test intake was at 2 hr Test followed for 8 hr.	Well designed and executed study. Changes in serum TG varied linearly with fat content (SFA predominately) of test meal. Fat intake test within limits of how used in general population.
Curzio 1989 (Ref. 26).	Dietary intervention, randomized, free-living, diet counseling.	124 male, female 6 mo >61/gp, hypercholesterolemic hypertensive patients, age 56.5 year.	6 month.....	Low fat, high carbohydrate diet.	Compared to baseline values in 1987, both group's serum cholesterol decreased significantly. Diet intervention group decreased more in weight, TC, TG, LDL-C compared to controls. HDL-C remained unchanged.	Decrease in total cholesterol and LDL cholesterol in non-dietary group may be due to spontaneous changes in diet due to media coverage.
DeBacker 1989 (Ref. 28)	Diet, randomized..... Survey MONICA Project screening program.	134 men, 45 to 64 year, Belgium.	3 day food record.	Food consumption diary identify fatty acids, and serum lipids.	Need an objective marker to measure diet compliance within population, as well as, in individuals. Found a highly significant relationship between diet and serum CE fatty acids, but not between diet and total serum lipids.	Diet: fat 39.9%, SFA 16.6%; MUFA 14.5%, PUFA 7.1% and cholesterol 392 mg. Serum CE fatty acids: linoeate (18:2) 58%; oleate (18:1) 22%; palmitate (16:0) 13%; arachidonate (20:4) 6%.

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
Dreon 1990 (Ref. 37).	Diet intervention, cross-over, controlled, randomized. Diet evaluation by dietician advise and home visits.	19 males, 20 females: free-living Mormons (did not smoke, no caffeine, no alcohol, mean age 48 years).	12 wk/diet 30 wk/study 12 wk/run in.	2 Diets 1. PUFA enriched 2. MUFA enriched PUFA Saf oil MUFA O oil. Total fat 30% of calories; carbohydrate 55% of calories.	No significant change in VLDL, LDL-C, TC, HDL-C or TG due to PUFA or MUFA enriched diet. Subfraction of HDL did change HDL-2 was 50% higher and HDL-3 was slightly lower with PUFA compared to MUFA diet. APO B was 5.4% lower on PUFA diet.	Study well designed for a free living study; included eliminated many risk factor because subjects were Mormons. The authors saw no advantage of one UFA over the other with respect to total HDL-C. When subjects on low fat diet, changes in type of UFA may not alter serum-lipid levels.
Edington 1989 (Ref. 41).	Dietary intervention, crossover, free-living. Evaluation of diet by diet records.	58 men; hyperlipidemic/48 Normal chol or hyporesponders.	3 month	Low Fat diets 3 periods 1. + 410 mg chol 2. + 90 mg chol 3. +410 mg chol	Hyperesponders = those whose plasma cholesterol increased >8%; hyporesponders + those whose plasma cholesterol increased less than 5% when diet supplemented with 3 eggs. Dietary cholesterol intake has small effect on blood cholesterol when SFA intake is low; confounders with cholesterol supplements are low SFA and high fiber.	Possible application to general population ie free living and contained both hyper and hypo responder to dietary cholesterol. On low fat diet, added dietary cholesterol may not increase TC.
Frantz 1989 (Ref. 42).	Double blind, randomized trial of dietary fats, serum lipids, and CHD risk. Institutionalized Single end point	Minnesota state mental hospitals 1 nursing home 4393 men and 4664 women.	Longest on diet 4.5 yr., mean day on diet 384, 1568 on diet > 2 yr.	Diets 1. High SFA + high chol. 2. Low SFA + low chol Control diet= no. 1= (18% SFA, 5% PUFA, 446 mg chol); test diet no. 2 = (9% SFA, 15% PUFA, 166 mg chol).	Diets had equivalent amounts of fat but differed in SFA, MUFA and PUFA Lower SFA, high PUFA reduced TC from 203 to 175 mg/dl. No differences were observed in MI events, CVD death or total mortality when all age groups averaged. Slight increase in death (MI) in men and women on low SFA and High PUFA diets in age 45 to 55 group but not in 35 to 39 year old group.	Patients in study (81%) in hospital <1 yr, question on outside hospital compliance. Deaths from external causes higher in patients on low SFA, high MUFA, PUFA diets. Age group differences in MI and deaths.
Friday 1991 (Ref. 43).	Dietary intervention study on metabolic ward, self-controlled, cross-over.	3 men & 2 women Familial hypercholerolemia (FH); 5 normal aver age 40.	3 wk/diet 3 wk/washout.	3 Diets, natural foods; differ in source of FAs. 1. Butter (SFA) 2. Saf oil (n-6) MUFA 3. Salmon oil (n-3) PUFA caloric intake adjusted to maintain individual energy requirement.	Normal subjects and similar reduction in TC, LDL-C as FH (heterozygous) patients. VLDL did not significantly change in normals but was reduced 44% in FH. PUFA diet reduced TC, LDL-C apo B slightly in FH patients compared to MUFA diet.	Very few subjects; may also have sex differences which mask final results. Both FH and normal controls, however, responded to diets (substitution of MUFA and PUFA for SFA) in similar fashion & therefore may have application to general population.
Fumeron 1991 (Ref. 44).	Diet intervention, crossover, randomized. Evaluation of diet by diet history.	36 healthy males average 23 yr.	3 wk/diet	2 diets Differ in source of FAs 1. 70 g Butter (SFA) 70 g control diet. 2. Sunflower oil (high PUFA) test diet.	Compared to butter diet, the sunflower oil (more PUFA) in diet reduced TC, TG, LDL-C and HDL-C. When total fat intake is high, but not excessive (even if P:S ratio is high as part of diet). there was a diminution in protective HDL and HDL-2.	Well designed study. Decrease in SFA and increasing PUFA reduced serum lipids levels (TC and LDL-C); however, also reduced HDL-C.

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
Ginsberg 1990 (Ref. 45).	Diet intervention, randomized, double blind, controlled. Evaluation of diet by 5 day diet record.	36 healthy, free-living, young men, 22-32 year old.	10 wk/ run in; 10 wk/ Step 1 diet; Control diet, typical American diet.	3 Diets 1. AHA Step 1 2. AHA Step 1 + 18% MUFA. 3. Amer diet AHA diet fat '30% of calories. American diet, fat '30% of calories. American diet, fat '38% of calories.	Compared two experimental diets with typical American diet effect on serum lipoprotein. Step 1 Diet reduced TC and LDL-C significantly, while TG and HLD did not change. Step 1 diet with additional MUFA (not substituted for SFA) did not significantly increase beneficial effects of Step 1 diet.	Large degree of variability in results; would have been better to use cross over design and subjects serves as own control. Carefully analyzed study. Dietary compliance stated as 85% in free living subjects, difficult to assess.
Grundy 1988a (Ref. 53).	Diet intervention; reanalysis retrospective, random.	10 to 17 men/study 4 studies patients high to normal TG and cholesterol.	6 wk/diet	4 Liquid diets 1. linoleic vs lard 2. linoleic vs palm oil 3. oleic vs palm 4. oleic vs coconut oil	Summarized 4 studies: response to SFA is highly variable. SFA was not provided from a single type of fat. Source of SFA important "If it can be shown that people with higher cholesterol levels are more responsive to SFA than those with lower levels; this would add support to the high risk strategy in causation of primary hypercholestolemia".	Small number of subjects; well designed.
Grundy 1988b (Ref. 54).	Diet intervention; metabolic ward crossover 1 month run in order diet random.	10 healthy men mean age 64 6/10 smokers.	6 wk/diet	3 Solid Food diets 1. high SFA vs high cholesterol. 2. high MUFA vs low cholesterol. 3. high carbo vs low fat	High MUFA-Low chol and low fat diet both reduced total serum chol (32 mg/dl) and LDL-C equally effectively when compared to high SFA-high col diet. Low fat diet also reduced HDL-C 6 mg/dl compared to High chol-MUFA diet. Low fat diet AHA Phase III.	Small number of subjects, smoking confounder.
Hayes 1991 (Ref. 59).	Diet intervention, crossover, random.	Non-human primates; 3 species. 8 animals /species, 10-15 yr old.	12 week per diet.	5 diets isocaloric Fat 31% of calories, diets differ in P/S ratio (range 0.1 and 1.0).	When 16:0 replaced 12:0 and 14:0 there was a significant decrease in TC and LDL-C. When 16:0 replaced 18:2 however, there was a slight increase in TC and LDL-C. 18:1 was weakly hypocholesterolemic. Plasma cholesterol in all three species affected in same direction (high P/S, lower TC) but the magnitude of the shift varied. Cebus monkey were most responsive, dropping 2.5 mmol/l TC when diet P/S ratio went from 0.12 to 1.04. Rhesus monkey was least responsive, therefore, resistant to hypercholesterolemic effect of 12:0 and 14 0.	Well designed study. Impact of any given dietary fatty acid depends upon chain length, relative saturation and relative concentration of all fatty acids available (diet, storage, part of active metabolic fats).

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
Hudgins 1991 (Ref. 64).	Clinical study of trans-fatty acid intake and adipose tissue storage, randomized.	76 healthy males aver age 46.8 yr free living.	N/A	Gluteal adipose tissue fats; clinical lipids. isomeric forms of fatty acids.	Dietary *trans*-fatty acid of 18:1 and 18:2, concentrate in adipose tissue. Found no strong assoc between CVD risk factors and conc of *trans*-fatty acids in adipose. Autopsy data show however, show slight + correlation of *trans*-fatty acid with hyperlipidemia.	Careful study. Possible negative correlation of consumption of *trans*-fatty acids and risk of CVD.
Johnson 1990 (Ref. 66).	Clinical trial of effect of dietary cholesterol on serum lipids. Cross-over, blinded, randomized.	10 healthy, free-living males, normal lipidemic, age 27 yr athletic.	4 wk/diet	Two Diets 1. 200 mg chol 2. 600 mg chol 30% fat, 55% carbohydrate chol ' eggs natural food.	High cholesterol diet increased LDL-C and apo 8 (10 and 13% respectively) in healthy males. High cholesterol diet did not change TG, HDL-2 and HDL-3 significantly. Individual responses were highly variable. Three subjects had LDL increases >25%, 2 increased between 10-25%.	Well designed study. Small no. of subjects. Importance of exercise—25 minutes aerobic exercise per day, did not prevent the cholesterol raising effect of dietary cholesterol. Dietary restriction may, therefore be justifiable even on low fat diet with exercise. Response to dietary cholesterol highly variable.
Katan 1988 (Ref. 67).	Clinical trial of effect of dietary saturated FA and cholesterol on serum lipids. Controlled, cross-over.	24/group, men and women; age 28 to 54 previously identified as hyper-responders to cholesterol:. Normal Egg eaters, Not defined what is normal egg or what HAb egg eaters consumption not defined,.	3 wk/diet	Two Diets Regimens 1. Norm-Egg 21% PUFA, 11% SFA (high P/S). 2. HAB-EGG 5% PUFA, 23% SFA, (low P/S).	Question raised was do individuals who are hyperresponders to dietary cholesterol, also hyperresponders to SFA. On both diet regimens, HDL and TC increased on SFA diets and decreased on PUFA rich diets in Normal group, those who responded to increased dietary cholesterol also responded to SFA In habitual egg group, however, this was not true. Suggested that there are persons in the normal population who are both hyperresponders to dietary cholesterol and SFA Chronic egg consumption may change metabolism Dietary membranes—especially linoleic/oleic acid ratios.	Subjects in Habitual egg group were older than normal group. Small number subjects, diet short term. The authors suggest response to both dietary SFA and cholesterol congruent.
Kestin 1989 (Ref 69).	Clinical trial of effect of fats on serum lipids. Cross-over, randomized. Evaluation of diet by dietary records and diet analysis (Each subject completed 2 diets out of 6 possible combinations).	26 healthy men average age 44.	6 week/diet	3 Fat modified Diets 1. High fat (HF)=(AUS) 2. Lacto-ovo-vegetarian (LOV). 3. Lean meat-LM	LOV and LM diets decreased BP, TC, LDL-C compared to high fat (42%) AUS diet. Both LOV and LM diets increased TG C12:0, C14:0, and C16:0 higher in AUS HF diet by minimum of 2x than LOV or LM diets. Protein source raised as possible influence on chol; wheat protein in diets LOV and LM not soy; wheat contains enriched amounts of glutamate, which may be hypocholeste olemic.	Well designed study. LM and LOV diets have similar effects on serum lipids. Compared to diet high in SFA both LM and LOV diet will reduce serum lipids. Source of protein may be important determining serum lipid levels.

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
Leren 1989 (Ref. 76).	Diet intervention, effect of dietary fat on CHD risk on those with and without previous MIs.	412 men, 30-64 yr who had MIs in 1956-58; half serve as control Oslo. 1232 nonhypertensive, high risk CHD age 40-49 in 1972-73.	5, 8.5, 11 yr	Low fat diet. Fat 39% of cal, 21% SFA, 26% MUFA, 53% PUFA. Control habitual diet. Fat 40-50% of cal., primarily SFA.	Results of secondary trial: after 5 years diet intervention group has fewer recurrent MI and fatal MI than control: Diet—43 MI/34 patients Control 64 MI/54 patients. After 11 years CHD death in Diet group was 79 and 94 in controls. In the Primary trial: measured at 5 and 8.5 years high risk CHD males which had no previous MI results showed dietary intervention reduced MI death nonfatal MI by approximately half MI death 6 diet group and 14 in control; non fatal MI 13 in diet group and 22 in control. Same trend at 8.5 years	Estimates of recurrence of MI from secondary trial (already had MI) in those on low fat diet compared to habitual diet.
Lopes 1990 (Ref. 82).	Observational study of effects of FA intakes on serum FA. Evaluation of diet by food frequency questionnaire.	12 male/female aver age 34 yr.	22 month	Diet fatty acids compared to plasma FA in TG, PL, FFA, CE over time.	Fatty acids found in plasma in greatest abundance: 16:0-palmitic; 16:1-palmitoleic; 18:0 stearic; 18:1 oleic; 18:2-linoleic, 20:4-arachidonic. Diets vs TG-FA were most strongly correlated in men, No strong correlation between diet vs TG-FA in women; but did in FFA (18:1). Sexual difference in FA: CE:FA 20:4 male>female; PL-FA 20:4 male>female; TG-FA male 2x>than female. Fatty acid most strongly correlated with ethanol intake 16:1.	Small number of subjects and is the food frequency questionnaire adequate record of dietary intake.
Luria 1991 (Ref. 84).	Clinical study of relationship of serum lipids to extent of athersclerosis.	380 high risk men/ women average 59.	7.5 yr	Serum lipids, and rheologic arteriographic. Pathological analysis and risk factor clustering.	Ratio TC/HDL-C closely related to presence—extent of coronary artery reduction. Divided into quartiles of highest or lowest risk. Suggested ratio is a marker for clustering of potential risk factors.	Well designe and executed study. High levels TC and low levels HDL correlated with size of coronary obstruction (reduction). An increase in the number of risk factors, the greater the risk of CVD.
Mannien 1990 (Ref. 85).	Dietary trial demonstrating effect of reduced serum lipids on CHD. Randomized, placebo control.	2590, Fredrickson Type IIa men; average age 50.	5 year	Gemfibrozil	Two independent variables and one is neg and one pos; difficult to predict disease outcome. Gemfibrozil raised HDL-C while lowering LDL-C. With similar LDL-C levels; those with higher HDL-C have 5x less risk of CAD. Drugs more effective against highest risk groups.	Well designed study. Medical intervention which reduces LDL-C and increase HDL-C decreases CVD risk significantly.

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
Manttari 1991 (Ref. 86).	Diet/drug intervention study of effect of reduced serum on apoproteins. Randomized, double blind. Evaluation of diet by diet interviews.	230 Finnish men high risk CHD half had MI during study.	15 month, part of the Helsinki Heart Study.	Gemfibrozil 600 mg 2x day; placebo low fat—low chol diet all subjects. Habitual diet; fat=37-40% of total calories. Diet intervention: fat=30-35% of total calories.	Subjects at baseline chosen to have similar TC and LDL-C levels, all were dysplipidemic. Out of 230 subjects 96 expressed E4 and 171 expressed E3 phenotype or in other words, 151 did not carry E4 allele. Those with dietary counseling, who expressed apo E4 allele, had the largest reduction in TC and LDL-C. For those who were treated with gemfibrozil, the same reduction in TC and LDL-C occurred with and without apo E4 allele.	Did not record SFA or cholesterol content at baseline or during the study, therefore, cannot relate specific fat with apo E regulation. Excellent laboratory analysis of apo E and possible clinical applications.
Marzuki 1991 (Ref. 88).	Observational study comparing effects of two types of dietary fats on serum lipids. Residential, self-controlled, run in/wash out diets used.	110 healthy Malay males, age 16.5 year Malaysian diet.	6 wk/diet	Solid food cooked in: 1. Palm olein 2. Soybean oil fat 35% of total calories.	Regardless of cooking oil used (Palm or Soy) plasma chol and lipid profiles were unaltered Palm oil rich in 16:0 and 18:1 while Soy rich in 18:2 fatty acids.	All subjects were healthy young men, consuming native diet, with no other risk factors for CAD.
McDonald 1989 (Ref. 89).	Clinical study of effects on specific fats on serum lipids. Cross-over, self-controlled. Diet evaluation by diet analysis.	8 healthy males, age 19 to 32 yr.	48 days 18 days/diet	Solid food 1. Canola (>MUFA) 2. Sunflower (>PUFA) fat 36% of calories. Canola = 59% oleic Sunflower = 73% linoleic. CanSun diet vs SunCan diet.	Canola oil rich in 18:1 while Sunflower oil rich in 18:2. Both CANSUN and SUN-CAN regiment reduced total chol; but SUN-CAN lower chol > than CAN-SUN. Neither oil altered HDL-C. Canola increased prostacyclin > than SUN. Thromboxane B-2 decreased by CAN and SUN compared to mixed fat diet CAN prolonged obstruction time.	Unlike other studies linoleic acid (18:2-SUN-PUFA) did not decrease HDL-C. Like other studies, oleic acid (MUFA) lowered TC without lowering HDL-C. Well designed study.
Mendis 1990 (Ref. 92).	Clinical study of effects of specific fats on serum lipids. Cross-over, wash out 3 wk.	25 normolipidaemic males 20-26 yr. Sri Lankan prison	8 wk/diet	Two Diets differ in P/S ratio. 1. P/S = 4 2. P/S = 0.25 Fat soya-bean and coconut oil.	Compared to baseline soya-bean diet reduced TC, LDL-C, TG and HDL significantly. Coconut diet increased TC. Normal Sri Lankan diet is 27% fat, high carbohydrate. The fat of Sri Lankan diet is primarily SFA derived from coconut oils.	Well designed and executed study. Another study that shows reduction in dietary SFA reduces TC and LDL-C.

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
Mensink 1989a (Ref. 93).	Clinical study of effects of specific fats on serum lipids. Randomized, controlled, diet run-in 17 days, inst food.	58 Dutch men and women 19-48 years healthy 29/gp.	36 day/test diet, 17 day run-in on high SFA diet.	Control diet: SFA 19% of energy, MUFA 11.5%; PUFA 4.6%. Test diet 1. MUFA rich, SFA 12.9%; MUFA 15.1%; PUFA 7.9%. 2. PUFA rich SFA 12.6%; MUFA 10.8%; PUFA 12.7% caloric intake adjusted to maintain energy requirements.	Compared to control diet MUFA enriched diet decreased TC and LDL-C, apo B slightly more than PUFA enriched diet in both men and women. Both test diets had lower SFA content than control diet. Test diets had a mixture of MUFA and PUFA, which in the specific test diet was enriched. Both test diets reduced HDL-C (PUFA>MUFA) was more in men than women.	Compliance determined by fatty acid content in serum CE. Individuals on MUFA diet had more oleic acid in CE and those on PUFA had more linoleic in CE. MUFA enriched diet as effective or better than PUFA enriched diet in lowering serum cholesterol. Several subject had influenza like symptoms concomitantly with decreased HDL-C. Well designed and executed study.
Mensink 1989b (Ref. 94).	Clinical study of effects of specific fats on serum lipids. Diet run-in, controlled...	48 healthy adult men/women, Dutch and 76, 8 to 10 years old Cretes.	36 day/test diet 17 day run in on high SFA diet.	Diets 1. Control diet high SFA 20%, 38% total fat; 47% Carbo. 2. High Carbo 62%; low fat 22%; SFA 6.7%. 3. Olive oil fat 40.6%, SFA 9.8%, MUFA 24% carbo 46%.	Results from clinical study compared to Crete boys diet and serum lipids. Dutch study: TC decreased 0.44 mmol/1 on high carbohydrate diet and 0.46 mmol/1 on olive oil diet HDL-C fell on high carbohydrate diet 0.19 mmol/1 and increased on olive oil diet (0.03 mmol/1). Epi study and clinical study did not agree on effect of olive oil diet on serum lipids.	Compared 8 to 10 year old boys in Crete with adult men/women in Holland. Used pooled blood samples to analyze lipoprotein profile in Crete boys. Food intake examined on two consecutive days. Study tried to compare to many subgroups and cross study design types. Compares apples and oranges.
Mensink 1990 (Ref. 95).	Clinical study of effect of specific fats on serum lipids. Cross-over, randomized, controlled, no wash out.	34 women 25 men average age 25 healthy 8 women on oral contraceptives.	3 week/diet	3 Diets Diets differ fatty acids (10%). 1. oleic, cis 2. elaidic, trans 3. SFA, 12:0, 16:0	Diet were identical, varied only 10% fatty acid as either. 1. oleic, cis; 2. elaidic trans or 3. SFA lauric and palmitic. Compared to oleic acid, *trans* form increased LDL-C significantly (14 mg/dl) and decreased HDL-C by 7 mg/dl. SFA increased LDL-C (18 mg/dl) but HDL-C was unchanged.	Excellent well designed and executed study, well controlled. *Trans*-F.A. could increase risk CVD at higher levels than currently consumed. *Trans*-fatty acid not only raised LDL-C but lowered HDL-C as well. The concentration of *trans*-fatty acid used was higher than current availability data in US population.
Miettinen 1989 (Ref. 96).	Clinical of effect of dietary cholesterol on cholesterol metabolism. Cohort evaluation of clinical results with dietary intake, randomized diet. Evaluation of diet by dietary records.	63, 51 year old males, normal, free living, random selection.	>1 week	0.14, uCi Chol; 0.28, uCi B-Sitosterol; 200 mg Cr203. Cholesterol: 487 mg/day Fat: 108 g/day Habitual diet	Cholesterol absorption efficiency reduced by obesity. Absorption of dietary chol increased with intake. The more fractional and absolute chol absorbed; the more chol synthesis inhibited. 1 mg.kg/day chol=decrease 2.2 mg.kg/day of chol synthesis. The higher the synthesis of biliary chol the lower the absorption of dietary chol. Plant sterol reduced fractional chol absorption; enhanced fecal chol elimination.	Well designed study. The authors conclude that the amount of chol absorbed may regulate both chol synthesis and elimination in some individuals more than others.

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
MRFIT Research Group 1990 (Ref. 101).	Community trial of diet and lifestyle intervention on serum lipids and CHD risk. Randomized, controlled. Special Intervention (SI).	12,866 CHD high risk men, 35 to 57 years.	10.4 years	SI 1. Diet low fat, chol 2. Smoking 3. Drug for hypertension	Intervention group had lower mortality at 10.5 yrs from all causes (−7.75), CHD (−10.6%) and CVD (−8.3%). There was a 24% reduction in death due to acute MI in special intervention (SI) group. Risk factors for CHD declined in both groups. SI group had increase in death related to respiratory and intrathoracic organs (+20.1) and digestive system (+36.8%). Used blood pressure reducing drug: chlorthalidone and hydrochlorothiazide.	Well designed and executed study. The more risk factors reduced, the greater reduction of CVD risk.
Nervi 1989 (Ref. 102).	Clinical study of effect of high carbohydrate diet on serum lipids and gallstones. Institutional food consumed 6 days/week.	20 (18-22 year) healthy men Chilean.	1 month/diet	Two diet regiments 120 g/day legumes vs isocaloric no legumes.	Legume diet compared to control diet: decreased LDL-C, HDL-C, increased biliary cholesterol saturation in 19 out of 20 subjects by at least 50%. Legume consumption suggested as a risk factor for cholesterol gallstone. Biliary total lipids concentration same however, PL concentration down and cholesterol and bile salts up.	Well designed and executed study. An 8% amino acid solution was used to stimulate gallbladder contraction; different legumes used have variable concentration of possible active components, such as saponin.
Ng 1991 (Ref. 103).	Clinical trial of effect of types of FAs on serum lips. Randomized, cross-over, double blind. Evaluation of diet by diet records (food provided).	123, Malay men (61) and women, age 24 random assigned to 3 test groups.	5 wk/test diet 15 wk/study	3 diet regiments 1. Coco-palm-coco 2. Coco-corn-coco 3. Coconut solid food cooked in oils.	Diet fat was 32% of total calories. The oil provided 75% of the total fat. Coconut oil raised chol 10%. Palm olein and corn oil reduced chol (−19 and 36%), reduced LDL-C ad HDL-C. Corn oil reduced TC, LDL-C and HDL-C more than palm olein. Corn oil hypotriglyceridemic.	Over simplification to judge an oil solely on basis of SFA content. No dietary baseline data provided, actual intakes, changes in body wt, adjustment for confounders not reported.
O'Dea 1990 (Ref. 105).	Clinical study of effect of dietary fats on serum lipids. Controlled Evaluation of diet by diet records.	10 healthy men/women, average 25.2 yr.	5 wk/study run in 1 wk.	Very low fat [fat-lean meat] vs added beef fat to very low fat=8% high fat=20-30%.	Within 1 week on extreme low fat diet, total chol dropped 9%, LDL-C dropped significantly and HDL-C dropped but not significantly TG increased significantly on low fat diet. Beef fat, not beef meat, identified as dietary risk factor in raising blood chol. Beef fat 20 and 30% of total calories raised blood cholesterol. The higher the P:S ratio the more the HDL falls along with LDL-C. Diets, not excessively low in SFA nor increasing in PUFA do not generally raise HDL-C levels.	Small number of subjects. Short run in for diet. Study results indicate that it is the fat from beef that increases serum cholesterol and not the beef.

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
Ornish 199 (Ref. 106).	Clinical trial of effect of diet and lifestyle on serum lipids and atherosclerosis. Prospective, controlled.	48 high risk CHD, free-living men, 5 women; age 56 year (expt) 50 year (control) have atherosclerosis. Coronary arteries assessed at baseline and after 1 yr.	1 year	Diet Intervention 1. Low fat veg diet non-smoking stress management moderate exercise. 2. Usual Care	Short term life style intervention (1 year) reduced the diameter of the stenosis in patients with atherosclerosis and appeared to reduce the progression of the disease. TC, LDL-C reduced, HDL-C unchanged, TG elevated in intervention group. Fat intake reduced to 6.8% of total calories in intervention group compared to 30% in cholesterol.	Well designed and executed study. Results suggest that low fat, vegetarian diet reduced the profession (or regression) of atherosclerotic placque.
Rifail 199 (Ref. 111).	Clinical study of effect of amounts of fat in test meal on serum lipids. Method(s) compared to calculated values.	16, healthy males, 23-34 yr non smokers postprandial effects.	8 hour	High fat test meal, 70 gm fat, 580 mg chol, 1110 calories: 56% fat.	A single high fat meal increased TG and VLDL. Maximum response to test meal at 3 hr HDL's Apo A's and apo B were not altered by fat meal by 8 hr. Differences between measured directly (LRC Method) versus. Calculated values by Friedwald equation. If patient not fasted, the LDL-C concentration will be significantly underestimate. To minimize postprandial effect on plasma lipoprotein, a minimum of 8 hr fat is required for accurate measurement of VLDL. TC, HDL's, apo A and B can be determined adequately using non fasting serum.	Short time, small number subjects. Results should be considered when cross comparing design and results from different laboratories.
Sorci-Thomas 1989 (Ref. 127).	Animal study of effect of diet on serum lipids. Mechanism, dietary intervention.	25 adult male African green monkeys.	1 year, 5 yr form most animals (male).	4 Diet Regiments Low Chol + high PUFA. Low Chol + Low PUFA. High Chol + high PUFA. Low Chol + Low PUFA. Chol 0.03 or 0.8 mg/kcal P/S ratio, 0.3 or 2.2.	Diet high in chol., generally increased TC, LDL-C and apo B. PUFA enriched diet reduced TC, HDL-C and plasma apo A-1 in monkeys fed high choiesterol diet by 13, 28 and 16% respectively. PUFA also decreased rate of A-1 production in the liver but not in the intestine. Effect of PUFA on apo A-1 synthesis was tissue specific.	Well designed and executed study. Monkeys respond to dietary changes in a manner similar to humans. Dietary effect of PUFA on synthesis of CHD protective factor. PUFA reduced the synthesis of apo A-1 and therefore could increase CHD risk (mechanism).
ıkkanen 1990 (Ref. 138).	Clinical trial of amount and type of dietary fats on serum lipids and apoproteins. Dietary intervention apo E phenotype.	110 North Karelian (Finland) 30-50 y.o. 56 men and 54 women healthy fresh blood.	6 wk/diet, and 12 wk/diet, with 5 wk/ switch back.	Test diet Diet 1. Low fat, P/S = 1. Diet 2. Low fat low salt, P/S 0.4. Baseline diet, high SFA high chol.	Plasma chol correlated inversely with apo E 3/4 isoforms. Highest plasma chol found in apo E4/4. Subjects with apo E3/2 has lowest plasma chol. Association weaker on low fat, low chol diet. Greatest reduction in TC in apo E4/4. When diet switched back, these subjects had highest increase in TC.	Excellent study; The apo E phenotype may in part, determine the amount or response to dietary fat and chol which results in alteration of serum lipids levels. An apo E allele sum of 7 or more are greatest risk and most responsive to dietary lipids (mechanism).

TABLE 2.—LIPIDS AND CARDIOVASCULAR DISEASE: CLINICAL STUDIES (SCIENCE SUMMARY UPDATE)—Continued

Reference	Study design	Study population	Duration	Method/test/dose	Results	Assessment/comments
Wardlaw 1990 (Ref. 144).	Clinical study of effect of types of dietary fat on serum lipids. Double blinded, randomized, cross-over.	20 men, average 34.7 yr normal diet fat 37-43% calories.	5 week diet phase; 7 wk/ washout; cross-over and repeat.	Diets..... 1. Butter—2 wk..... 2. Corn-PUFA..... 3. Sun-MUFA	Both vegetable oil diets (PUFA and MUFA) reduced chol 16-21%, LDL-C 21-26% and TG by 10-21% compared to butter diet. Serum chol falls within 1 wk on vegetable oil diets. Dietary chol raised from 190 to 500 mg/day while on vegetable oil diet did not change serum TC, LDL-C, HDL-C or TG. High Concentration of PUFA may have pharmacological effects on lowering HDL-C, however, diets containing 35% of calories from fat and P-S ratio, < 1.5 are not likely to lower HDL significantly.	Well designed and executed study. Applicable to men who consume high SFA diet (did not include women). Consumption of low fat diet reduced serum lipids levels in young healthy men who had previously consumed high fat diet. Furthermore the authors suggest some risk may be involved as reduce SFA in diet, especially substitute PUFA for MUFA.
Wood 1991 (Ref. 145).	Clinical study of effect of diet and exercise on serum lipids. Randomized, controlled. Evaluation of diet and activity by clinical activity logs, 7 day diet records, and telephone interviews.	Moderately overweight, sedentary men and women (132 each), 25 to 49 yr old; 119 men & 112 women completed study; non-smokers, low alcoholic consumption.	1 year.....	Divided into 3 cohorts 44 men & 44 women in each cohort: 1. Control, habitual diet..... 2. Hypocaloric NCEP diet. 3. Hypocaloric NCEP diet (+) exercise.	Both NCEP groups reduced body fat significantly and BP. In men: Diet (+) exercise increased HDL, while decreasing TG, apo B HDL increased significantly (13%) in men who exercised over diet alone. In women: Diet alone & (+) exercise significantly reduced BP, TC, apo B compared to controls. Women in diet alone group, had significantly lower HDL-2 and apo A-1 compared to control. Addition of exercise decreased the reduction of HDL-2 by low fat diet.	Well designed and well executed study. Suggests multifactorial approach for reduction CVD. Exercise is important in increasing level HDL. Diet is important in reduction of TC and LDL-C.

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21 CFR Part 101

[Docket No. 91N-0097]

RIN 0905-AD08

Food Labeling: Health Messages; Dietary Lipids and Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to authorize health claims on foods and food labeling that state that diets low in total fat may reduce the risk of some types of cancer, particularly colon, breast, and prostate, in the general population. The agency reviewed this topic under the provisions of the Nutrition Labeling and Education Act of 1990. The agency's conclusion is based on its review of the publicly available scientific literature. The strength and consistency of the scientific data supports such claims. Under this proposal, it also may not imply any particular degree of risk reduction. The proposed rule requires that to bear such a claim, the food or food product must meet the criteria proposed in § 101.62 for a "low fat" claim. FDA is proposing to permit foods that qualify to use a combined cancer-cardiovascular disease label statement and is requesting comments addressing scientific and compliance issues that may arise from the use of such combined health claims.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based on this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville. MD 20857.

FOR FURTHER INFORMATION CONTACT: He-Chong C. Lee, Center for Food Safety and Applied Nutrition (HFF-265), Food and Drug Administration, 200 C St. SW Washington, DC 20204, 202-485-0358

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (Pub L. 101-535) (the 1990 amendments), which amends the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorize the Secretary of Health and Human Services (the Secretary) (and by delegation FDA) to issue regulations authorizing nutrient content and health claims on the label or labeling of foods. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under the act (21 U.S.C. 343(r)(1)(B)).

Published elsewhere in this issue of the **Federal Register** is a proposed rule entitled "Food Labeling: General Requirements for Health Claims for Food," which establishes general requirements for health claims that characterize the relationship of nutrients, including vitamins and minerals, herbs, and other nutritional substances (referred to generally as "substances") to a disease or health-related condition on food labels and in labeling. In that companion document, FDA tentatively determined that such claims would only be justified for substances in dietary supplements as well as in conventional foods if the agency determines, based on all of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

Sections 3(b)(1)(A)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x) of the 1990 amendments require that within 12 months of their enactment, the Secretary shall issue proposed regulations to implement section 403(r) of the act, and that such regulations shall determine, among other things, whether claims respecting 10 topic areas, including fats and cancer, meet the requirements of the act. In this document, the agency will consider whether a claim on food or food products, including conventional foods and dietary supplements, on the relationship between fats and cancer would be justified under the standard proposed in the companion document on general requirements for health claims.

B. Public Health Aspects

1. Prevalence and Economic Impact

The importance of cancer as a public health problem in the United States cannot be disputed. All forms of cancer taken together are ranked as the second leading cause of death in the United States and account for one in five deaths. Deaths due to cancer numbered more than 475,000 in 1987. The overall economic cost of cancer, including the direct health care costs and losses due to morbidity and mortality, was estimated to be $72.5 billion. The social impact of cancer can be measured in part by the potential years of life lost by death before age 65. Potential years of life lost were 18 million years for cancer compared to 15 million years for heart disease (Ref. 1).

Risk of occurrence differs markedly for various types of cancer. In 1990, the leading types of cancer in men in the U.S. were lung (35 percent of all cancer deaths), colorectal (11 percent), and prostate cancer (11 percent). For women, the leading types were lung (21 percent), breast (18 percent), and colorectal cancer (13 percent) (Ref. 1).

2. Dietary Lipids in the United States

Lipids (fat and oils) with dietary importance include fatty acids, phospholipids, and cholesterol. As dietary components, lipids are commonly referred to as "fats." Henceforth, the colloquial term, "fat" will be used in place of the more technically correct term "lipids."

The fatty acid components of fat are classified as short chain (less than 6 carbons), medium-chain (6 to 10 carbons), or long-chain (12 or more carbons). Fatty acids are also classified as saturated (lacking double bonds), monounsaturated (containing a single double bond), or polyunsaturated (containing more than one double bond). The polyunsaturated fatty acids are subdivided into those whose first double bond occurs either three carbon atoms from the methyl carbon (omega-3) or six carbon atoms from the methyl carbon (omega-6).

Dietary fats serve several major physiological functions, and only a brief overview will be given here. Fats facilitate the intestinal absorption of the fat-soluble vitamins. Small amounts of linoleic and linolenic acid, two polyunsaturated fatty acids, are essential in the diet as precursors of eicosanoids and phospholipids. Phospholipids, as well as cholesterol, are major components of all cell membranes and myelin, the coating around nerve fibers. Cholesterol is also the precursor of the steroid hormones and of bile acids.

Fat is the most concentrated source of dietary energy of all the nutrients, supplying nine calories per gram (g) as compared to four calories per g from either carbohydrate or protein. More than one-third of the calories consumed by most people in the United States are provided by fat. In 1985, estimated average intake of fat was as follows: 19 to 50 year old men, 36 percent; 19 to 50 year old women, 37 percent; 1 to 5 year old children, 34 percent of energy (calorie) intake. The largest contributors to total fat intake for all sex and age groups were meat, poultry, and fish as well as grain-products (including baked goods and cakes) and dairy products. For adults, meat, poultry, and fish contributed 32 to 38 percent of total fat intake, grain products contributed 19 to 22 percent, and dairy products contributed 13 to 15 percent. For children, from 1 to 5 years, dairy products (28 percent) was the largest contributor to total fat, while meat, poultry, and fish contributed 22 percent and grain products contributed 24 percent (Ref. 2).

3. Relation of Dietary Fats to Cancer

Fat consumption in the United States is in excess of that needed to meet the physiological needs for energy and essential fatty acids. Recent U.S. Government nutrition guidelines and goals recommend an American diet with lower fat (30 percent or fewer of the calories), saturated fat (10 percent or fewer of the calories), and cholesterol (less than 300 milligrams (mg) daily). The available evidence shows that this excess intake of fat has significant consequences for the American population. While the most convincing evidence supports a relationship between dietary fat intake and the risk of cardiovascular disease, high fat diets also appear to be linked to increased risk of some types of cancer and obesity A recent National Research Council's (NRC's) Report, "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 3) concluded that although there was less persuasive evidence for the relationship between fat and cancer as compared to fat and cardiovascular disease, the weight of evidence from epidemiologic and experimental animal studies suggested that dietary fat may influence the risk of some types of cancer, particularly cancer of the breast, colon, and prostate and possibly the pancreas, endometrium, and ovary. Although the

precise quantification and the nature of the association between dietary fat and the overall risk of cancer has not been determined, all recent general dietary guidelines from the Federal Government and the NRC have recommended that lower fat intakes should be encouraged in the United States (Ref. 1, pp. 119–120).

C Dietary Fat: Regulatory History

Because there was a lack of agreement on the relationship between fat and cholesterol and good health when the agency's current regulations were adopted, FDA limited the amount of information that could be provided on the food label about these food components. Current relevant regulations are § 101.9(c)(6) (21 CFR 101.9(c)(6)), which requires that the fat content of a food be included in the nutrition label (38 FR 2132, January 19, 1973; and amended at 38 FR 6951, March 14, 1973), and § 101.25 (21 CFR 101.25) (42 FR 14302, March 15, 1977), which provides for the voluntary listing of cholesterol and fatty acid content as part of the food's nutrition label. No other information on fat or cholesterol content is permitted.

In 1986, however, with the emergence of a consensus that limiting dietary cholesterol would contribute to good health, FDA published a proposal to define terms that describe the cholesterol content of foods (51 FR 42584, November 25, 1986) and also proposed to require that, whenever these or other terms describing cholesterol content are used on the label, the fatty acid content of the food must be declared on the nutrition label.

As part of the Secretary's food labeling initiative, FDA issued a tentative final rule on cholesterol labeling in the **Federal Register** of July 19, 1990 (55 FR 29456). In that document, the agency proposed to limit the fat and saturated fatty acid content of foods bearing cholesterol claims. FDA proposed to limit the use of "cholesterol free" and "low cholesterol" to foods which, in addition to containing the requisite cholesterol levels, contain not more than 5 g of fat and not more than 2 g of saturated fats per serving. On a dry weight basis, these foods could contain not more than 20 percent fat and not more than 6 percent saturated fat.

For a complete description of FDA's regulation of the fat and saturated fat content of foods, see the proposal on fat, saturated fat, and cholesterol descriptors published elsewhere in this issue of the **Federal Register**.

In response to industry initiatives in which health messages about the relationship of low fat diets to reduced risk of cancer were placed on labels of breakfast cereals, FDA proposed to define health messages on August 4, 1987 (52 FR 28843). In that proposal, a "health message" was described as a claim for a food that addressed the relationship between that food in a diet and health. That relationship included the linkage between certain health problems (e.g., heart disease) and certain food factors and dietary habits. Because of a number of comments suggesting that this proposal was vague and unworkable, after seeking comments in an advanced notice of proposed rule making on August 8, of 1989 (54 FR 32610), FDA published a reproposal for regulating health messages in February 13, 1990 (55 FR 5176). In that document, the agency stated that it intended to review available scientific evidence to address whether a claim may be made with respect to a number of different topic areas, including fats and cancer.

On November 8, 1990, as stated above, the 1990 amendments were enacted, and FDA was charged with reviewing 10 topic areas. This document presents the results of FDA's review of the relationship between dietary fats and cancer.

D. Evidence Considered in Reaching the Decision

The agency has reviewed all relevant scientific evidence on fat and its relationship to cancer. The scientific evidence reviewed included all conclusions reached in: "The Surgeon General's Report on Nutrition and Health" (Ref. 4) and the U.S. Department of Agriculture (USDA) and U.S. Department of Health and Human Services (DHHS) report "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 6). It also considered documents from other recognized and scientific bodies, including: NRC's "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 3); NRC's "Recommended Dietary Allowances" (Ref. 5); The World Health Organizations (WHO), "Diet, Nutrition, and the Prevention of Chronic Diseases" (Ref. 7); and the Life Sciences Research Office (LSRO) report "The Role of Dietary Lipids in Cancer" (Ref. 8). FDA relied on these reports for a review of all evidence available before 1988.

The agency updated the conclusions reached by these reports by reviewing all human and animal studies released since these documents were completed.

To ensure that its review of relevant evidence was complete, FDA requested, in the **Federal Register** of March 28, 1991 (56 FR 12932), scientific data and information on the 10 specific topic areas identified in section 3(b)(1)(A) of the 1990 amendments. The topic of fat and cancer was among the 10 subjects on which the agency requested information.

E. Comments Received in Response to FDA Request for Scientific Data and Information

In response to the March 28, 1991 **Federal Register** request for scientific data and information on fats and cancer, FDA received 15 comments from the food and dietary supplement industries, a consumer advocacy organization, trade associations, a state health department, the Government of Canada, a private nutrition research foundation, an organization of public health professionals, and a consumer.

The comments dealt with the issues of fat and cancer and related food label requirements, as well as the general goals and requirements of the 1990 amendments. FDA reviewed all of the documents including letters, press releases, scientific articles, review articles, and recommendations included in submissions. FDA included the data submitted in scientific articles in its review of scientific literature which is discussed below.

The comments received from the food industry, the private nutrition research foundation, the consumer advocacy organization, and the consumer suggested that there was adequate scientific evidence and scientific agreement to justify claims for fat and cancer. The comments from the dietary supplement trade association and nutritional supplement manufacturers stated that the conclusions in several authoritative documents filed in the FDA docket on this topic are negative with respect to the role of nutritional supplements in providing the protective nutrients that are associated with disease. The dietary supplement trade association suggested that FDA exercise its independent judgment in reviewing the evidence on nutrient-disease relationships and not rely solely on conclusions drawn in the authoritative documents.

Comments from a state health department and an organization of professional public health nutritionists recommended caution in approving health claims and the need to prevent possible abuse of health claims or misinterpretation by the general public. These comments also expressed concern about the many topics that are candidates for health claims under the 1990 amendments.

A comment from a major grain food manufacturer suggested that one of the requirements for a fat and cancer health

claim should be that the food product contains a minimum amount of dietary fiber and a standard level of all other important nutrients commonly found in that food. Criteria for qualifying levels for fat were suggested as 10 percent of calories from food.

A major manufacturer of food oils and related food products suggested that fat intake should be reduced primarily by lowering saturated fatty acid intake. This comment raised questions about the possibility of increasing the risk of heart disease among consumers by reducing the relative proportions of polyunsaturated fatty acid intakes along with reductions in total fat intakes. It suggested that health claims for fat and cancer were justified only for foods especially low in saturated fat rather than total fat.

Finally, the Government of Canada submitted information that it considered helpful in the context of increased harmonization of regulations or standards affecting trade in specific products. The Director General, Food Directorate, Health and Welfare Canada, described the official position of Canada on the relationship of diet and nutrients to disease, including cancer, and the metabolic effects of nutrients, including fat, as stated in the volume "Nutrition Recommendations, the Report of the Scientific Review Committee—1990" (Ref. 9).

The conclusions of the Canadian Scientific Review Committee on fat and cancer were that "the present level of total fat, and particularly of saturated fat, in the Canadian diet constitutes a risk factor for cardiovascular disease and possibly for certain other diseases including some forms of cancer." The Committee recommended that total fat intakes of Canadians be no more than 30 percent of energy. The Director General also stated that food label health claims or messages regarding the role of fat in cancer risk could result in a food product being classified as a drug because the Food and Drug Act in Canada "prohibits the advertising and sale to the general public of a food that is represented either by label or in advertising as a treatment, preventative or cure for some 46 diseases, disorders or abnormal physical states including cancer."

II. Review of the Scientific Evidence

A. Federal Government Documents

In "The Surgeon General's Report on Nutrition and Health" (Ref. 4), the potential relationship of dietary fat to cancer risk was evaluated by reviewing results of a range of different types of studies. The report concluded that, although not yet conclusive, epidemiological and animal data support an association between dietary fat and the risk of cancer, especially breast, colon, and prostate cancer. The report stated that the effects of different types of dietary fat (i.e., saturated versus unsaturated) have not been separated in most human studies and considerable uncertainties remain to be resolved.

The Surgeon General's report concluded that the weight of the studies are strongly suggestive of the role for dietary fat in the etiology of some types of cancer (Ref. 4, p. 194).

The conclusions of the other authoritative documents from the Federal government listed above support the positive relationship between dietary fat and the risk of some types of cancer, particularly breast, colon, and prostate. These conclusions were the basis, in part, for the "Nutrition and Your Health: Dietary Guidelines for Americans" report that recommended calorie intake from total fat be less than 30 percent (Ref. 6).

B. Other Documents and Statements

The NRC's report "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 3) included the recommended goal to reduce total fat intake to 30 percent or less of calories. It stated that although less persuasive than the data supporting the fat and cardiovascular disease relationship, the weight of the evidence indicates that high fat diets are associated with a high risk of several types of cancer, especially of the colon, prostate, and breast. This report reviewed epidemiologic data as well as supportive evidence from animal studies that examined the mechanism of carcinogenesis.

The WHO study group report, "Diet, Nutrition, and the Prevention of Chronic Diseases" (Ref. 7) that presented the collective views of an international groups of experts, concluded that—

> * * * even though the "relationship between specific dietary components and cancer are much less well established than those between diet and cardiovascular disease, * * * a review of the evidence indicated that a high intake of total fat and in some case-control studies also saturated fat is associated with an increased risk of cancers of the colon, prostate, and breast. The epidemiological evidence is not totally consistent, but is generally supported by laboratory data from studies in animals. * * * [I]ntakes of less than 30 percent of total energy will be needed to attain a low risk of fat-related cancers. * * * [M]ost expert groups now consider it prudent to reduce fat intakes in Western societies from the prevailing figure of about 40 percent of energy towards 20 to 30 percent figure.

C. Review of the Scientific Literature

1. Evidence Considered

To the extent possible, the agency evaluated data from studies in humans as well as in animals. The criteria that the agency used to select pertinent recent studies required that they have been published and conducted after NAS' "Diet and Health" was published (i.e., after 1988), and that they:

(1) Present primary data carried out in animal or in human studies;

(2) Be available in English;

(3) Include direct measurement of dietary fat intake as a single nutrient or as a component of foods; and

(4) Include direct measurement of risk of cancer (prognostic indicator, incidence, development, prevalence, or mortality).

FDA considered that experiments in different animal species can take genetic variability into account and permit more intensive observation under controlled experimental conditions. However, the agency believes that extrapolation of data from animal studies to humans is limited by the differences in metabolism and physiology between animals and humans.

Various types of epidemiologic studies in humans also have limitations in methodology. The strengths and weaknesses of different kinds of epidemiologic studies and the methodologies for dietary assessment relevant to risk of chronic diseases are reviewed elsewhere (Ref. 3, pp. 23–32). Despite the limitations in epidemiologic studies, repeated and consistent findings of an association between certain dietary factors and diseases are likely to be real and indicative of a cause-and-effect relationship. Studies in animals can be used to confirm findings in humans and to elucidate mechanisms involved.

2. Evaluation Criteria

The data in humans and animals have been evaluated against general criteria for good experimental design, execution, and analysis. The criteria used in evaluating studies in animals include:

(1) Whether experimental diets were within physiological ranges of intake, particularly whether levels of fish oil or total fat in the diet were within the range of current human consumption and whether the diet provided adequate linoleic acid for growth of the host and tumor cells (There is evidence to support a linoleic acid requirement for optimal tumorigenesis. In a dose-response study, O'Connor et al. (Ref. 27) tested

azaserine-induced pancreatic tumorigenesis by measuring the development of atypical acinar cell nodules (AACN) in rats. AACN development was not affected when the diet contained less than 5 weight-percent corn oil but was increased as the omega-6:omeg-3 fatty acid ratio increased if the diet contained more than 5 weight-percent corn oil. This result is consistent with the reports by Ip et al. (Refs. 20 and 71) that there is a linear relationship of linoleic acid intake to mammary tumor development in rats up to an intake level of 4 to 5 weight-percent.);

(2) Whether confounding factors were controlled, particularly whether isocaloric diets were used;

(3) Whether the animal species selected for study were sufficiently similar to humans in responses to dietary modification;

(4) Whether the number of subjects was large enough to produce reliable data;

(5) Whether duration of exposure and period of observation were appropriate; and

(6) Whether the methods used in the measurement of disease endpoints were reliable and accurate.

The criteria used in evaluating human epidemiological studies included:

(1) Reliability and accuracy of the methods used in food intake analysis and measurement of disease endpoints;

(2) Choice of control subjects (e.g., hospital-based versus population based);

(3) Representativeness of subjects;

(4) Control of confounding factors, particularly energy intake which has a high correlation with fat intake, in data analysis;

(5) Potential for misclassification of individuals with regard to dietary exposure or disease endpoints;

(6) Presence of recall bias and interviewer bias; and

(7) Degree of compliance and how compliance was assessed.

FDA evaluated the weaknesses and strengths of individual studies (see Tables 1 and 2, assessment column). The strength of the overall combined evidence (e.g., epidemiologic studies and animal studies) was then assessed taking into account the strength of the association, the consistency of findings, specificity of the association, evidence for a biological mechanism and presence or absence of a dose-response relationship. FDA's conclusions reflect the strength, consistency, and weight of the data.

3. Review of the Evidence

a. *Animal studies.* Twenty-one animal studies were reviewed and critiqued in Table 1. Most studies used rats or mice, and a few studies used hamsters. Most rodent studies used a known cancer initiator, promoter, or both in conjunction with fats. A few studies used the transplant technique of existing tumor cells or cell lines.

i. *Level of fat in the diet.* Fourteen of the reviewed animal studies examined the effect of levels of dietary fats on incidence or development of cancer at the following sites: mammary gland (Refs. 10, 11, and 12), colon (Refs. 13 through 16), pancreas (Refs. 17 through 19), lung (Refs. 12, 21, and 22), gallbladder and common duct (Ref. 19), and skin (Ref. 23). The range of fat level tested, in most studies, was 5 to 20 percent by weight. The major dietary fat source was corn oil or beef tallow. Eleven of the studies examined the effect of omega-3 fatty acids in the development of cancer at the following sites: mammary gland (Refs. 12, 24, and 25), colon (Refs. 15, 16, and 26), pancreas (Ref. 27), lung (Ref. 12), skin (Refs. 28 and 29), as well as lymphoma and thymoma (Ref. 30), and sarcoma (Ref. 31). The major omega-3 fatty acid sources tested were menhaden oil and maxEPA. MaxEPA contains both eicosapentaenoic acid and docosahexaenoic acid as its major fatty acids, while menhaden oil contains only eicosapentaenoic acid as its major fatty acid.

Although there were few studies that examined the effect of fat consumption with lung and skin cancer, their results are consistent. All three studies of lung tumorigenesis showed an adverse effect of high fat versus low fat diets (Refs. 12, 21, and 22). Similar results were observed for the single study of skin tumorigenesis (Ref. 23).

However, mixed results were observed for tumorigenesis at the mammary gland, colon, and pancreas. One study showed a high risk of mammary cancer with high fat intakes (Ref. 11). Two studies showed no significant relationship of mammary tumorigenesis with fat intakes (Refs. 10 and 12). Shao et al. (Ref. 10) also reported no association between intake of total fats and mammary tumorigenesis in mice. However, the very high nontumor-related death rate (26 of 60 total) observed among the experimental animals makes it difficult to interpret the findings.

For colon cancer, one study (Ref. 16) showed a high risk of colon tumorigenesis with high fat intakes. A second study (Ref. 15) showed a significant relationship of a high fat diet to tumor incidence, but not tumor multiplicity. A third study (Ref. 14), however, showed no association. Sinkeldam (Ref. 13) also reported a significant effect of high fat on N-methyl-N'-nitro-N-nitrosoguanidine-induced colon tumorigenesis in rats. However, the results might have been confounded by an inadequate provision of linoleic acid in the diet.

Similarly, for pancreatic cancer, one study (Ref. 17) showed a positive relationship, but another showed inconsistent effects, of fat intake on different lesions: adenoma, adenocarcinoma, or carcinoma in situ (Ref. 19). Appel et al. (Ref. 18) did not find a significant difference in azaserine induced pancreatic neoplasms in rats between a group of rats given the 20 percent by weight lard (20 percent of the diet as measured by weight, not calories) and a group receiving a combination of 4.5 percent by weight lard and 0.5 percent by weight safflower oil. However, the low lard diet might not have provided adequate linoleic acid for growth of tumor cells.

Although the results of the animal studies are not in complete agreement, taken as a whole, and considered in the light of the aforementioned criteria, rodents consuming a high fat diet experienced significant elevation in the occurrence of tumors as measured by incidence, multiplicity, or metastasis. As discussed above, some animal studies showed significant reductions in the risk of tumorigenesis by reducing fat intakes from 20 percent by weight to 5 percent by weight. However, there was no dose-response study that quantitatively delineated the level of fat reduction in the diet necessary to cause reduced tumorigenesis. Tumor yield was enhanced when a high fat diet was fed after, but not before, initiation of tumorigenesis, which suggests a promotional effect of dietary fat (Refs. 16 and 23).

ii. *Fat level versus energy (calorie) intake.* Intake of dietary fat is highly correlated with energy (in this document, energy is used in place of calorie) intake, and the question has been raised as to whether energy intake or fat intake is the major dietary factor affecting tumorigenesis. In many recent animal studies, researchers have tried to determine the independent effect of dietary fats on tumorigenesis by using isocaloric diets or by training experimental animals to consume similar energy. Most of these studies with similar energy provisions among test groups showed significant associations between dietary fat level

and cancer risk: mammary tumors (Ref. 11), pancreatic tumors (Ref. 17), and skin tumors (Ref. 23). One study (Ref. 19), however, with similar energy provisions showed inconsistent results in N-nitrosobis (2-oxopropyl) amine-induced pancreatic ductular tumorigenesis. In this study, high fat significantly increased multiplicity of carcinomas in situ but not multiplicities of adenomas or adenocarcinomas. In addition, from a Murine mammary tumor virus-induced mammary tumor study in mice, Shao et al. (Ref. 10) reported that energy consumption rather than fat level affects tumorigenesis. However, this study had severe limitations in its methodology and execution because of a high, unexplained, nontumor death rate (26 of 60 total mice) which was even higher than the tumor death rate (19 of 60 total).

Abundant data have shown that energy restriction itself significantly reduces cancer risk probably through different mechanisms than the one through which dietary fat exerts its effect (Ref. 11). Although both fats and energy have been shown to have independent effects, precise relative contributions of fat and calories to cancer incidence is beyond the scope of this document.

iii. *Types of fat.* The effects of different types of fat (saturated fat, monounsaturated fat, and polyunsaturated fat) on tumorigenesis have not been studied extensively, and the results that do bear on this issue are as yet inconclusive. Generally, both a high corn oil diet (Refs. 11, 12, 17, 21 and 23) and a high lard diet (Ref. 13) exerted tumor-enhancing effects.

iv. *Fish oil, omega-3 rich.* The relationship of omega-3 fatty acids to cardiovascular disease is addressed specifically as a separate topic area. Therefore, this text will discuss only scientific data relevant to the association of omega-3 fatty acids with cancer.

Most studies, although concluding that a diet high in fish oil suppresses tumorigenesis, are limited by flaws in methodology. The main limitation is that the testing dose of fish oil in the diet, from 10 to 20 percent by weight in most studies, is unrealistically high for the current U.S. diet. Another limitation is that the diets under study often contained fish oil as the sole fat source or contained very high amounts of fish oil with very low amounts of corn oil.

Those very high fish oil diets would not have provided adequate linoleic acid for growth of the tumor cells. There may be a dietary requirement of linoleic acid at 3 to 5 percent by weight to yield a maximum carcinogenesis at the mammary gland and pancreas in rodents. The amount of linoleic acid required for maximal tumorigenesis is higher than the linoleic acid requirement for growth of the rodents, exclusive of the tumor cells (1 to 2 percent energy, which means 1 to 2 percent of the total dietary intake as measured in calories). The linoleic acid requirement for tumorigenesis has not been examined for tumors other than mammary and pancreatic. However, it is not possible to rule out the possibility that linoleic acid deficiency, rather than fish oil, might have caused, at least in part, the observed tumor suppression in fish oil studies. Therefore, FDA did not include fish oil studies in which the animals received very limited linoleic acid provision in their diets in the following discussion.

There are few fish oil studies in which the linoleic acid provision seems adequate for growth of tumor cells as well as for the animal in which the tumor is present (Refs. 12, 15, 16 and 27). Reddy et al. (Ref. 16) reported that azoxymethane-induced colon tumorigenesis in rats was significantly suppressed by a very high level of fish oil (18.5 percent by weight) diet compared to high levels of corn oil in the diet. Unlike the effect of total fat on tumorigenesis, the effect of fish oil was evident during the initiation as well as the postinitiation period.

O'Connor et al (Ref. 27) studied the relationship of a linearly increased omega-3:omega-6 fatty acid ratio in the diet with azaserine-induced pancreatic AACN. In this study, test levels of fish oil and total fat included the level of current consumption by the U.S. population. An increased omega-3:omega-6 ratio at 0.01 to 7.0 significantly decreased AACN in number and volume. There was significant regression between an increased omega-3:omega-6 ratio and decreased AACN diameter.

Deschner et al. (Ref. 15) reported a biphasic response of fish oil on azoxymethane-induced colon cancer in mice. In this study, a 4.4 percent fish oil to 16 percent corn oil diet significantly enhanced the tumorigenesis while a 10.2 percent fish oil to 10.2 percent corn oil diet suppressed it. Because the corn oil level is not held constant as the fish oil concentration is varied, it is not possible to comment on the tumorigenic effect of fish oil alone, though this does suggest that an increase in the fish oil to corn oil ratio may cause a decrease in tumor production. Adams et al. (Ref. 12) reported a nonsignificant tumor inhibiting effect of high (15.5 to 20.5 percent by weight) fish oil on transplanted mammary tumorigenesis in rats.

Although most studies consistently concluded that there is a suppressive effect of fish oil on tumorigenesis, the results cannot be extrapolated to humans because of study design limitations described above.

v. *Biochemical mechanisms.* Although several mechanisms have been proposed, the biochemical mechanism by which fats affect tumorigenesis has not been definitely established. While the required level of linoleic acid intake for optimal expression of mammary and pancreatic carcinogenesis in rats has been determined to be 4 to 5 percent by weight in the diet, how linoleic acid affects tumor development is not yet clear.

Several hypotheses about the mechanism of enhancement have been debated. One suggestion is that eicosanoid synthesis and changes in the fluidity or microenvironment of cell membranes affect tumorigenesis (Ref. 32). Another proposed mechanism is that polyunsaturated fatty acids may promote fat peroxidation at cell membranes or subcellular sites such as deoxyribonucleic acid (DNA), mitochondria, or microsomes, leading to the initiation of carcinogenesis (Ref. 32). A third suggestion is that dietary fats alter immune function, gene expression, and metabolism of chemical carcinogens (Refs. 34 and 35). Fats may also increase levels of estrogen and androgen, thereby enhancing the risk of such endocrine-responsive tumors as cancer of the breast and prostate (Ref. 36).

With regard to colon cancer, the effects of free fatty acids and bile acids on the colonic epithelium have also been debated. The ionized forms of these substances may be irritating and toxic to colonic epithelial cells and may increase cancer risk by promoting or possibly initiating colon carcinogenesis. Bile acids, particularly those modified by intestinal enzymes, may also increase cancer risk by accelerating turnover of intestinal mucosal cells (Ref. 33). Omega-3 fatty acids found in fish oil may suppress tumorigenesis by an altering eicosanoid production.

b. *Human studies.* FDA considered the following kinds of human studies in this review of the role of dietary fats in cancer: (1) Correlational (ecologic) studies—correlational studies examine the relationship between the exposure and health outcome among populations using grouped data. Because these studies do not examine relations among individuals, they have been regarded traditionally as useful for generating hypotheses rather than definitively

testing such hypotheses; (2) analytic epidemiologic studies—studies that involve comparisons of individuals have been regarded as the strongest type of observational evidence in human populations. In case-control studies, the relationship of an attribute to the disease is examined by comparing persons who already are diagnosed with cancer (cases) to persons without cancer (controls). A potentially serious limitation of the case-control study is that diet is assessed in the cases after diagnosis, so that cases may unintentionally overestimate or underestimate fat intake. Cohort studies compare individuals who have been exposed to a risk factor to those who have not and observe the individuals over time to determine if disease develops. In cohort studies, diet is assessed at the beginning of followup, before cancer develops.

Two criticisms have been raised in regard to results of the analytical epidemiologic studies of dietary fats and cancer. Such studies are often carried out in populations with a fairly narrow range of fat intake. Thus, it is difficult to show a dietary fat effect, especially if the true protective effect of a low-fat diet emerges only at a level below the intake of most members of the study population. Also, because there is considerable error in the assessment of diet, there may be considerable measurement error resulting in misclassification of a substantial proportion of subjects. Homogeneity of dietary intake in populations, together with misclassification of dietary data, tends to weaken the observed association and limits the ability of epidemiologic studies to demonstrate a true direct relationship between dietary fats and cancer.

Thirty-one original epidemiological research articles published since 1987 were reviewed and are critiqued in Table 2.

i. *Breast cancer.* In relation to breast cancer, 2 ecologic studies (Refs. 37 and 38), 2 cohort studies (Refs. 39 and 40), 11 case-control studies (Refs. 41 through 51, and Refs. 87 and 89), 2 surveys (Refs. 52 and 53), and 6 studies examining prognostic indicators of breast cancer (Refs. 53 through 58), and 1 metaanalysis of 12 case-control studies (Ref. 73) are included in Table 2.

The Hursting, et al. correlational (ecologic) study (an international correlation study combining data from 20 countries (Ref. 38)) found significant associations between estimated total fat intake and the incidence of breast cancer. Energy intake, which is highly correlated with fat intake, was adjusted in the data analysis. Therefore, the effect of dietary fat on the cancer incidence was assessed independently of the effect of energy intake. When the results were adjusted for intake of other component fats as well as total calories, the intake of saturated fatty acids was significantly associated with the incidence of breast cancer. The intake of omega-6 polyunsaturated fatty acid was also associated with breast cancer incidence. However, intake of monounsaturated fatty acids or omega-3 polyunsaturated fatty acids was not associated with any cancer risk.

In another correlational study, Prentice (Ref. 37) also examined the relationship between estimated per capita fat intake and breast cancer in 21 countries. Dietary fat, but not protein or carbohydrates, was significantly associated with breast cancer incidence.

In conclusion, the correlational studies demonstrated a significant positive association between dietary fat and breast cancer. The effect of dietary fat on breast cancer risk seems to be independent of the effect of energy. No specific fat type was found to be responsible for the observed risk of breast cancer.

Most of the case-control studies found a significant association between dietary fat intake and breast cancer risk (Refs. 44, 46, 47, 50, 51 and 87). Among those six studies with positive results, three studies (Refs. 46, 50 and 87) adjusted energy intake in the risk estimation. Gerber (Ref. 43) reported a borderline ($p=0.07$) association but did not adjust for energy intake. Holm (Ref. 53) reported that patients with higher fat-energy intakes had larger tumors than patients with less fat-energy and higher carbohydrate-energy intakes. However, the authors did not consider the possible confounding effect of lead time (the period of time between start of tumor growth and clinical diagnosis of cancer) among individuals with different levels of fat intake. A case-control study investigating the relationship between diet and histologic types of benign breast disease among Canadian women (Ref. 89) found that severe atypias and borderline carcinomas in situ were associated with frequent meat fat consumption but the results were not statistically significant.

Two studies (Refs. 42 and 45) resulted in no associations. In one (Ref. 42), intakes of energy, protein, or carbohydrates were also not associated with the risk of breast cancer. However, dietary habits of the population may have been homogeneous, thus reducing the ability to detect variation in disease risk associated with variation in dietary intakes. In the other negative study by Pryor (Ref. 45), subjects (ages 20 to 54) were asked about their food habits during the adolescent period. Errors in recall of dietary intake up to 40 years before might have biased the results, because of a selective memory difference between the cases and the controls.

In a study of 85 Israeli women, Eid and Berry (Ref. 52) reported that fatty acid composition in breast tissue was not associated with the risk of breast cancer. In this study, the percent composition, but not the amount of fatty acids, was reported. Studies in rodents have demonstrated that after a requirement for linoleic acid is met, total amount rather than type of fat in the diet is responsible for tumorigenesis. Therefore, the results of Eid and Berry are not contradictory to the current fat and cancer hypothesis. On the other hand, Neoptolemos et al. (Ref. 59) found that tissue arachidonic acid was decreased in colon cancer patients whereas there was no difference in dietary intake. The authors suggested a possible disturbance in fat metabolism in cancer patients.

Howe (Ref. 73) performed a meta-analysis of 12 case-control studies of diet and breast cancer. He found a consistent, statistically significant positive association between breast cancer risk and saturated fat intake in post menopausal women. However, he was unable to adjust the results for total caloric intake.

Considered together, the case-control studies support the conclusion that there is a positive association between dietary fat and breast cancer. The effect of fat intake on the risk of breast cancer is independent of the effect of energy intake. The total amount of fat rather than any specific type of fat seems to be responsible for the elevated risk of breast cancer.

The Howe et al. cohort study, (Ref. 40) found a weak but significant association between total fat intake and the risk of breast cancer in a prospective study in a large cohort (56,837 women, 519 cases during a 5-year followup). The group that consumed the highest amount of fat demonstrated a risk of developing breast cancer that was 1.3 times as great as the group that consumed the least amount of fat after adjustment for other sources of energy. Intake of various types of fat (saturated, monounsaturated, and polyunsaturated fatty acids) showed a general pattern of increasing risk of breast cancer with exceptions in the lowest quartile for intake of saturated and monounsaturated fatty acids. On the other hand, in a 20-year prospective study with a smaller cohort (3,988

women, 54 cases) in Finland, Kneckt et al. (Ref. 39) found no association between energy-adjusted fat intake and risk of breast cancer. The strength of the association between fat intake and the breast cancer risk could have been underestimated in this study because of possible changes over time in dietary habits during the 20 years before diagnosis.

The results of these two prospective studies are contradictory regarding the relationship between dietary fat and cancer. To date, only a small number of prospective studies that have examined this association have been completed. Because of the long latency period of breast cancer, a suitable length of time for a prospective study is likely to be 20 years or more, which presents many difficulties in its administration. In addition, in order to demonstrate an effect, the fat intake of the population would have to show sufficient variation to detect an effect.

To test the feasibility of low-fat dietary maintenance over time, a 2-year intervention study by Insull et al. (Ref. 60) required that subjects maintain a diet comprised of only 20 percent of total calories for 2 years. Compliance was good, thus supporting the authors' inference that studies that requiring maintenance of a low-fat diet are feasible.

ii. *Colon cancer.* There have been few studies published on the relationship of dietary lipids to colon cancer since the authoritative documents. An overview of these studies is given in Table 2 and discussed below.

The Hursting, et al. correlational (ecologic) study (Ref. 38) found a significant association of energy-adjusted, estimated total lipid intake and the incidence of colon cancer. When the results were adjusted for intake of the saturated fat component of lipids as well as total calories, the intake of saturated fat was significantly associated with the incidence of colon cancer. The intake of omega-6 or omega-3 polyunsaturated fatty acids were not associated with the risk of colon cancer. (See Table 2 for detailed critiques for each study.) Morales Suarez Varela-et al. (Ref. 90) evaluated the relationship between Spanish diet and rectal or colon cancer and found a positive correlation between rectal or colon cancer and total fat consumption. However, the results were not adjusted for total energy intake or for lifestyle confounders such as tobacco smoking.

A case-control study in Utah (Ref. 61) also reported a significant association of total fat intake with the risk of colon cancer in both females and males. In females, the group consuming the greatest quantity of total fat exhibited 1.9 times the risk of colon cancer as the group consuming the lowest quantity. In males, the risk was 2.0 times as great. However, various lipid types (saturated fat, monounsaturated fat, and polyunsaturated fat) were not consistently associated with the risk. Energy intake, not adjusted in the risk assessment, may have confounded the results.

De Verdieu (Ref. 77) in a Swedish case-control study of colorectal cancer found an increased risk with increased energy intake and with increased total fat intake but only the trend of increasing risk with increasing consumption levels was statistically significant. None of the individual fat consumption levels was associated with increased risk of colorectal cancer. The results were adjusted only for fiber intake and not for total energy. Also, there was a high nonresponse rate among the cancer cases, 21 percent, which may have biased the results.

Slattery, et al. (Ref. 88) conducted a case-control study of colon cancer in Utah that found a nonsignificant increase in cancer associated with total fat intake. The results were not adjusted for total energy intake.

Cohort studies—a prospective study of 88,751 registered nurses was performed by Willett. et al. (Ref. 62). During a 6 year followup period, 150 colon cancer cases were identified. After adjusting for the difference in age and energy intake, a positive association was found between fat and colon cancer. Specifically, the group with the highest total fat consumption demonstrated a risk of developing colon cancer that was 2.0 times as great as the group with the lowest fat intake. The groups with the highest consumption of animal fat, saturated fat, and monounsaturated fat also showed a higher risk of developing colon cancer of 1.9, 1.4, and 1.7 times the groups with the lowest consumption, respectively. Intakes of linoleic acid, vegetable oil, and cholesterol were not associated with cancer risk.

A prospective study of 8006 Hawaiian Japanese men (Ref. 85) was conducted to assess the impact of fat and calcium intake on the risk of developing colon or rectal cancer. The cohort was followed for 22 years. The results, which were not adjusted for total energy intake, demonstrated that fat intake did not affect colon or rectal cancer risk.

Thus, recent human studies on fat and colon cancer show an inconsistent association between intake of total fat and the risk of colon cancer. Many of the studies are difficult to interpret because the results were not adjusted for the effects of energy.

iii. *Other cancer.* Correlational (ecologic) studies (Ref. 38) demonstrated a significant association of energy-adjusted, estimated total lipid intake and prostate cancer but not with the incidence of cervical or lung cancer. When the results were adjusted for intake of component fats as well as total calories, the intake of saturated fat and omega-6 polyunsaturated fat was significantly associated with the incidence of prostate cancer. The intake of monounsaturated fat or omega-3-polyunsaturated fat was not associated with of risk of cancer. See Table 2 for detailed critiques for each study.

Ghadirian et al. case-control studies (Ref. 63) found significant associations of total lipid and saturated fat intake with the risk of pancreatic cancer in a case-control study in Montreal; however, cholesterol was not significantly associated with risk. Age, sex, energy intake, response status, and cigarette smoking habits were adjusted in the data analysis.

Baghurst, et al. (Ref. 75) in a case-control study of pancreatic cancer found an increased risk with increased cholesterol intake but not with polyunsaturated fatty acids. Thus, the results are somewhat contradictory. A well done case-control study of pancreatic cancer (Ref. 78) found no increased cancer risk associated with consumption of total fat, saturated fat, cholesterol, or omega-3 fatty acids. The results were adjusted for total caloric intake as well as for all major risk factors for pancreatic cancer other than diet. Finally, LaVecchia, et al. (Ref. 82) also found no relationship between pancreatic cancer and indicators of dietary fat in a well-controlled case-control study.

A case-control study in Hawaii (Ref. 64) showed that male lung cancer patients consumed significantly more fats (total fats, saturated fats, and monounsaturated fats) compared to the controls after adjustments for age, ethnicity, and cigarette smoking. However, there was no significant association between lipid intakes and risk of lung cancer in females. Another case-control study of lung cancer (Ref. 79) found a borderline increased risk of lung cancer associated with high levels of cholesterol consumption but not with total fat consumption. A case-control study of laryngeal cancer found no association with indicators of dietary fat (Ref. 81).

Steineck (Ref. 65) reported a dose-response relationship between total fat intake and the risk of urothelial cancer

in a case-control study in Sweden. Gender, age, and smoking habits, but not energy intake, were adjusted in the data analysis. Maclure, et al. (Ref. 83) found a weak association between risk of renal cancer and fat consumption. (See Table 2 for detailed critiques of these studies.)

Slattery, et al. (Ref. 86) in a case-control study of prostate cancer found no association with a high fat diet consumed as adolescents and a slight association with a high fat diet consumed by cases as adults.

Thus, one correlational study found a positive, energy-independent association of total fat intake with the risk of prostate cancer but not with the risk of cervical or lung cancer. One case-control study found a positive, energy-independent association of total fat intake with the risk of pancreatic cancer, but three other case-control studies of pancreatic cancer found no association with fat intake. The results of two case-control studies of lung cancer were not consistent for males and females, thus raising questions of interpretation. Various types of fat did not show any specific effects on risk of the various cancers examined. In conclusion, there is some evidence that total fat intake may increase the risk of prostate cancer but not the risk of pancreatic, cervical, pancreatic or lung cancer. The effect of fat seems to be independent of the effect of energy.

iv. *Studies testing fat-containing foods.* A few studies tested the association of lipids as constituents of food with the risk of breast cancer (Refs. 41, 44, 46, 48, 49, 62 and 65 through 68). The results of these studies were contradictory. Meat consumption was positively associated with risk of colon cancer or rectal cancer (Refs. 62, 66 and 67) and with stomach cancer (Ref. 76), but not with risk of breast cancer (Refs. 41, 44, 46 and 49), lymphoma (Ref. 68), urothelial cancer (Ref. 65), or oral cavity or pharyngeal cancer (Ref. 69). An additional case-control study of stomach cancer found a decreased cancer risk with increasing consumption of vegetable fat (Ref. 74). Consumption of whole milk (Ref. 48) or milk (Ref. 68) was significantly associated with the risk of cancer of the breast, colon, rectal, lung, bladder, prostate, oral cavity, and of lymphoma, but not with ovarian cancer (Ref. 84). Consumption of dairy products was significantly associated with the risk of cancer of the breast (Ref. 46), rectum (Ref. 67), and lymphoma (Ref. 68) but not with the risk of colon cancer (Ref. 67). Consumption of margarine was not associated with the risk of colon cancer (Ref. 66).

Methodological limitations inherent in case-control studies using food frequency questionnaires may have contributed to the difficulty of interpreting these results. These limitations include recall bias, interviewer bias, inconsistency in estimation of food consumption, and homogeneity of the population tested. Interactions among nutrients or other food components beyond fat might also have weakened the results.

4. Other Relevant Information

a. *Breast cancer and colon cancer: public health aspects.* Breast cancer is the second leading cause of cancer death among women. In 1990, approximately 44,000 women died of breast cancer in the U.S., while 150,000 new female cases were diagnosed. Approximately 1 woman in every 10 will develop breast cancer in her life (Ref. 1, pp. 415–6). The prevalence of breast cancer in the United States was estimated to be 1,517,882 cases in 1990. Thus breast cancer represented 24 percent of all cancers in 1990 and 39 percent of all cancers in females (Ref. 73).

Breast cancer risk increases with age, but the slope of the age-specific incidence is different before and after menopause. Risk rises rapidly up to about the age of 50 to 55, at which time the rate of increase slows or even reverses in some populations. After menopause, another rise occurs in high-risk populations.

Breast cancer has tended to be more common among higher socioeconomic groups and among Caucasians. Recently, however, rates have been rising among blacks, Hispanics, and people of Asian origin. The health care costs for breast cancer for 1990 are estimated at $8.5 billion, with an additional $16.5 billion, if lost wages due to disability and early mortality are considered (Ref. 73).

Colon cancer is a common disease in developed countries. It is the third leading cause of cancer death in the western world, exceeded only by lung and breast cancer. In the United States, colon cancer is a major cause of illness and death, accounting for 14 percent of all cancers diagnosed. The current U.S. age-adjusted incidence rate for colon cancer is 34.7 new cases per 100,000 population (Ref. 70). In 1990 the prevalence was 338,980 cases in men and 432,435 cases in women in the United States (Ref. 73). Both incidence and mortality from colon cancer have been relatively stable for the past 30 to 40 years. Recently, however, there has been an indication that mortality is decreasing among women in North America and possibly among men in the United States (Ref. 3, p. 118). Health care costs for colon cancer (1990) were estimated at $4.3 billion, with an additional $8.4 billion in lost wages due to disability and early mortality (Ref. 73).

b. *Potential safety concerns of dietary fat intake restriction.* Restriction in the intake of dietary fat may reduce the consumption of essential fatty acids. The requirement of linoleic acid to avoid essential fatty acid deficiency is 1 to 2 percent of total caloric intake. Currently, the average linoleic acid consumption in the U.S. ranges between 5 and 10 percent of total calorie intake, and deficiencies of essential fatty acids are rare in the U.S. Thus, a reduction of total fat consumption from the current 36 to 37 percent of total calorie intake to about 30 percent is not likely to cause essential fatty acid deficiencies in the general population.

5. Conclusions

Although the results of animal studies are not entirely consistent, taken as a whole, the results show that high fat diets enhance carcinogen-induced tumor development of the mammary gland, colon, pancreas, and lung, independent of the effect of energy intake. There seems to be an optimal intake of linoleic acid to yield maximum mammary and pancreatic carcinogenesis in rats. The amount of dietary linoleic acid (3 to 5 percent by weight) for maximum mammary tumorigenesis in rodents is higher than the linoleic acid requirement for the rodent, exclusive of the tumor cells (1 to 2 percent by energy), and approximates the current, average consumption of linoleic acid in the U. S. Once the linoleic acid requirement is met, the total amount of fat in the diet, rather than types of fat, seems to be responsible for tumor development (Refs. 20 and 71).

The effects of different types of fat on tumorigenesis have not been studied extensively, and the results are as yet inconclusive. Generally, both a high saturated fat diet and a high polyunsaturated fat diet show tumor-enhancing effects. Most studies that examined the effects of omega-3 fatty acid-rich fish oils on tumorigenesis consistently concluded there was a suppression of tumorigenesis. However, most of these studies were flawed in biological plausibility, and the results are not easily extrapolated to humans. The mechanism by which fat affects tumorigenesis has not been definitively established.

International correlational studies of human populations reported that dietary

lipid intake, independent of energy intake, is associated with tumorigenesis particularly of the breast, colon, and prostate but not with the incidence of cervical or lung cancer. These results suggest that the effect of fat intake on cancer incidence may be site-specific.

Four cohort studies were reviewed. In a 20-year followup study in Finland, energy-adjusted total fat intake was not associated with the risk of breast cancer. In a large, 5 year followup study in Canada, the energy-adjusted intake of total fat was weakly but significantly associated with the risk of breast cancer. All three fat types (saturated, monounsaturated, and polyunsaturated) showed a general pattern of increasing risk with increasing fat intake. In a large cohort study of 88,752 nurses, Willett et al. (Ref. 62) found a significant association of dietary total fat, animal fat, saturated fat, and monounsaturated fat with the incidence of colon cancer. However, a Japanese cohort study demonstrated that fat intake did not increase the risk of colon or rectal cancer (Ref. 65).

The total fat intake was associated with the risk of breast cancer in most, but not all, case-control studies: Six studies found a significant relationship, one study found a borderline association, and two studies found no relationship. As in the animal studies, no specific effects of different types of fat were found in these studies. In some studies, all types of fatty acids were associated with carcinogenesis; in some other studies, only saturated or monounsaturated fatty acids were associated.

Because energy intake and lipid intake are highly correlated, it is possible that the association between dietary fats and cancer is confounded by energy intake. It also has been demonstrated in animal and human studies that energy intake in excess of an essential requirement is of primary importance in determining the incidence of induced and spontaneous tumors. However, FDA s evaluation of recent research reports, both in animal and human studies, provides convincing evidence that the effect of dietary lipids on tumorigenesis is independent of the effect of energy.

Few studies evaluated fats in the context of overall food consumption. The results of studies of the association between the risk of cancer and consumption of meat, milk, or dairy products are inconsistent. Methodological limitations may have obscured any association that exists.

There have been no clinical trials or dietary intervention studies examining the quantitative relationship between reduction in fat intake and altered cancer risk in populations. Therefore it is not possible to conclude how much reduction in fat intake is necessary, or how soon in life it must commence, to reduce the risk of cancer in the U.S. population. Intervention studies of cancer are difficult to perform because the rarity of outcome for specific types of cancer requires enormous sample sizes. In addition, the long latency, 20 to 30 years for most types of cancer, makes such studies difficult and costly. For this reason, observational epidemiology studies are generally accepted as sufficient, as was the case for the first Surgeon General s Report on smoking. Nevertheless, the weight of evidence shows that a diet that is low in total fat is consistent with a low risk of some types of cancer.

The 17-year followup study of the National Center for Health Statistics' First National Health and Nutrition Examination Survey (Ref. 72) examined the relationships between dietary fat and the risk of cancer of the breast, prostate, and colon in 5,454 men and 7,876 women. No evidence of increased risk of cancer in the group with the highest fat intake was found. The difference in fat intake between the groups with the highest and the lowest fat intakes, 37 percent energy versus 32 percent energy, was not as great as the differences in fat intakes between countries. These results suggest that a reduction in fat intake to less than 30 percent of total calories may be needed to observe any reduction in cancer risk in the United States.

Thus, the conclusions of the authoritative reviews that dietary fats have an important influence on cancer incidence and mortality, particularly at sites such as the breast, colon, and prostate, are supported by the results of recent animal and ecological studies. Results of human prospective and case-control studies are less supportive, in part because of limitations in the experimental design. However, the majority of case-control studies are consistent with the conclusion that fat intake is associated with the risk of breast and colon cancer.

Although cancer at many sites was affected by fat intake in animal studies, epidemiologic studies failed to show convincing evidence for the fat and cancer relationship at various sites. Furthermore, an international ecologic study found an association between fat intake and cancer of the breast, colon, and prostate but not of the cervix or lung. These results suggest that the effect of fat on cancer may be site-specific.

From the review of other authoritative documents and recent research reports, the agency concludes that dietary fat intake may affect the risk of breast, colon, and prostate cancer. More studies are needed to examine the relationship between fat intakes and cancer at other sites.

No scientific evidence is available that demonstrates that any specific fat type is more causative of cancer than another. All types of fat (saturated, monounsaturated, and polyunsaturated) may be associated. Therefore, total fat content, rather than any specific type, may be responsible for the tumor enhancing activity of fat in the current diet of the U.S. population.

III. Tentative Decision to Authorize a Health Claim Relating Ingestion of Dietary Fat to Reduced Risk of Cancer

FDA has reviewed the Federal government and other review documents as well as recent research and review articles relevant to dietary fat and cancer risk. In addition, the agency considered all comments received in response to the **Federal Register** notice of March 28, 1991, requesting scientific data and information on fat and cancer. The agency has tentatively concluded that all the publicly available evidence supports an association between dietary fat and cancer risk. FDA tentatively finds, based on this evidence and the authoritative reports, that there is significant scientific agreement among qualified experts. The agency is proposing to authorize a health claim for fat and cancer on the label and labeling of foods provided that such statements comply with the requirements of proposed § 101.73. Under this proposal, the claim will convey the message that diets low in fat may reduce the risk of some types of cancer, particularly breast, colon, and prostate. FDA also tentatively concludes that the message must be restricted to these three types of cancer because of the limitations of scientific data about other types of cancer.

IV. Description of and Rationale for Regulations

A. Relationship Between Dietary Fats and Cancer

Based on all of the evidence, FDA has tentatively determined that there is significant scientific agreement among experts qualified by training and experience to evaluate such claims, that all of publicly available evidence supports the conclusion that diets high in fat increase the risk of cancer, and,

more importantly, that diets low in fat is associated with the reduced risk of cancer. FDA recites this fact in proposed § 101.73(b)(1) and states that the research to date shows that it is total fat, and not any particular type of fat that is associated with cancer risk.

The specific health claim topic, as described in section (3)(b)(1)(A)(vi) of the 1990 amendments was dietary lipids and cancer. FDA has tentatively found that the intake of dietary lipids is associated with cancers of the breast, colon, and prostate. This tentative finding is based on the conclusions of a number of comprehensive reports by the Federal Government and the NRC which identified cancers at these particular sites as having a relationship to dietary fats. It is also supported by research published since the authoritative reports to determine if more recent research would necessitate modification of previous conclusions.

B. Significance of the Relationship

To reflect, in part, proposed § 101.14(d)(2)(v), FDA is including in proposed § 101.73(b)(2) dietary guidelines to recommend that total fat intake be at or below 30 percent of calories. Currently, adults in the United States consume, on average, a total fat intake of 37 percent of calories. The proposed regulation states that significant public health benefits can be derived from decreased consumption of foods high in fat, including the reduced risk of breast, colon, and prostate cancer.

C. General Requirements

1. Conformity With Proposed § 101.14

Proposed § 101.14 sets forth the general provisions applicable to health claims. In proposed § 101.73(b)(3)(i), FDA is proposing that health claims relating to an association between dietary lipids and cancer must meet all requirements for health claims proposed in § 101.14, as set forth elsewhere in this issue of the **Federal Register**.

2. Qualifying Nutrients: Total Fat

In proposed § 101.73(b)(3)(ii), FDA is proposing that a health claim relating diets low in fats to reduce the risk of cancer must meet requirements for "low fat" or "fat free."

The evidence for the association between intake of dietary lipids and risk of cancer pertains to total dietary fats. In the companion document on general requirements for health claims for food (published elsewhere in this issue of the **Federal Register**), FDA is proposing that for a substance such as dietary fats for which a low level of intake is needed to achieve dietary goals, the substance be present in a food at a low enough level to justify a claim. FDA is proposing that that level be the level that is necessary to make a "low fat" or "no fat" claim. As proposed in the companion document on "Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Foods," these levels are, for a "low fat" claim, less than 3 g of fat per reference amount customarily consumed, per labeling serving size, and per 100 g. For a "no fat" claim, FDA is proposing that the food contain less than 0.5 g of fat per reference amount customarily consumed and per label serving size.

As explained in the companion document on general requirements for health claims, FDA is proposing that the food contain "low" or "no" fat to ensure that it contains a level of fat that is appropriate for inclusion in a diet that is low in fat. FDA seeks comments on whether a food that qualifies for a "reduced fat" or comparative claim should also qualify to bear this health claim.

D. Specific Requirements

In proposed § 101.73(b)(4)(i), FDA is proposing to require that any health claim made relating to dietary lipids and cancer specifically state that it is diets that are low in fats that may reduce the risk of some types of cancer.

In proposed § 101.73(b)(4)(ii), to reflect the strength of the scientific evidence regarding the relationship of dietary lipids to risk of cancer, FDA is proposing that any health claim make clear that ingestion of diets low in fats "may" reduce the risk of cancer. This requirement is based on this relationship and is supported by evidence documented and summarized in Federal government reports, in other authoritative documents, and in the science review incorporated previously in this document. However, given the fact that the etiology of cancer is multifactorial the claim cannot state that a low fat diet will definitely reduce the risk of this disease.

In respect to the multifactorial nature of the disease in proposed § 101.73(b)(4)(iii), the agency is proposing to require that health claims acknowledge the existence of other risk factors for cancer in addition to the dietary risk factor of fat intake. The agency believes that this additional information provides a context that is essential for an understanding of the nutrient to disease relationship.

As for terminology, in proposed § 101.73(b)(4)(iv), FDA is proposing that health claims refer to the nutrient disease relationship using the term "total fat." This terminology is consistent with colloquial usage. Thus, the claim will be clear and not misleading to the public. It also reflects the available evidence. In proposed § 101.73(b)(4)(iv), FDA provides that a combined fat and cancer and fat and cardiovascular claim may be used if a food qualifies for both claims. In proposed § 101.73(a), FDA is summarizing the scientific evidence that establishes a relationship that exists between saturated fat, cholesterol, and total fat and cardiovascular disease. FDA is proposing to authorize health claims on qualifying foods that meet the criteria for "low" saturated fat, cholesterol, and total fat or no cholesterol and total fat.

For the estimation of attributable risk, in proposed § 101.73(b)(4)(v), FDA proposes that no statement may be made on the precise level of reduction of risk of cancer that may be expected as a result of consuming a diet low in total fat. This requirement is proposed in conformity with proposed § 101.14(d)(2)(iii) which requires that the claim not be misleading. The review of Federal government documents and other authoritative reports and more recent scientific evidence revealed no scientific agreement on a precise level of risk reduction for the relationship of dietary fat to cancers.

In § 101.73(b)(4)(vi), FDA is proposing that the claim may not specify the particular types of fats and fatty acids that may be related to the risk of cancer. FDA tentatively finds that the evidence is not sufficient to characterize the relationship more specifically than between cancer and total fat.

E. Optional Information

For total dietary context, in proposed § 101.73(b)(5)(i), FDA proposes to permit claims to refer to the latest U.S. Dietary Guidelines for Americans (Ref. 6). The agency is proposing to permit such references to help ensure that the claim is presented in a way that will help consumers to understand it in the context of a total daily diet. The agency recognizes that a statement about the importance of good nutrition that does not make a connection between any substance and a particular disease, as is the case with many of the Dietary Guidelines, is not a health claim. H. Rept. 101-538, 101st Cong., 2d sess. 20 (1990). However, as is stated in the document on the general principles for health claims, FDA believes that it is appropriate for it to provide for the use of governmental dietary information in conjunction with a health claim to

ensure that that information is used in a consistent and nonmisleading manner.

Providing additional health claim information, in proposed § 101.73(b)(5)(ii), the agency is proposing to allow manufacturers to provide more detailed information to consumers. This information may provide a more accurate and complete description of the relationships among both dietary fats and risk of cancer and heart disease. A statement on how to obtain this additional information may be provided in or near the health claim. Such additional information, however, is not a substitute for that required in a health claim.

F Sample Health Claims

FDA is also providing in proposed § 101.73(b)(6) two sample health claims. These model claims have been prepared by the agency to reflect all the requirements of proposed § 101.73. They are only samples, however, if these sample health claims are adopted by the agency, manufacturers will be free to use them. They will also be free to devise their own message provided that it complies with the regulation.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

VII. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

IX. Appendix to the Preamble—Consumer Summary on Dietary Lipids and Cancer and Dietary Lipids and Coronary Heart Disease

As described in the companion document (published elsewhere in this issue of the **Federal Register**) on general requirements for health claims, the agency is requesting comment on the need for consumer health claims summaries. The focus of the consumer summary would be to provide factual information to aid the consumer in understanding the diet-disease relationship. The following appendix is a proposed consumer summary on dietary lipids and cancer. The role or relationship of dietary fats to cancer risk is discussed, along with the relationship of dietary fats to coronary heart disease. FDA solicits comment on this document as explained in the proposal on general health claims published elsewhere in this issue of the **Federal Register**.

Appendix—Dietary Lipids and Cancer and Dietary Lipids and Coronary Heart Disease

Under the provisions of the Nutrition Labeling and Education Act of 1990, manufacturers may put clear information on the food label about the relationship between a nutrient, such as fat or cholesterol, and a disease or health-related condition. To prevent consumers from being misled, the Food and Drug Administration (FDA) allows only truthful label statements about diet and health relationships that are firmly supported by the current scientific evidence. There is agreement that the scientific evidence is strong enough to allow health claims about the association between total fat in the diet and the risk of some types of cancer and the association between saturated fat and cholesterol in the diet and the risk of coronary heart disease.

Many consumers have said that health claims on food labels could be useful to them in making improvements in their diets. However, label space is often limited. Therefore, this pamphlet provides information about diet and health claims that supplements what you may see on food labels.

In addition to the association between fat and cancer and between saturated fat and cholesterol and heart disease, FDA is allowing health claims about calcium and osteoporosis and sodium and hypertension. For information about these other diet and health relationships, write to: [TO BE INSERTED]

What is Coronary Heart Disease?

Coronary heart disease is a broad term that includes a number of diseases for which various medical names are used, including heart disease and atherosclerosis. Narrowing of blood vessels (medically called atherosclerosis) occurs in these diseases, which results in decreased flow of blood to some part of the body. The diseases include coronary heart disease that affects the heart and its supporting blood vessels, and other diseases that affect the blood vessels in other areas of the body Atherosclerosis can result in angina pectoris, heart attack, sudden death, stroke or other serious problems.

Atherosclerosis occurs because of raised fatty or fibrous deposits (plaque) that develop in the walls of blood vessels in the affected area. The process of plaque development is gradual, and often begins in childhood.

What is Cancer?

Cancer is not one disease, but more than 100 different diseases. In each of these diseases, cells begin to grow out of control at one site in the body, and these abnormal cells spread to other parts of the body.

Why Are Heart Disease and Cancer Major Public Health Concerns?

Coronary heart disease and cancer are public health concerns because they are the two leading causes of death in this country. Illness and death from these diseases cost billions of dollars in health care costs and in lost work. Moreover, early deaths from these two diseases cheat many victims of valuable years of life.

Despite the recent sharp decline in the death rate from this condition, coronary heart disease still accounts for the largest number of deaths in the United States. Cancer is the second leading cause of death in this country. The leading causes of cancer death are lung cancer, colorectal cancer, breast cancer, and prostate cancer.

What Causes Cancer and Coronary Heart Disease?

Both of these diseases are caused by a combination and interaction of multiple environmental, behavioral, social, and hereditary factors. It is clear that diet, one of the environmental factors, plays

an important role in the development of these diseases.

Heredity and other factors, including elevated blood serum cholesterol, cigarette smoking, high blood pressure, obesity, and an inactive life style, are known to increase a person's risk of developing coronary heart disease. Elevated blood cholesterol, one of the major risk factors for coronary heart disease, is associated with excess fat, especially saturated fat, and cholesterol in the diet.

Many studies have established a strong association between a diet high in saturated fat and cholesterol and increased risk of coronary heart disease. High saturated fat and cholesterol diets are estimated to be associated with one-third of the cases of coronary heart disease reported in this country.

The way diet affects blood cholesterol varies among individuals. However, blood cholesterol does increase in most people when they eat foods high in saturated fat and cholesterol and excessive in calories. Of these, saturated fat has the greatest effect; dietary cholesterol has less.

Cancer has many causes and several stages in its development. The risk factors for developing cancer include a family history of a specific type of cancer (such as breast, prostate or colon cancer), cigarette smoking, alcohol consumption, radiation, and dietary factors.

Currently, the strongest scientific evidence relating diet to cancer is that the amount of total fat in the diet may have a relationship with cancer. In particular, many experts agree that a high fat diet may influence the risk for developing breast, colon, and prostate cancers.

Not enough is known currently for scientists to decide whether different kinds of fats (animal or vegetable; saturated or unsaturated) may be responsible for an increased risk of developing cancer.

Because of scientific agreement that reducing total fat and saturated fat is likely to lower the rates of these two major chronic diseases, it is recommended that Americans 2 years of age and older choose a diet low in total fat and saturated fat. Animal products are the source of all dietary cholesterol. Eating less fat from animal sources will help to lower the cholesterol as well as the saturated fat in your diet.

Do Most People Get Too Much Fat, Saturated Fat and Cholesterol in What They Eat?

The average U.S. diet, it's estimated, contains about 37 percent of calories from total fat, 13 percent of calories from saturated fat, and 360 milligrams (mg) of cholesterol per day. Health experts recommend diets that contain 30 percent or less of calories from total fat, 10 percent or less of calories from saturated fat, and 300 mg or less of cholesterol a day. The U.S. Public Health Service has set a national health goal that all persons who are 2 years of age and older consume these levels of fat and cholesterol by the end of this decade.

How Do You Learn How Much Fat and Cholesterol Foods Contain?

You may or may not be able to tell that there's fat in a food by looking at it. Butter, margarines, shortenings, and oils are the more obvious sources of fat. In other foods, such as cheese, baked goods, nuts, and salad dressings, the fat is not as easily detected. Cholesterol content is not obvious at all in foods.

A good way to learn about fat and cholesterol content is to read nutrition labels. Most foods now have nutrition information on their labels.

The amounts of total fat and saturated fat in a serving of food are listed in grams (g) on the nutrition label. Cholesterol is listed in mg.

"Daily values" for fat, saturated fat, and cholesterol also appear on food labels. These numbers have been established by FDA for several nutrients that are important in diet and health relationships. The daily values are to help you learn how the amount of a nutrient in a serving of food relates to a reasonable amount for the day.

The daily value for total fat is 75 g, and for saturated fat is 25 g. That means total fat for a day of 75 g, of which no more than 25 g should be from saturated fat. These numbers are based on a 2,350-calorie diet that has 30 percent of calories from fat and 10 percent from saturated fat. A 2,350-calorie diet is about the calories recommended for an adult woman.

If you consume a different number of calories a day, it's not hard to figure out your own daily values for total fat and saturated fat. First, multiply the number of calories you consume by 30 percent (for example, $2000 \times .30 = 600$). Then divide that number by nine, which is the number of calories each g of fat provides (600 divided by $9 = 67$ g of fat a day). Repeat for saturated fat ($2000 \times .10 = 200$; 200 divided by $9 = 22$ g of saturated fat a day).

The daily value for cholesterol is 300 mg, which is an upper limit that is generally recommended for healthy people. A food that contains 150 mg of cholesterol per serving, therefore, would provide about half of the daily value for cholesterol.

What Do Label Claims About Fat and Cholesterol Mean?

In addition to the amount of fat and cholesterol listed on the nutrition label, you may see other claims about fat and cholesterol content on some food packages. There are two types of these claims—nutrient content claims and health claims.

Nutrient content claims describe the amount of fat, saturated fat, or cholesterol a food contains. These types of claims can be used on a label only if a food meets several definitions established by FDA.

Cholesterol Claims

A "cholesterol free" food has less than 2 mg of cholesterol and 2 g or less of saturated fat in a serving.

A "low cholesterol" food has 20 mg or less of cholesterol in a serving and in 100 g of food and 2 g or less of saturated fat in a serving.

A "reduced cholesterol" food has its cholesterol content reduced by 50 percent or more compared to the regular food product and contains 2 g or less of saturated fat in a serving.

Cholesterol claims may be made only on foods that contain a limited amount of fat (no more than 11.5 g per serving and per 100 g) unless the claim also tells the total amount of fat, for example, "cholesterol free, contains 12 g of fat per serving."

Fat Claims

A "fat free" food has less than a ½ g of fat in a serving and no added fat or oil.

A "low fat" food has 3 g or less of fat in a serving.

A "reduced fat" food has a 50 percent or more reduction in fat with at least a 3 g reduction in fat content.

A "low saturated fat" food has 1 g or less of saturated fat in a serving and no more than 15 percent of its calories from saturated fat.

A "reduced saturated fat" food has its saturated fat content reduced by 50 percent or more compared to the regular food product with at least a 1 g reduction in fat.

Also, the labels of some foods in which fat or cholesterol has been significantly reduced, but not enough to meet the definitions above, may have a statement that tells how much less fat or cholesterol the product contains than a comparable product; for example, "This pound cake contains 40 percent less fat than our regular pound cake."

Foods such as fruits and vegetables that meet the definitions for fat or cholesterol without special processing may have claims on them. However, the

label must say that fat or cholesterol is not usually present in the food, for example, "broccoli, a fat-free food," "frozen perch, a low fat food," or "raspberries, a low saturated fat food."

Health claims are those made about the relationship between the amount of a nutrient you eat and the risk of a disease, for example, between total fat and cancer or between saturated fat and cholesterol and heart disease.

Health claims about the relationship between fat and cholesterol and heart disease can only be made on products that are low in saturated fat and cholesterol, and have 15 percent or less of their calories from fat. To make a health claim, the product also cannot contain another nutrient that increases the risk of a diet-related disease other than atherosclerosis, for example, a high amount of sodium which has a relationship to high blood pressure.

Health claims about the relationship between fat and cancer can be made only on foods that are low in fat and do not contain another nutrient that increases the risk of a diet-related disease other than cancer.

These are some of the kinds of foods on which you may see health claims about nutrients related to cancer and heart disease: fruits, fruit juices, vegetables, breakfast cereals, dried peas and beans, skim milk, pasta products, and diet salad dressings.

Other Risk Factors for Cancer and Heart Disease

Coronary heart diseases and cancer are complex diseases with multiple causes, and they (usually) develop over a long period of life. Hereditary as well as environmental factors contribute to the risk for developing these diseases. In addition to practicing good nutrition, several other controllable factors are part of a healthy lifestyle and may help to decrease your chances of cardiovascular disease and cancer. These include maintaining a healthy body weight and good physical fitness, not smoking cigarettes, drinking only in moderation if at all, and not abusing drugs.

Facts To Keep in Mind

It's the total combination of foods that you eat regularly—both the kinds and the amounts—that is important in terms of good nutrition. Eating a particular food or a specific food is not a magic key that will assure you have a more healthful diet.

Eating a healthy diet, in itself, does not guarantee good health. A healthy diet, however, is an important part of a healthy lifestyle.

In addition to what you eat, many factors may be related to your own chance of developing a particular disease, for example, your heredity, your environment, and the health care that you get. Our knowledge about most diet-health relationships is incomplete, and will improve as scientific knowledge increases. However, enough is known today about some of these relationships to encourage specific dietary practices that are believed to be beneficial.

X. References

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR Part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6, of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. Section 101.73 is amended by adding paragraph (b) to read as follows:

§ 101.73 Health claims: lipids and cardiovascular disease and lipids and cancer.

* * * * *

(b) *Cancer*—(1) *Relationship between lipids (fat) and cancer.* (i) Cancer is not one disease, but a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both environmental and genetic risk factors may be involved in affecting the risk of cancer occurrence. Risk factors include a family history of a specific type of cancer, cigarette smoking, alcohol consumption, ultraviolet or ionizing radiation, and dietary factors.

(ii) The strongest positive association between fat intake and cancer risk has been found between total fat intake and some types of cancer. Based on the totality of the evidence available at this time, and despite some inconsistencies found in results of human studies, there is significant scientific agreement among experts, qualified by training and experience to evaluate such evidence, that diets high in total fat are associated with an increased cancer incidence. Research to date, although not conclusive, demonstrates that the total amount of fats, rather than any specific type of fat, is positively associated with cancer risk. The mechanism by which total fat affects cancer has not yet been established.

(iii) A question that has been the subject of considerable research is whether the effect of fat on cancer is site-specific. Studies which compared fat intake and cancer mortality in different countries or population groups found an association between total fat intake and cancer of the breast, colon, and prostate, but not at other sites. Although both human and animal studies are consistent in the association of fat intake with specific sites, the studies relying on animal data are more compelling. FDA concludes that the claim must be restricted to cancer of the colon, breast, and prostate due to the lack of adequate evidence for other types of cancer.

(iv) The question of whether the association of total fat intake to cancer risk is independently associated with fat intakes, or whether the association of fat with cancer risk is the result of the higher energy (caloric) intake normally associated with high fat intake, has been raised. After reviewing the evidence, FDA has concluded that there is adequate evidence from both animal and human studies to find that total fat intake alone, independent of energy intake, is associated with cancer risk.

(2) *Significance of fat intakes and risk of cancer.* Currently the average U.S. diet is estimated to contain 36 percent to 37 percent of calories from total fat. Current dietary guidelines and nutrition goals for the nation recommend that dietary fat intake be reduced to a level of 30 percent or less of energy (calories) from total fat. The scientific evidence supports the conclusion that this

lowered level is associated with a potential reduction in the risk of breast, colon and prostate cancer. Although there is evidence that reductions in total fat intake below the level of 30 percent of calories from total fat may confer even greater health benefits, the recommended levels for total fat were set at 30 percent of calories because they can be achieved without drastic changes in usual dietary patterns and without undue risk of nutrient deficiency.

(3) *General requirements.* A food label or labeling may contain a health claim stating that diets low in total fat may reduce the risk of some types of cancer, particularly colon, breast, and prostate cancer, in the general population provided that the following conditions are met by the product:

(i) The food meets all general requirements of § 101.14 for health claims.

(ii) The food meets requirements of § 101.62 for a "low fat" or "fat free" food.

(4) Health claims may be used on the label and labeling provided such statements comply with the following specific requirements:

(i) The claim states that diets low in fat (i.e., total fat) may reduce the risk of some types of cancer;

(ii) The claim is stated using words such as "may" or "might" in accordance with the strength of the evidence for the relationship;

(iii) The claim states that cancer has many causes, and that high total fat diets are only one of several factors associated with the risk of cancer;

(iv) In specifying the nutrient, the claim shall use the term "total fat", unless the food also meets the qualifications for a label statement on the cardiovascular disease-fat relationship in which case a combined statement may be used;

(v) The claim shall not quantitate the degree to which the risk of cancer may be reduced by diets low in total fat content; and

(vi) The claim shall not specify types of fats or fatty acids that may be related to the risk of cancer.

(5) Health claims describing the relationship between dietary lipids and cancer may include the following as optional information:

(i) The claim may indicate that low fat intake as part of a total dietary pattern is consistent with the latest U.S. Dietary Guidelines for Americans published jointly by the U.S. Department of Agriculture and the Department of Health and Human Services. Concepts or quotes from this publication may be used on the label provided that they are truthful and not misleading; and

(ii) The claim may include a reference that would direct interested consumers to more complete consumer information on the relationship of low total fat diets and cancer risk.

(6) The following sample health claims may be used on the label or labeling of a food to convey the relationship between dietary lipids (i.e., total fat or fat) and cancer:

Sample Health Claims

Developing cancer is associated with many factors, such as a family history of the disease, cigarette smoking, and what you eat. Eating a healthful, low fat diet may help reduce the risk for some cancers, including breast, colon, and prostate cancer.

Cancer is associated with many dietary and other risk factors. A diet low in total fat may reduce the risk of some types of cancers, including breast, colon, and prostate cancer.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-M

Table 1

Dietary Lipids and Cancer: Animal Studies 1989-April 1991

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Shao et al., 1990 (Ref. 10)	The effects of energy source and energy restriction on tumor development and survival rate	Female, 4 to 5 month-old, C3H/Bi mice, 15 per group	40 weeks	Ad lib and 40% energy restriction High fat: 68.2% energy lard, free carbohydrate Low fat: 4.5% energy lard, 63% energy carbohydrate	Murine mammary tumor virus (MuMTV)	Mammary: No significant difference in incidence or survival rates between high fat and low fat groups Significantly increased incidence and survival rates with energy restriction Combined mortality from all causes (tumor-related and nontumor-related) were higher in the order of: low fat, ad lib > high fat, ad lib > high fat, restriction > low fat restriction (statistics not tested)	Energy consumption, not fat intake, may play a greater role in MuMTV-induced mammary tumorigenesis; however, the nontumor-death rate was very high (26 of 60 total) which greatly reduces the significance of the findings
Welsch et al., 1990 (Ref. 11)	The effect of caloric consumption and fat level on mammary cancer	Female, 55-day old, Spargue-Dawley rats, 41 to 42 per group	16 weeks	Ad lib. and 12% energy restriction High corn oil: 20 weight % Low corn oil: 5 weight %	7,12-Dimethylbenz(a) anthracene (DMBA)	Mammary: High fat diet significantly (~2 times) increased the yield (number and weight) of mammary carcinoma A 12% energy restriction significantly reduced the yield (number) of mammary carcinogenesis in high corn oil group, but not in low corn oil group The 12% energy restriction abolished the effect of fat level	When energy intake was sufficient, high fat corn oil significantly enhanced DMBA-induced mammary tumorigenesis in rats Because caloric intakes among groups were the same, the fat effect was independent of the energy effect Fat and energy might have separate functions in mammary tumorigenesis

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Sinkeldam et al., 1990 (Ref. 13)	Interaction of dietary fat (lard) and fiber on colon cancer	Male, 4-week-old, wistar rats, 30 per group	37 weeks	Ad lib 15 energy % lard 0.7 g fiber 2.2 per 3.8 100 Kilocalories (kcal) 27.5 energy % lard 0.7 g fiber 2.2 per 3.8 100 kcal 40 energy % lard 0.7 g fiber 2.2 per 3.8 100 kcal	N-methyl N-Nitro-N-nitrosoguanidine (MNNG)	Colon: High fat diet significantly enhanced incidence and multiplicity (see below, data pooled) % incidence fat energy% polyps carcinoma total tumor 15 44 9 48* 27.5 51 23* 60 40 61 11 62 fat energy % Multiplicity (#/tumor-bearing rats) Polyps Carcinoma Total Tumor 15 1.6 1.1 1.7 27.5 1.5 1.1 1.7 40 2.4* 1.5 2.6 High fiber significantly decreased body weights and abolished the effects of fat level on colon tumorigenesis *Means significantly different from other fat energy % within tumor type	High fat enhanced MNNG-induced colon tumorigenesis in rats; however, the response was neither dose-dependent nor consistently significant The results might have been confounded by inadequate provision of linoleic acid in 15% and 27.5% lard diet groups Energy intakes were similar among different fat groups; therefore, the fat effect was independent of energy effect

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Newberne et al., 1990 (Ref. 14)	Interaction of fat and vitamin A in colon tumorigenesis	Male, weanling, Spargue-Dawley rats, 25 to 30 per group	24 weeks	5 or 24 weight % corn oil Vitamin A 3 mg per kg 10 mg per kg 30 mg per kg	Dimethylhydrazine dihydrochloride (DMH)	Colon: High fat versus low fat: no significant difference in the incidence or malignancy Vitamin A significantly lowered the incidence in low fat group, but not in high fat group	Diets were not isocaloric; food consumption, body weights were not reported The differences in energy intakes and body weight changes might have confounded the effects of fat The high peroxidation level of high corn oil diet, which was not controlled to approximate human dietary conditions, might also have confounded the results
Birt et al., 1989 (Ref. 17)	To determine the energy effect in pancreatic tumorigenesis	Male, 6-week-old, Syrian hamster, 30 per group	91 weeks	Corn oil: 4.3 weight % 20.5 weight %	Tumor initiator: N-nitrosobis-(2-oxopropyl) amine (BOP)	Pancreatic ductular carcinoma: Both incidence (%) and yield (# carcinoma per effective animal) were significantly (3 to 4 times) enhanced in the high fat group compared to the low fat group; no differences in survival rates	Ad lib or pair feeding Caloric intakes were similar between groups; therefore the fat effect was independent of energy effect

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Die*	Additional Treatment	Results	Assessment
Appel et al., 1990 (Ref. 18)	Whether the linoleic acid level or the total fat level is the main determinant of pancreatic carcinogenesis	Male, weanling, SPF albino Wistar rats, 40 (lard group) or 23 (chow group) per group	15 month	High fat: 20 weight % lard 1.2 weight % linoleic acid Low fat: 4.5 weight % lard 0.5 weight % safflower oil 0.6 weight % linoleic acid Low fat supplemented: 1.4 weight % lard 3.6 weight % corn oil 2 weight % linoleic acid Chow: 6 weight % fat (3% linoleic acid)	Tumor inducer: azoserine	Pancreatic neoplasm: Linoleic acid supplementation did not significantly affect pancreatic neoplasm Fat level also did not significantly affect pancreatic neoplasm	The amount of dietary fat did not significantly affect azaserine-induced pancreatic carcinogenesis in rats; however, levels of linoleic acid in the test diets might not be adequate for optimal tumorigenesis The level of linoleic acid supplementation was too narrow to test the effect of linoleic acid Energy intakes were similar among groups

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Birt et al., 1990 (Ref. 19)	The effect of type or level of fat on pancreatic carcinogenesis	Male, 4 to 8-weeks-old, Syrian hamsters, 30 per group	84 weeks after BOP treatment	Control: 4.3% corn oil High corn oil: 20.5% corn oil Low beef tallow: 0.5% corn oil and 3.8% beef tallow High beef tallow: 0.6% corn oil and 19.9% beef tallow High mix: 5.1% corn oil and 15.4% beef tallow (as weight %)	Tumor inducer: BOP	Pancreatic ductular tumor and gall bladder and common duct tumor Pancreatic ductular tumor: Incidence and multiplicity of adenoma and adenocarcinoma, but not carcinoma in situ, was significantly higher (~2 times) in beef tallow than corn oil groups High fat (both corn oil and beef tallow) significantly increased carcinoma multiplicity in situ compared to low fat groups; however, fat level did not affect adenoma or adenocarcinoma multiplicity	The effect of the level and type of dietary fat differed with each of lesions of BOP-induced tumors examined The comparison of fat types might have been hampered by the fact that high or low beef tallow diets did not provide adequate linoleic acid for tumor development Caloric intakes were similar among groups The results in gallbladder or common duct tumor might have been weakened by the low

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Imaida et al., 1989 (Ref. 21)	The effect of high fat on lung tumorigenesis	Male, 6-week-old, ICR mice, 30 per group	25 weeks	Control: CRF-1 diet (3.5 kcal per g) High fat: 20% Corn oil supplementation to CRF-1 (4.7 kcal per g) Main fatty acid composition(%) Control / High fat oleic 22.4 / 32.8 linoleic 50.2 / 51.9 linoleic 4.6 / 1.8	Lung carcinogen: 4-nitro-quinoline 1-oxide (NQO)	Lung: Corn oil supplemented high fat diet significantly enhanced incidence (80% versus 58%, high fat versus control) and yield (# tumor per mouse, 2.5 versus 1.2) compared to the control group	High fat (or high corn oil) in the diet significantly enhanced lung tumorigenesis in mice; however, diet composition, except main fatty acid was not reported There are apparent mistakes in the reported main fatty acid composition and we do not know the adequacy of linoleic acid in test diets Furthermore, nonisocaloric diets used and body weight gains were significantly different between groups which might have confounded the effect of fat level

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Katz and Boylan, 1989 (Ref. 22)	The effect of polyunsaturated fatty acid (PUFA) level on metastasis of transplanted mammary tumor	Female, aged virgin (14 to 16-month-old) or retired breeders (10 to 12-month-old), Fischer 344 rats, 12 per group	4 weeks before and 6 weeks after tumor transplant	High fat: 23% corn oil (4.59 kcal per g) Low fat: 5% corn oil (3.68 kcal per g) purina chow (6% fat)	13,762 rat mammary adenocarcinoma transplanted subcutaneously into just posterior to the 4th nipple	Pulmonary: High fat, fed either before or after the tumor implant, significantly enhanced pulmonary metastasis in rats (495 versus 135 mm^3, high fat versus low fat) This tumorigenic effect of high fat was abolished by previous feeding with chow diet; metastasis was comparable between chow and low fat groups	High fat (or high corn oil) in the diet significantly enhance pulmonary metastasis implanted from the 13,762 mammary tumor in rats; however, nonisocaloric diets were used Because energy intakes and body weight changes were not reported, energy-independent fat effect is not clear in the report

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Birt et al., 1989 (Ref. 23)	The effect of corn oil level on initiation and promotion of skin tumor	Female, 4-week-old, SENCAR mice, 30 to 40 per group	43 weeks	Corn oil 24.6 weight % 5.0 weight %	Tumor initiator: 12-O-tetradecanoylphorbol-13-acetate (DMBA) Tumor promoter: 12-O-tetradecanoylphorbol-13-acetate (TPA)	Skin papilloma: Incidence was not affected by fat level during DMBA period but promotion was significantly enhanced by high corn oil compared to low corn oil during TPA treatment period Final carcinoma yield (# per effective animal) was not affected by fat level	High fat (or high corn oil) diet significantly accelerated DMBA- and TPA-induced skin tumorigenesis in SENCAR mice The effect was evident during the promotion period, but not during the initiation period Because mice consumed similar energy by training, the effect of fat level was independent of the effect of energy or body weight changes
Borgeson et al., 1989 (Ref. 24)	The effect of fish oil on transplanted mammary tumor	Female, heterozygous BALB/cnu/+mice, 11 to 12 per group	32 days	Corn oil 10 weight % MaxEPA 10 weight %	Human mammary carcinoma MX-1, transplanted subcutaneously on the left side of each nude mouse	Mammary: fish oil significantly depressed the growth (mg tumor yield) compared to corn oil	Fish oil depressed transplanted mammary tumorigenesis; however, the total fat level was very low and the fish oil diet did not provide adequate linoleic acid for growth of the host and tumor

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Fritsche and Johnston, 1990 (Ref. 25)	Whether n-3 fatty acid would affect transplanted mammary tumor growth and metastasis	Female, weanling, BALB/C mice, 10 to 15 per group	3 weeks prior to and 45 days to 13 weeks after the transplant	Corn oil 10 weight % Fish oil (menhaden oil and corn oil) at 10 weight % Linseed oil 10 weight % Corn oil 2% n-3 Fatty acid 53% n-6 Fatty acid Fish oil 24% n-3 Fatty acid 14% n-6 Fatty acid Linseed oil 56% n-3 Fatty Acid 18% n-6 Fatty Acid	BALB/cfc 3H mouse mammary tumor cell lines 410 and 410.4 (derived from spontaneously arising mammary adenocarcinoma) transplanted subcutaneously into the inguinal area of each mouse	Transplanted mammary tumor cells at inguinal area Different fat types did not significantly affect incidence of tumor; linseed oil, but not fish oil, significantly reduced the yield of tumor (weight) compared to corn oil Linseed and fish oil significantly reduced prostaglandin-E synthesis; fish oil reduced 410.4 tumor prostaglandin-E synthesis more than linseed oil, yet tumor growth was significantly inhibited only by linseed oil	The effects of n-3 fatty acid rich fish oil and linseed oil on transplanted mammary tumor growth were not consistent; however, fish oil and linseed oil might not have provided adequate linoleic acid for optimal tumor growth

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Adams et al., 1990 (Ref. 12)	The effect of fish oil on metastasis of transplanted mammary and lung tumor	Female, weanling, Fischer 344 rats, 15 per group	8 weeks before and 3 to 5 weeks after tumor transplant	Low fat: 5% corn oil High fat: 23.5% corn oil 8% corn oil and 15.5% fish oil 3% corn oil and 20.5% fish oil Fish Oil=Max EPA	13,762 NF mammary adenocarcinoma sublime (spontaneous model) was injected into thigh: 13,762 MAT:B ascites tumor cell sublime (experimental model) was injected into tail vein and grown in lung	Transplanted mammary and lung tumor 13,762 NF mammary tumor Levels or types of fat did not significantly affect incidence or growth 13,762 MAT:B lung tumor Low fat significantly inhibited the growth of the metastatic foci compared to high fat, high corn oil group 15.5% fish oil, but not 20.5% fish oil, significantly inhibited the growth of metastatic fish oil compared to high corn oil 20.5% fish oil significantly inhibit the growth of the metastatic foci compared to high corn oil, in one experiment, but not in another	The effects of corn oil level or fish oil level on metastasis of transplanted mammary or lung tumor were not consistent Diets might have provided adequate linoleic acid for growth of tumor; however, the fish oil level used were unrealistically high

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Sakaguchi et al., 1990 (Ref. 26)	The effect of n-3 fatty acid on human colon cancer cell lines inoculated into nude mice	6 to 8-week-old, BALB/c nude mice, 12 to 13 per group	4 weeks	Control: Low fat: 4.6 weight % lipids (chow diet) High saturated fatty acid (SFA): High fat: 19.2 weight % coconut oil and 0.8 weight % lipids High n-3 fatty acid: 19.2 weight % Max EPA and 0.8 weight % lipids % of n-6 Fatty acid Control 12.7 High SFA 4.0 High n-3 fatty acid 2.5	Human colon cancer cell lines, COLO-320 or HT-29 were injected subcutaneously into dorsum of the chest wall	Transplanted colon tumor: Fish oil significantly reduced (~50% reduction) volume and weight of tumor compared to the control and high SFA groups; there was no difference in tumorigenesis between the control and high SFA groups	High level of fish oil in the diet significantly suppressed the development of transplanted human colon cancer cells in mice; however, the test diets used might not have provided adequate linoleic acid for growth of tumor and the level of fish oil was unrealistically high. Isocaloric diets were used and there was no differences in body weight changes among groups

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Deschner et al., 1990 (Ref. 15)	Combination of Max EPA with various levels of corn oil on colon tumor	Female, 5-week-old, CFI mice, 10 per group	2 weeks before and 48 weeks after azoxy-methanol treatment	16% corn oil and 4.4% Max EPA 10.2% corn oil and 10.2% Max EPA 4.4% corn oil and 16% Max EPA 20.4% corn oil 4.4% corn oil 4.4% corn oil was fed ad lib; the remaining diets were provided in controlled amounts as 40 g per cage per 2 days or 50 g per cage per 3 days to maintain body weights and reduce wastage	Azoxy-methanol	Colon: 4.4% fish oil diet group showed significantly higher incidence compared to 10.2% fish oil, 16% fish oil and 4.4% corn oil diet; there was no difference in incidence among 10.2% fish oil, 16% fish oil, and 4.4% corn oil groups 10.2% fish oil diet significantly reduced tumorigenesis compared to 4.4% fish oil diet (incidence: 30% versus 87.5%, # tumor per tumor bearing mouse: 1.3 versus 2.9) 16% fish oil diet did not affect incidence but significantly elevated tumor yield compared to 10.2% fish oil diet Compared to high corn oil diet, low corn oil diet significantly reduced the incidence (40% versus 63.3%): Effect of fat level on tumor yield was not significant	Biphasic response has been observed; 4.4% fish oil elevated, 10.2% fish oil suppressed, and 16% fish oil again elevated the tumorigenesis Corn oil level did not consistently affect the tumorigenesis Antioxidants were used

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Reddy et al., 1991 (Ref. 16)	The effect of n-3 rich fish oil and n-6 rich corn oil fed either during the initiation or/and during the postinitiation period on colon carcinogenesis	Male, 5-week-old, F344 rats, 39 per group	2 weeks before and 42 weeks after the treatment	Low corn oil: 5% corn oil High corn oil: 23.5% corn oil High fish oil: 18.5% menhaden oil and 5% corn oil	Azoxymethane	Colon: High corn oil diet, fed during the postinitiation period but not during the initiation period, significantly increased azoxymethane-induced tumorigenesis (incidence and multiplicity of colon adenoma and adenocarcinoma) compared to low corn oil diet High fish oil fed either during the initiation or the postinitiation period, significantly reduced azoxymethane-induced incidence and multiplicity of colon adenoma and adenocarcinoma compared to high corn oil; there was no difference in tumorigenesis between low corn oil and high fish oil diet groups	Azoxymethane-induced colon tumorigenesis in rats were significantly enhanced by high fat (high corn oil) diet and significantly suppressed by high fish oil diet; however, the fish oil level, tested, was unrealistically high Caloric intakes were similar among groups and there was no difference in body weight gains; therefore, the effect of corn oil level (total fat) was independent of energy effect

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
O'Connor et al., 1989 (Ref. 27)	The effect of n-3 fatty acid:n-6 fatty acid ratio on the development of pancreatic preneoplastic lesions	Male, 14-day-old, Wistar rats, 15 per group	4 months	Corn oil varied from 0 to 20 weight % menhaden oil varied from 20 to 0 weight % n3:n6 = 0.01 to 7.0 total fat = 20 weight %	Azaserine	Pancreatic tumor: Increased ratio of n-3:n-6 in the diet resulted in significantly decreased atypical acinar cell nodules (AACN) in the number and volume Type Oil / #AACN per cm^3 / % vol of pancreas 20% corn oil 632 6.01 20% menhaden oil 318* 2.37* *Significantly different from the corn oil group There was significant, but unstable, regression between increased n3:n6 ratio and decreased AACN diameter More than 15 weight % menhaden oil (less than 5 weight % corn oil) in the diet did not further suppress the AACN development High menhaden oil significantly decreased serum prostaglandin-thromboxaneB_2, prostaglandin-E_2 and 6-Keto-prostaglandin-$F_{1\alpha}$	Preneoplastic lesion, not tumor, was tested Because less than 5 weight % corn oil (more than 15 weight % menhaden oil) in the diet did not affect the tumorigenesis, 5 weight % of n-6 fatty acid rich corn oil may be required for optimal tumorigenesis The results suggest that high n-3 fatty acid in the diet may suppress the development of azaserine-induced preneoplastic lesion of the pancreas in rats Isocaloric diets were used, and there were no differences in body weight changes among groups

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Orengo et al., 1989 (Ref. 28)	The effect of menhaden oil on photocarcinogenesis in hairless mouse	4 to 5 1/2 month-old, 40 SKH-Hr-1 mice, 40 per group	2 weeks before and 20 weeks after ultraviolet radiation	Corn oil 0.75 weight % 4 weight % Menhaden oil 4 weight % 12 weight % total fat = 0.75 ~ 12 weight %	Ultraviolet radiation	Skin: 12% menhaden oil significantly prolonged latency period compared to 4% menhaden oil, 4% corn oil, or 0.75% corn oil 4% menhaden oil significantly prolonged latency period compared to 4% corn oil, but not 0.75% corn oil 12% menhaden oil significantly suppressed multiplicity compared to 4% corn oil, but not 4% menhaden oil or 0.75% corn oil 4% menhaden oil significantly suppressed multiplicity compared to 4% corn oil, but not 0.75% corn oil Latency (med. tumor time, week) / Multiplicity (# tumor per animal at 20 week) Corn oil 4% 19.0[A] 1.43[D] 0.75% 21.9[B] 0.47[E] Menhaden Oil 4% 23.2[B] 0.41[E] 12% 26.1[C] 0.23[E] Different letter as a superscription shows a statistically significant difference	n-3 fatty acid-rich fish oil in the diet significantly suppressed the development of ultraviolet radiation-induced skin tumorigenesis in mice; however, the test diets, except 4% corn oil, might not have provided adequate linoleic acid for growth of tumor and the host animal Total fat level was very low Iso caloric diets used

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Locniskar et al., 1990 (Ref. 29)	The effect of fish oil on skin tumorigenesis	Female, weanling SENCAR mice, 30 per group	4 weeks initiation period and 42 weeks promotion period	(wt%) Menhaden oil / Corn oil / Coconut Oil 0 / 1.5 / 8.5 1 / 1.5 / 7.5 4 / 1.5 / 4.5 8.5 / 1.5 / 0 0 / 10 / 0 Total fat 10 weight %	Initiator: 7,12-dimethyl benz(a) anthracene (DMBA) Promoter: 12-0-tetradecanoyl phorbol-13-acetate (TPA)	Skin: No differences in the incidence of papilloma or carcinoma, and in the multiplicity among groups	Fish oil was not protective in the DMBA- and TPA-induced skin tumorigenesis in mice; however, test diets, except 10% corn oil, might not have provided adequate linoleic acid for tumor growth The total fat level was very low Caloric intake, food consumption, and body weight changes were similar among groups
Yam et al., 1990 (Ref. 30)	The effect of n-6 fatty acid:n-3 fatty acid ratio on transplanted tumors	Male, 26 to 30-weeks-old, C57BL/65 mice, 30 per group	12 to 16 days	Soybean oil 4 weight % Linseed oil 4 weight % Fish oil 4 weight %	Transplant of EL4-lymphoma cells (insulin producing cells) or thymoma cells (insulin-dependent cells) into right flank muscle	Transplanted lymphoma and thymoma cells In EL4 mice, linseed oil, but not fish oil, significantly suppressed the growth of tumor (weight) compared to the soybean oil group In thymoma mice, fish oil, but not linseed oil, significantly suppressed the growth of tumor compared to the soybean oil group	Test diets contained unrealistically low total fat and the findings cannot be extrapolated to normal human physiology Furthermore, linseed oil and fish oil diets might not have provided adequate linoleic acid for tumor growth

Table 1--continued

Reference (author, date)	Objective	Test animals	Duration of Study	Diet	Additional Treatment	Results	Assessment
Ling et al., 1991 (Ref. 31)	The effects of fish oil and medium-chain triglyceride in parenteral nutrition regimen on transplanted tumor	Male, Sprague-Dawley rats (age not reported), 90 to 100 g, 10 per group	11 days	Control: Intralipid containing 2.4 weight % lipids Test: 2.6 weight % fish oil with medium-chain triglyceride of 40% fish oil: 60% medium-chain triglyceride	Transplant of Yoshida Sarcoma cells by subcutaneous injection Intravenous tumor necrosis factor (TNF)	Transplanted Sarcoma cells The replacement of long-chain fatty acid with fish oil of medium-chain triglycerides in the TPN solution significantly inhibited tumor growth as volume, but not as w	Fish oil with medium-chain triglyceride TPN regimen did not provide adequate linoleic acid for growth of the host animal and tumor

able 2

Dietary Lipids and Cancer: Human Studies 1988-April 1991

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Prentice et al., 1988 (Ref. 37)	Ecologic; 21 Countries: 45 to 69 year old women	To offer explanations for international variations in breast cancer rates	Food disappearance data rather than actual food intakes are used to estimate per capita consumption	Breast cancer	Breast cancer incidence was strongly correlated with national estimates of per capita intake of dietary fat, but not with other calorie sources (protein and carbohydrate) There was a weak correlation for total calories ($p = 0.09$) Total calories alone explained only 14% of the variation in breast cancer incidence compared with 58% for fat calories alone When fat and other sources of calories are entered simultaneously into regression analysis, fat calories remained highly significant ($p = 0.0004$) with unchanged regression coefficient Nonfat calories were not significant ($p = 0.88$)	Ecological studies all suffer from ecological fallacy Comprehensive controlling of confounding factors is not possible In this study, adjustment for other dietary factors - total calories was done by regression Because food disappearance data was used, more affluent countries would incorrectly show higher consumption, reflective of higher waste

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Hursting et al., 1990 (Ref. 38)	Ecologic: Registry data in 20 countries for 35 to 64 year olds	To test the hypothesis that different kinds of fatty acids have different tumor-promoting capabilities	Per capita dietary intakes were obtained form food balance sheets for 1975 to 1977 and assessed by a multiple regression analysis	Breast, cervix, lung, colon, and prostate	The incidence of breast cancer was significantly associated with intakes of total fat (r=0.72), Saturated fat (r=0.57), n-6 polyunsaturated fat (n=0.5), but not with monounsaturated fat or n-3 polyunsaturated fat The incidence of female colon cancer was significantly associated with intakes of total fat (r=0.62) and saturated fat (r=0.47), but not with polyunsaturated fat, monounsaturated fat, n-6 polyunsaturated fat, or n-3 polyunsaturated fat The incidence of prostate cancer was significantly associated with intakes of total fat (r=0.69), saturated fat (r=0.55), and polyunsaturated fat r=0.46), but not with n-3 polyunsaturated fat; n-6 polyunsaturated fat intake showed a borderline association (r=0.46, p=0.074) The incidence of both cervical and lung cancer was not significantly associated with any type of fat intake or total fat intake Total calorie intake was not associated with cancer at any site when controlled for total fat intake	Dietary assessment: Dietary fat consumption disappearance increases with social and economic development and may simply be a marker for affluence, which would affect the incidence figures for cancers, such as improved cancer detection N-3 polyunsaturated fat intake among the populations was relatively small and invariable Confounding: All regression analyses were adjusted for age and intakes of all other component fats as well as for total calories As is the case with all ecologic studies, because populations, rather than individuals are measured, associations may be spurious Comprehensive controlling of confounding factors is not possible Correlations were reported only for female cancers and male prostate cancer; results reported to be similar for males were not shown

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Kneckt et al., 1990 (Ref. 39)	Prospective; 20 year followup; 3,988 initial cancer-free Finnish women aged 20 to 69 years From 30 different regions of Finland: 54 cases were identified	To examine the relationship between dietary fat and breast cancer	Examined role of total fat, saturated fatty acid (SFA), monounsaturated fatty acid (MUFA), polyunsaturated fatty acid (PUFA), cholesterol intakes, and energy intake through dietary history	Breast Cancer	The overall relative risk (RR) for the association between relative fat intake and occurrence of breast cancer is: Overall RR 1.7 (0.6-4.8)* SFA intake 1.4 (0.5-3.7)* MUFA intake 2.7 (1.0-7.4)** PUFA intake 1.2 (0.6-2.8)* Cholesterol intake 2.2 (1.0-5.0)** * = Nonsignificant ** = borderline significant Breast cancer is inversely associated with energy intake, but not significantly related to fat intake	Method of dietary assessment: Dietary history was collected 20 years prior up to diagnosis, so recall bias is eliminated However, changes in diet over the 20 year followup interval were not evaluated Dietary confounders: Adjustment was made for total energy intake Confounders: Adjustments were made for age, body-mass index, stature, smoking, parity, menopausal status, and rural versus urban geography

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Howe et al., 1991 (Ref. 40)	Prospective study; 5 year followup period (1982-1987); 56,837 women, 40 to 59 years enrolled in the Canadian National Breast Screening study; 519 breast cancer cases were identified during the followup	To examine the relationship between energy sources and breast cancer risk	The self-administered diet-history questionnaire on 86 food items; and an interview-administered dietary history; subjects had completed the dietary questionnaire before diagnosis	Breast cancer	Except for the lowest quartile, there was a significant association between increasing fat intake and the incidence of breast cancer (RR for the highest quartile=1.3 : 95% HIGHEST =1.00-1.82) All three fat types (SFA, MUFA, and PUFA) showed a general pattern of increasing risk of breast cancer with increasing intake The exceptions were the first quartiles for SFA and MUFA (The mean % of calories from fat was 31% and 47% for the lowest and highest quartiles, respectively) Menopausal status did not affect the results	Dietary measure: Comparison of the results from the interview-administrated dietary history and the self-administered dietary history showed good validity and reliability Subjects had completed the dietary questionnaire before diagnosis, eliminating recall bias Confounders in diet: The association between fat intake and risk was assessed after adjusting for other sources of calories Total calorie intake was not associated with increased risk Adjusted for education, age at menarche, age at first pregnancy, nuliparity, surgical menopause, age at menopause, history of benign breast disease, and breast cancer in first degree relatives

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Mills et al., 1988 (Ref. 41)	Nested case-control; 142 fatal breast cancer and 852 age-matched controls among CA Seventh-day Adventist women from 1960 to 1980; 30 to 85 years; whites	To test the hypothesis that breast cancer mortality is related to the usual frequency of use of specific foods of animal origin, including meat, cheese, milk and eggs	A 21-item food frequency questionnaire	Breast	No significant relationship between the consumption of animal products (meat, milk, cheese, eggs) and breast cancer risk Among women with relatively early age at menopause (≤ 48 years), a suggestive but nonsignificant, positive association between meat consumption and the risk of breast cancer was noted	Although there was significant variation in the frequency of meat consumption between cases and controls, both groups were low meat consumers by American standards: 47% of the total population never or only occasionally consumed meat Dietary measure: The 21-item food frequency questionnaire was not sufficiently detailed to allow analysis of specific nutrients; therefore, the consumption of fat specifically was not tested for its relationship with the risk of breast cancer

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Rohan et al., 1988 (Ref. 42)	Case-control: 451 female Australian case-control pairs; 20 to 74 years old; Cases were with first diagnosis with breast cancer 1982 to 1984 Controls were without a history of breast cancer; randomly selected from the electoral roll; age matched with the case 113 premenopausal pairs and 262 postmenopausal pairs The remainders were either premenopausal or discordant on menopausal status	To test the hypothesis that the risk of breast cancer increases with increasing intake of total fat, protein, and energy; and decreases with increasing intake of vitamin A	A 179 food item, self-administered food frequency questionnaire; cases were instructed to disregard any dietary changes that had occurred subsequent to their diagnosis of breast cancer	Breast	No significant association between dietary intake of fat, energy, protein, or carbohydrate and breast cancer risk	Dietary measure: Instructing the cases to disregard dietary changes subsequent to their diagnosis of breast cancer may have helped eliminate some of the recall bias The range of total fat intake among the total population was 35% versus 46% in the lowest versus highest quintile of fat intake Dietary fat intake in this population may not be sufficiently heterogeneous to detect variation in disease risk Dietary confounders: The difference in fat intakes between the cases and the controls was not reported Energy intake was not adjusted in the risk analysis for lipid intake

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Gerber et al., 1989 (Ref. 43)	Case-control: Hospital-based population of French women 25 to 65 years; Cases: 120 with a first diagnosis of breast cancer Controls: 109 with admission for neurologic syndromes of other than cardiovascular or tumoral origin, or for lumbalgias or disc pathologies	To address the question of the specific role of fatty acids in relation to breast cancer	Nutritional data from a questionnaire on the dietary history: Weekly or monthly frequency of consumption for 55 key food items in lipid and vitamin consumption	Breast	Pre-menopausal and postmenopausal groups considered separately Intakes of total lipids, SFA, MUFA, PUFA, and olive oil were greater in cases than in controls (borderline-significance: p=0.07) Intakes of sunflower oil was greater in cases Fatty acid serum distribution is comparable in both samples, except arachidonic acid, which is significantly lower in premenopausal patients than in premenopausal controls Plasma lipid peroxidation is significantly lower in patients than controls	Major confounding factor: The association between calcium and decreased peroxidation can be fortuitous or reflect the decreased rate of lipid peroxidation association with an increased rate of cell division The authors admit that the fat intake result is controversial and have undertaken a larger case-control study

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Toniolo et al., 1989 (Ref. 46)	Case-control: Cases: 250 women with breast cancer, but no metastases; Controls: 499 women from a randomized, stratified sample of the general population All < 75 year old and from the Vercelli province in Italy	To investigate the role of diet in breast cancer	An interviewer-administered dietary history questionnaire	Breast	Cases consumed more calories (2,419 vs 2,294 kcal per day) and total fat (94.4 vs 88.2 g per day) compared to the control Age and calorie-adjusted relative risk showed a significant association for SFA intake (p=0.001) and total fat intake (p=0.056) The intake of dairy products was significantly associated with the risk of breast cancer Neither meat consumption nor poultry consumption significantly increased the risk	Well-done study; Dietary assessment: Questionnaire had been tested previously, validated, and used in a study with, which produced comparable results Variation of fat intake in diet is 26% to 46% in this study, as opposed to only 32 to 44% in Willet's Confounding for nondietary risk factors: Adjusted for age at menarche, age at menopause, age at first birth, height, weight, Quetelet index (weight divided by height squared), sociceconomic status, and martial status
Ewertz and Gill et al., 1990 (Ref. 47)	Case-control: 1,486, breast cancer cases diagnosed over a 1 year period in Denmark; <70 year 1,336 age-stratified random sample from the general population as the control	To elucidate the influence of dietary factors and hormones on breast-cancer risk	Self-administered questionnaire, given 1 year after the diagnosis: the semi-quantitative food-frequency questionnaire collected food intake data for the year prior to diagnosis for 21 food items	Breast	Total fatty acid intake was significantly and linearly associated with breast cancer risk (RR for the highest quartile=1.45; p<0.001 for the test of a trend)	Dietary measure: The 21 food item included in the questionnaire covers about 80% of fat consumption The questionnaire was designed with two global questions to monitor the frequency of consumption of meat and vegetables The sum of the frequencies of consumption was compared with the global frequency and weights were assigned to adjust overestimations Confounders: Effect of energy intake was not controlled

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Mettlin et al., 1990 (Ref. 48)	Case-control Cases: 3,334 men and women (50% of each); ages 19 to 97 years Controls: 1,300 men and women, hospital-based	To test the hypothesized positive association between fat and cancer, and hypothesized inverse association between cancer and vitamin A, D, riboflavin, and calcium	Dietary questionnaire for milk-drinking habits	oral, stomach, colon, rectum, lung, Breast, uterus, cervix, prostate, bladder	Controls were more likely to never drink whole milk than cases, after adjusting for sex, age, smoking, education and county of residence Findings were significant only when comparing whole milk to no milk (reference group) and for the oral cavity, stomach, colon, rectum, lung, bladder, prostate and breast	This study is of little value because it does not address the correlation of milk intake with dietary fat intake Many other factors which may be associated with milk drinking habits were not controlled Biases inherent in hospital based sample
Boyd et al., 1988 (Ref. 54)	Randomized clinical trial; 295 women with ≥ 50% of the breast volume occupied by mammographic dysplasia; ≥ 30 year (mean age 44), (147 control and 48 intervention): 5% of the control group and 20% of the treatment group lost during followup; 76% of subjects premenopausal	To determine (1) if long-term compliance with a low fat diet can be achieved and (2) if mammographic dysplasia increases one's risk of breast cancer	Dietary advice: Control group to maintain healthy diet without changing dietary fat intake Intervention group to reduce fat intake to 15% of the calories A 3-day food record and a 1-day dietary recall	Breast cancer	(1) Combined control and intervention groups experience higher cancer than expected in the general population (2) Dietary compliance was maintained over the 1-year intervention period	This study is important as an precursor for future intervention trials; it tells us that compliance is possible for at least 1 year, and it supports the hypothesis that mammographic dysplasia is a high risk factor in breast cancer development However, the time is too short and the numbers too small to draw any conclusions about dietary fat and the incidence of breast cancer

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Verreault et al., 1988 (Ref. 55)	Survey of 666 women with a newly diagnosed infiltrating breast carcinoma 1982 to 1984; Quebec City area, Canada	To study the possible effect of diet on the progression of breast cancer, once it has occurred	An interviewer administered food frequency questionnaire covering 114 food items for the year preceding diagnosis	Breast	After the adjustment for energy intake, total fatty acid intake showed no association with the frequency of nodal development after diagnosis After adjusting for energy intake, age, body weight, and tumor size, the intake of SFA was not significantly associated with the frequency of axillary node development at diagnosis among post-menopausal patients PUFA intake was negatively and significantly associated with nodal development	Dietary measures: The type of PUFA is not identified The study assessed a growth of nodes (proxy for progression of the disease), but not directly the risk of cancer
Boyd et al., 1989 (Ref. 56)	Case-control; 30 women with extensive mammographic dysplasia (≥ 75% of the breast involved) and 16 women without dysplasia (≤ 25% dysplasia); 30 to 50 years; Breast center at Women's College Hospital and National Breast Screening Center at the Mt. Sinai Hospital	To determine biochemical associations with mammographic dysplasia	A 7-day recall plus a 4-day food record	Breast	No significant difference in consumption of total fat, different types of fat, cholesterol, total calories, carbohydrate, or protein for those with and without dysplasia	Dietary concerns: There may be an insufficient difference in nutrient intake between the two groups to detect an effect Confounders: Because the study's objective was to determine plasma lipid levels, dietary fat was examined as a confounder for lipid plasma levels - the study did not examine for confounders of dietary fat intake

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Eid and Berry et al., 1988 (Ref. 52)	Case-control; 85 Israeli women (ages not given) who were undergoing biopsies for breast masses 37 had carcinoma, 27 had fibroadenoma, 21 had other types of masses	To study the effects of the quality of fat (i.e., saturated versus polyunsaturated) and carcinogenesis	Dietary measures not necessary; fatty acid composition measured directly through biopsy Breast tissue from each individual was analyzed for fatty acid composition (16 also had adipose tissue biopsied from buttocks to compare breast tissue fat as an indicator for overall subcutaneous body fat: 98% correlation)	Breast	The quality of dietary fat does not appear to be associated with the development of neoplasia of the breast: Fiber-adenoma Other PUFA:SFA Cancer Ratio 0.99 0.98 1.03 The PUFA:SFA ratio was no different between the group with cancer, fibroadenoma, or other tumors	Age is a possible confounder However, an analysis of 400 biopsies revealed insignificant correlation between age and polyunsaturated to saturated ratio All subjects are patients with breast lesions Data was reported only as a ratio for tissue fatty acids; the actual amount is important as well
Brisson et al., 1989 (Ref. 57)	Case-control; 290 newly diagnosed breast cancer patients and 645 women who participated in the Canadian National Breast Screening Study as the control; 40 to 62 year; in Quebec	To evaluate the association of the morphology of breast tissue seen on mammograms with breast cancer risk and to assess the relation of diet, especially intake of fat and vitamin A, to the high-risk mammographic images	An interviewer-administered food frequency questionnaire of intake of 114 food items during the previous year	Breast Cancer	Among controls, energy adjusted intakes of saturated fat, but not polyunsaturated fat or cholesterol was significantly associated with an increase in extent of high-risk mammographic features The risk of breast cancer incidence increases regularly with the extent of modular and homogeneous densities on the mammogram	Dietary measure: acceptable; suffers recall bias Confounding: adjusted for age, weight, parity, and education Fiber intake was measured and considered separately in analysis

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Pryor et al., 1989 (Ref. 45)	Case-Control; white females between the ages of 20 and 54; 172 cases are women who were diagnosed with histologically confirmed first primary breast cancer 190 matched controls	To assess how intake of dietary fat and fiber during adolescent years is related to the incidence of breast cancer	Used National Cancer Institute food frequency questionnaire to assess past intake during adolescent years	Breast Cancer	Stratified on groups High fat intake consistently lowered the odds ratio (OR) below 1.0 in premenopausal women, but not significantly (OR = 0.7, confidence interval (CI) = 0.2-2.1 for highest versus lowest quartile) The relationship was inconsistent and not significant in postmenopausal women (OR = 0.7, CI = 0.2-2.7 for highest versus lowest quartile) The relation of breast cancer to dietary intake during adolescence is not clear	Dietary measure: Very long recall period, producing bias Controlling: Done for age, education, age at first pregnancy through multiple logistic regression Fiber intake adjusted in analysis Fat from dairy products considered separately from other sources

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Holm et al., 1989 (Ref. 53)	Case-control; 240 women 50 to 65 years who had surgery for breast cancer (1983-1986); mainly post- menopausal	To examine the relationship between dietary habits and prognostic factors for breast cancer	A dietary history interview within 4 months after resection of the primary tumor for prediagnostic food consumption	Breast cancer	Patients with tumors ≥ 20 millimeter (mm) in diameter had significantly higher mean percent energy from total fat and monounsaturated fat, and significantly lower mean energy from carbohydrates compared to patients with tumors < 20 mm; there was no significant difference in the total energy intake mm Tumor size < 20 > 20 p Total energy, energy % 36.3 38.1 0.02 Monounsaturated fatty acid energy % 12.4 13.2 0.003 Carbohydrate energy % 46.3 44.6 0.06 Total energy in millijoules 8.2 7.8 Nonsignificant	Poor study due to lead-time bias: Timing not corrected for the women who have surgery earlier (more routine care, self-exam, better diets, etc.) Adjustment was made for fiber, carbohydrates, and total energy

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Iscovich et al., 1989 (Ref. 44)	Case-control; 150 women with breast cancer, diagnosed 1984 to 1985, 0 to 75 year mean 56 year; controls: for each case, one hospital control, matched by age and hospital, and one neighborhood control, matched by residential area and age	To uncover associations between diet and breast cancer	An interviewer-administered semiquantitative food frequency questionnaire on 147 food items during the 5 year period up to 6 months prior to interview	Breast cancer	Intake of energy total fat, protein, and carbohydrates were significantly associated with the risk of breast cance: Intakes of processed meat, fried meat, animal fat, eggs, grains, and pulses were significantly associated with the risk of breast cancer Intakes of fruit and vegetables were negatively associated Intakes of red meat, poultry, and vegetable oil were not significantly associated	Confounders: Adjustment for education, age, age at first pregnancy, and parity Adjustment for total calorie intake was not done No significant difference was found between the effects of fat, protein, and carbohydrates
Boyd and McGuire 1990 (Ref. 58)	Case-control; 30 women with extensive mammographic densities (≥ 75% dysplasia) and 16 controls without radiological changes (<25% dysplasia); 30 to 50 years	To determine if mutagenic products generated by lipid peroxidation may influence breast cancer rate	4 day food record	Breast cancer	The group with extensive mammographic dysplasia excreted twice the amount of malonaldehyde int the urine compared to the control group ($p<0.02$) The quantity of malonaldehyde in the urine is an indicator of lipid peroxidation in diet or tissue No difference in nutrient intakes including total fat between the two groups	Because the main objective of this study was to examine malonaldehyde, fat was just one of the selected variables considered for confounding Confounding for fat was not considered here

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Simard et al., 1990 (Ref. 49)	Case-control: 68 women with breast cancer age-matched and 343 women as the control; 40 to 49 year; in Montreal	To compare fibrocystic patients with age-matched controls selected within the same cohort population of women attending the Canadian National Breast Screening Study (NBSS)	A semiquantitative food-frequency questionnaire for the breast cancer patients A 24 hour dietary recall for the control subjects	Breast	The breast cancer patients consumed significantly more poultry, fish, pastry, and margarine; and, less milk and butter	Dietary Assessment: The method for collecting food consumption was different between the control and the cases The risk was assessed with current food consumption while it was noted that 16% of cancer patients had been on a reducing diet
Vaint Veer et al., 1990 (Ref. 50)	Case-control: 133 newly diagnosed breast cancer cases; 25 to 44 year (98% premenopausal) or 55 to 64 year (97% postmenopausal); 289 age-stratified healthy controls from general population; Netherlands	To design and carry out a study which examines the role of dietary fat in breast cancer, but overcomes problems of many other studies; specifically, methodological problems in dietary assessment and confounding by energy intake is corrected through the use of a standardized and reproducible dietary history technique	A 236 food item diet history interview was conducted to cover the dietary pattern in the 12-month period prior to diagnoses or the interview date	Breast	Age-adjusted dietary fat intake in breast cancer cases was significantly higher than that in healthy controls (120 vs 92 g) The age-adjusted OR showed a significant positive trend with increasing fat intake The multivariate adjusted OR was 3.5 for subjects in the highest quintile of fat intake compared to those in the lowest quintile The OR, adjusted for energy intake and age, was 1.54 per 24 g fat or 10% fat energy Intake of each type of fat (SFA, MUFA, PUFA) was positively associated with the risk as well	Dietary Measure: Reproducibility of the questionnaire was verified by a repeated measurement one year after in 39 control subjects Confounding by Nondietary factors: Adjustment was made for familial history, history of benign breast disease, education, employment, age at menarche, age at first full-term pregnancy, parity usage of oral contraceptives, smoking, body mass index, and alcohol intake

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Van't Veer et al., 1991 (Ref. 51)	Case-control: Newly diagnosed 133 women breast cancer cases and 289 population controls in the Netherlands; 25 to 44 and 55 to 64 year	To examine several combinations of dietary factors - total fat, fermented milk products and fiber on breast cancer occurrence because these dietary factors are hypothesized to alter estrogen metabolism by the intestinal microflora	A 236 food item, interviewer-administered diet history questionnaire; Dietary pattern in the 12-month period prior diagnosis	Breast	Dietary fat intake was positively associated with the risk of breast cancer after adjustment for age (OR=0.57; CI=0.36-0.90) When total fat is included as a main effect, fiber, fermented milk and total fat produce an interactive effect which is positively associated with the risk (OR=0.33; 0.15-0.73)	Dietary method: Most cases were interviewed within 6 months after diagnosis Energy intake was not adjusted Nondietary confounders considered: Age, alcohol intake, history of benign breast disease, familial history, smoking, educational level, oral contraceptive use, age at menarche, parity, body mass index and geographical area

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Willett et al., 1990 (Ref. 62)	Prospective; 88,751 registered nurses; 34 to 59 year; no history of cancer, inflammatory bowel disease, or familial polyposis; 150 colon cancer cases were documented during the 6-year followup (1980-86)	This is part of the Nurses' Health Study Cohort Its objective is to determine risk factors for cancer and coronary heart disease	A 61 food-item, interviewer-administered, semi-quantitative food frequency questionnaire focusing on fat and fiber foods was used The dietary interview was done in 1980	Colon	Total energy intake or body-mass index was not associated with the incidence of colon cancer Age and energy-adjusted intakes of total fat, animal fat, SFA, and MUFA were significantly associated with the incidence of colon cancer; intakes of vegetable fat, linoleic acid, and cholesterol were not RR C.I. Total fat 2.0 1.1-3.6 Animal fat 1.9 1.1-3.2 SFA 1.4 0.8-2.3 MUFA 1.7 1.0-2.9 Strongest associations with beef, pork, or lamb eaten as a main dish; daily eaters had 2 1/2 times the risk of those less than once a month eaters (P for trend = 0.01) Consumption of whole milk, cheese, and ice cream was not significantly related to the risk	Dietary assessment: The dietary method was validated by comparing its results with results of one-week weighed food record method in a random cohort Since the interview was done in 1980, prior to disease development, there is no recall bias Controlling dietary factors: Controlling for physical activity did not alter the association of the intake of animal fat or meat with the risk Energy adjustment was done

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
La Vecchia et al., 1988 (Ref. 66)	Case-control: 339 cases of colon cancer and 236 cases of rectal cancer; both sexes; 1985 to 1987; median ages, colon cancer = 61 year, rectal cancer = 62 year; northern Italy 776 controls; both sexes; median age = 58 years The controls were also patients admitted to hospital for acute, nonneoplastic or digestive disorders	To examine the relationship between diet and colorectal cancer in a population in which there is good heterogeneity in dietary consumption	A 29 food item interviewer-administered food frequency questionnaire on food consumption prior to diagnosis	Colon and rectal	Age and sex adjusted consumptions of beef or veal and pasta or rice were significantly associated with the risk of colon and rectal cancer Age and sex adjusted consumption of butter and olive oil, but not margarine, was significantly associated with the risk of colon cancer but not the risk of rectal cancer	Dietary method: Energy consumption was not adjusted in the data analysis Frequencies, but not quantities of food consumption were analyzed Confounding of nondietary factors: Adjustment was made through multiple logistic regression for age, sex, social class, and area of residence
Neoptolemos et al., 1988 (Ref. 59)	Case-control: Cases: 30 men and 19 women, between the ages of 49 and 92, with colorectal cancer Controls matched for age and sex	To assess the erythrocytic fatty acid profile in a relatively homogenous group of patients with cancer of the colon and rectum, using closely- matched controls	Fatty acids were determined in erythrocytes and adipose tissue An interviewer-administered 7-day dietary recall during hospitalization on the day before surgery	Colorectal	Marginally increased levels of stearic acid ($p<0.06$) and oleic acid ($p<0.06$) and decreased arachidonic acid ($p<0.04$) in cancer patients Marginally increased levels of stearic acid ($p=0.06$) and oleic acid ($p=0.06$) and decreased arachidonic acid ($p=0.04$ occurred in cancer patients These findings indicate a disturbed fat metabolism in cancer patients	The study did not address the association of diet intake and the risk of cancer

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
West et al., 1989 (Ref. 61)	Case-control: 231 colon cancer patients and 391 population controls Both sexes; 40 to 79 year; whites; 1979 to 1983 in Utah	To evaluate the role of fiber and fat ingestion on colon cancer development, as well as to study the associations between intake of energy, types of fat, protein, vitamins A and C, and cruciferous vegetables and the disease	A 99 food item interviewer-administered, food frequency questionnaire for 2 to 3 years prior to the interview; over 90% of foods eaten by Utah residents	Colon	Both in females and in males, total fat intake was significantly associated with the risk (OR=1.9 in females and 2.0 in males. in the highest quartile) Intakes of different types of fats (MUFA, SFA, PUFA) were not consistently associated with the risk	Dietary analysis: recall bias; omitted data due to physician's refusal (23 of 324 cases), patient's refusal (70 of 324), death before the interview (53 of 324) Dietary confounders: Adjustment of data by multiple logistic regression for fiber and body mass index; energy intake was not controlled in the data analysis
Benito et al., 1990 (Ref. 67)	Case-control: 286 colorectal cancer cases, 295 population controls, and 203 hospital controls; Majorcan residence; mean age and was 64 year both sexes	To investigate the role of dietary factors in the etiology of colon and rectum cancer	A 99 food item interviewer-administered food frequency questionnaire for average consumption for the previous year	Colorectal	A significantly increased risk of colon cancer was found for consumption of fresh meats (RR=2.87) while consumption of cruciferous vegetables afforded protection (RR=0.48) Consumption of dairy products significantly increased the risk of rectal cancer but not the risk of colon cancer Consumption of oil was not associated with the risk of colon or rectal cancer	Dietary survey: The average interval between diagnosis and interview was relatively short, 3 months Adequacy of controls: The results were reported by comparisons with the population controls only Adjustment of confounders: Age and sex, but not energy intake were adjusted in the data analysis

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Ghadirian et al., 1991 (Ref. 63)	Case-control: 179 pancreatic cancer patients in Greater Montreal from 1984 to 1988; 35 to 79 year; both sexes 239 population-based, age, sex, and place of residence matched controls	This study was a subset of the SEARCH collaborative Study Group for the case-control study of cancers of the pancreas, bile ducts and gallbladder of the International Agency for Research on Cancer	A more than 200 food-item and beverage, interviewer-administered food frequency questionnaire was used	Pancreatic	After adjustment for age, sex, energy intake, response status, and cigarette consumption, total fat intake (OR=2.24) and SFA intake (OR=4.32) were significantly associated with the risk of pancreatic cancer	Dietary intake measurement: 25% of the cases and 83% of the control were interviewed directly; 75% of the cases and 17% of the control were interviewed by proxy Confounders: Adjustments made for age, sex, energy intake, response status, and cigarette consumption
Goodman et al., 1988 (Ref. 64)	Case-control: 226 men and 100 women with lung cancer; 597 men and 268 women population-based controls, sex and age matched to the cases; five ethnic groups in Hawaii; 30 to 84 years	The specific objective of this study was to test the effects of dietary fat and cholesterol on lung cancer	An interviewer-administered diet history questionnaire on food consumption for a usual month prior to diagnosis; the food items would provide ≥ 85% of the intakes of cholesterol and fat	Lung	Intakes of total fat SFA and MUFA were significantly higher in the cases compared to the controls in men, but not in women; in women, only the same tendencies were found (nonsignificant) Cholesterol intake was significantly associated with the risk in smoking men (OR=2.2), but not in women or past smokers; the association was consistent for three of four ethnic groups analyzed separately	Dietary measurement: Among cases, 28% of men and 32% of women were interviewed by proxy Among controls, 6% of men and 7% of women were interviewed by proxy Dietary confounders: Fat intake was not adjusted in the assessment of cholesterol and the risk association; cholesterol was not adjusted in the assessment of fat intake and the risk association Adjustment for other confounders: Adjustments for age, ethnicity and cigarette smoking

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Franceschi et al., 1989 (Ref. 68)	Case-control: 208 nonHodgkins lymphoma cases and 401 control subjects who were in the hospital for acute, nonimmunologic or neoplastic conditions; men and women; 18 to 80 year; northeastern part of Italy	The role of various lifestyle factors, including dietary habits, was investigated in the etiology of nonHodgkins lymphoma	Food frequency questionnaire including 14 food items or groups of foods and 7 beverages	Lymphoma: NonHodgkins lymphoma is a heterogeneous group of disorders resulting from malignant transformation of lymphoid cells	The consumption of butter and oil was positively related with NonHodgkin's lymphoma risk The consumption of milk also was positively related with the risk The consumption of meat or fish was not related with the risk	Dietary survey: The questionnaire method was verified by a repeated telephone survey on a subpopulation Selection of controls: The controls were also hospitalized patients Confounders: The data was presented after adjustment for age and sex, but not for total fat or energy intakes
Steineck et al., 1990 (Ref. 65)	Case-control: 323 urothelial cancer cases in Stockholm, Sweden during 1985 to 1987 and 392 population-based controls selected by gender and age stratified random sampling	To investigate the association between urothelial cancer and dietary factors, with special reference to vitamin supplements, dietary vitamins, and fried foods	A 56 food item food frequency questionnaire; recall dietary habits 3 years prior to interview	Urothelial	A dose-response relationship was seen with an increasing intake of fat (RR=1.7 in the highest quintile) and the risk Adjustment for fried foods, in addition to gender, age, and smoking decreased the relative risk (RR=1.3 in the highest quintile) No association was noted for meat other than fried meat	Dietary measure: long recall period, inadequacy of the questionnaire to analyze fat intake Dietary confounders: failure to adjust energy intakes Other confounders: Adjustment made for gender, age and smoking

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Franceschi et al., 1991 (Ref. 69)	Case-control: 302 oral cavity and pharynx cancer cases and 699 controls admitted to hospital for acute, nonneoplastic, and non-digestive disorders; in Pardonone province, northeast Italy	To examine the relationship between dietary indicators and the risk of cancer of the oral cavity and pharynx	A 40 food item food frequency questionnaire	Oral cavity, pharynx	Intakes of beef, poultry, fish were not associated with the risk	Control group selection: The controls were hospitalized patients Method of Dietary measure: Food items questioned were limited and hardly allowed any inference concerning total macro- and micro-nutrient intake Dietary confounders: Total caloric intake was not adjusted for data analysis Other confounders: Adjustment made for age and sex, occupation, smoking, drinking
Howe, 1990 (Ref. 73)	Meta-Analysis of 12 Case Control Studies	To evaluate the consistency of 12 studies of diet and breast cancer	varied	breast	Consistent, statistically significantly positive association between breast cancer risk and saturated fat intake in post menopausal women (RR = 1.5 p < .0001)	Not controlled for: Total Caloric intake. Problem of multiple comparisons
Bulatti 1990 (Ref. 74)	case-control study in Italy: 1016 cases 1159 population-based controls	To evaluate dietary factors and their contribution to gastric cancer mortality	Dietary questionnaire: frequency of intake and portion size in 12 month period 2 years before interview (146 food items)	stomach	Decreased cancer risk with increased vegetable fat (statistically significant) No association with animal fat	Didn't adjust for total calories
Baghurst, 1991 (Ref. 75)	Case-control 104 cases, 253 population-based controls	Assess relationship of diet to pancreatic cancer	Quantitative food frequency questionnaire 179 food items (usual intake)	pancreas	Increased risk with increased cholesterol intake (significant); increased risk with decreased PUFAS (significant) Others not significant when controlled for total energy	Controlled for total energy Difficult to interpret results

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Demirer, 1990 (Ref. 76)	Case-control (Turkey) 100 cases 100 control population-based and hospital (39+61)	Assesses role of diet in stomach cancer	Dietary questionnaire assessed for past 15 years	stomach	Increased risk with decreased meat consumption (statistically significant)	Poorly controlled study Fat consumption is not measured directly
de Verdieu, 1990 (Ref. 77)	Case-control (Sweden) 720 cases (268 rectal, 452 colon) 624 controls population based	Assess association between colorectal cancer and intake of total energy, protein, fat, fiber and body mass	Quantitative food frequency questionnaire (55 food items) for previous 5 years	colorectal	The following are significant for trends only, not for individual levels: Increased risk with increased energy Increased risk with increased total fat (for both colon and rectal cancers) Also increased risk with increased saturated fat increased risk with increased monounsaturated fat increased risk with increased PUFAS rectum only	Adjusted for fiber intake only, not total energy. High non response rate among cases (21%)
Farrow and Davis, 1990 (Ref. 78)	Case-control (148 male cases, 188 population-based controls)	Assess relationship between diet and pancreatic cancer	Telephone interview and self administered food frequency questionnaire (135 food items assessed 3 years prior to diagnosis	pancreatic	Increased risk with increased protein only (statistically significant); no risk associated with total fat, saturated fat, cholesterol, or omega-3 fatty acids	Wives used as surrogates when necessary for cases and for controls Controlled for total caloric intake Adjusted for major risk factors of pancreatic cancer such as smoking Study is well done

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Jain, 1990 (Toronto) (Ref. 79)	Case control 839 cases 772 controls (pop-based)	Dietary factors and lung cancer risk	In-person interview diet consisted of 81 food items (usual intake)	lung	Borderline increased risk with highest cholesterol consumption level No association with fats	Dietary questionnaire focused on usual intake, which could be influenced by disease, rather than 2-3 years previously Controlled for smoking but not total energy
Kato, 1990 (Japan) (Ref. 80)	Case-control 427 cases 3014 controls(all underwent gastroscopic examination)	Assess stomach cancer risk factors for purposes of prevention	Dietary questionnaire self administered; limited number of food items-usual intake	stomach	No association with meat consumption or "Western-style breakfast (actual fat intake not measured)	No adjustment for confounding factors (smoking, total energy) Fat consumption not assessed directly Controls underwent gastroscopic exam so potentially could be diseased (i.e., misclassification bias)_
La Vecchia, 1990 (Italy) (Ref. 81)	Case-control (110 women cases and 843 hospital controls for acute conditions non-neoplastic, non-respiratory	Laryngeal cancer risk and dietary factors	In person questionnaire 10 indicator foods assessed prior to onset of symptoms	laryngeal	No relationship with indicators of dietary fat	Controlled for smoking and some other confounders but not total energy Limited dietary assessment
La Vecchia (1990) (Ref. 82)	Case-control 247 cases 1089 controls hospitalized for acute nonneoplastic or digestive conditions	Diet and pancreatic cancer	In-person questionnaire on 14 indicator foods assessed at least 1 year prior to onset of symptoms	pancreas	No relationship with indicators of dietary fat	Controlled for smoking and some other confounders but not total energy Limited dietary assessment

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Maclure, 1990 (Ref. 83)	Case-control 410 cases 605 controls (population based)	Assess dietary factors in risk of renal adeno-carcinoma	Questionnaire in person at home on average food consumption in early 1970's	Renal	Animal fat and saturated fat weakly associated with risk, with and without adjustment for energy Total energy not associated	Recall bias 20-year period for recall Well controlled Low participation rate (69% for cases and 59% for controls)
Mettlin, 1990 (Ref. 84)	Case-control (303 cases and 606 controls hospitalized for non-malignant diseases	Assess ovarian cancer risk in relationship to milk drinking (lactose)	Self-administered questionnaire with 66 food items assessed prior to onset of symptoms	ovarian	Total milk consumption not associated with increased risk Drinking whole milk regularly associated with increased risk compared with drinkers of skim and 2%	Can not use results of this study to assess risk of fat consumption Authors assume that whole milk is a major source of dietary fat among adults (but didn't assess cooking milk, etc)
Stemmermann, 1990 (Ref. 85)	Prospective 8006 Hawaii Japanese men ages 46-68 at the beginning of the study 22 years duration	To assess the impact of fat and calcium intake on the risk of developing cancer in each large-bowel subsite	24 hours diet recall interview	colon/rectal	Age-adjusted mean intake of fat in patients with colon cancer is lower than that of non-cases (P=.05) no difference between rectal cases and non-cases. No interaction between fat and calcium intake No difference in mean calcium intake between colon or rectal cancer cases versus non-cases	Not adjusted for total energy intake

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Slatery, 1990 (Ref. 86)	Case-control white males from Utah aged 45-74; 362 cases, 685 population-based controls	To evaluate prostate cancer risk associated with fat consumed during adolescent years	Food frequency questionnaire-compared reported results with national food consumption trends to assess the accuracy of the dietary instrument	prostate	Men who consumed a high fat dies as adults were at a slightly increased risk of developing aggressive prostate cancer after adjustment for adolescent diet (OR=1.8, P=.05) whereas men who consumed a high saturated fat diet as adolescents were not at increased risk of developing these tumors after controlling for adult diet.	Recall bias large factor Multiple confounders not adjusted for (only age and high saturated fat diet in adolescent) Total energy intake not adjusted Borderline significance
Zhang, 1990 (Ref. 87)	Case-control of Chinese women in Shanghai: 186 cases, 186 hospital controls, 186 neighborhood controls	To assess the relationship between diet and breast cancer	Diet Histories	Breast	Cases have a significantly greater daily caloric intake than controls. After adjusting for the total energy intake, increased consumption of total fat is significantly associated with breast cancer (RR is 1.7, p =.05) for the highest vs lowest quintile of fat intake.	Well-done analysis. Major confounders adjusted for. Both hospital and neighborhood control used.
Slattery, 1988 (Ref. 88)	Case-control - Cases: 119 females, 110 males Controls: 204 females, 180 males	To assess the relationships of physical activity and diet to the development of colon cancer in Utah.	quantitative food-frequency questionnaire	colon	Total fat intake shows borderline increase in the risk for colon cancer in males (OR = 2.1, P=.09) and females (OR = 2.0, P=.09) between highest and lowest range of intake. Adjusted for age, BMI and fiber intake	Total energy intake not adjusted for.

Table 2--continued

Reference (author, date)	Study Design and Population	Objective	Method of Dietary measure	Type of cancer	Results	Assessment
Hislop, 1990 (Ref. 89)	Case-control of Canadian women; Cases: 801 histologically confirmed benign breast disease Controls: 865 age-matched	to investigate the relation between diet and histologic types of benign breast disease	self-administered questionnaire consisting of usual frequency of consumption during the past year of 39 specific food items	breast	Severe atypias and borderline carcinoma in situ were directly associated with frequent meat fats consumption (result not statistically significant: OR = 3.2 ; 95% CI 0.75-13.21)	Small subgroups; findings not statistically significant
Morales Suarez-Varela, 1990 (Ref. 90)	cross-sectional	to evaluate the relation of Spanish diet to rectal cancer morbidity and mortality	consumption by province was determined from National Statistics Institute publications for total lipids, total animal fats, total vegetable fats (in g/person/day)	rectal and colon	a positive correlation between morbidity and mortality and total lipid consumption was found. All morbidity and mortality rate (males, females and total) showed correlation in excess of .4 (p<.001)	Total energy not adjusted Lifestyle confounders not adjusted (smoking, etc)

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21 CFR Part 101

[Docket No. 91N-0095]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Sodium/Hypertension

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to authorize health claims on food labels and labeling that state that a low sodium diet is associated with lower blood pressure in some people. The agency reviewed the relationship between dietary sodium intake and hypertension under provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). On the basis of this review, the agency tentatively concludes that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, and that the strength and consistency of the publicly available scientific evidence supports such claims. The agency's tentative conclusion is based on its review of the scientific literature and on review of conclusions and recommendations provided in Federal government and other authoritative documents.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the 1990 amendments.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville MD 20857.

FOR FURTHER INFORMATION CONTACT: Ellen M. Anderson, Center for Food Safety and Applied Nutrition (HFF-266), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5375.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535), which amended the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorize the Secretary of Health and Human Services (the Secretary) to issue regulations authorizing nutrient content and health claims on the label or labeling of foods. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)).

Published elsewhere in this **Federal Register** is a proposed rule to establish general requirements for health claims that characterize the relationship of nutrients, including vitamins and minerals, herbs, or nutritional substances (referred to generally as "substances") to a disease or health related condition on food labels and in labeling. In this companion document, FDA has tentatively determined that such claims would be justified for dietary supplements as well as conventional foods only if the agency determines based on the totality of the publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The 1990 amendments also require (section 3(b)(1)(A)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x)) that, within 12 months of their enactment, the Secretary shall issue proposed regulations to implement section 403(r) of the act (21 U.S.C. 343(r)), and that such regulations shall determine, among other things, whether claims respecting 10 topic areas, including sodium and hypertension, meet the requirements of section 403(r)(3) of the act (21 U.S.C. 343(r)(3)). In this document, the agency will consider whether a claim on food or food products, including conventional foods and dietary supplements, on the relationship between sodium and hypertension would be justified under the standard proposed in the companion document entitled "Food Labeling: General Requirements for Health Claims for Food: Proposed Rule."

B. Sodium/Hypertension Relationship

1. Hypertension

Hypertension, commonly referred to as high blood pressure, is a serious public health concern. One in three adults in the United States is hypertensive (Ref. 85) approximately 58 million adults (Ref. 23). Individuals with high blood pressure have an increased risk of developing stroke, heart disease, and several types of kidney disease (Refs. 43 and 62). Heart disease and stroke are 2 of the 10 leading causes of death in the United States (Ref. 43). In 1988, 35.3 percent of all deaths were attributable to heart disease and 7.0 percent to stroke (Ref. 82).

In spite of improvements in the awareness and control of hypertension and a decline in related mortality rates for heart disease and stroke, hypertension continues to be a serious public health problem. Developing strategies to lower blood pressure in the general population remains an important public health goal (Ref. 74).

2. Sodium and Salt

Sodium is an essential nutrient with a variety of physiological functions (Ref. 63). It is the major electrolyte of blood plasma and other noncellular fluid and is essential for maintenance of fluid and electrolyte balance within the body. Sodium is also necessary for normal kidney function, nerve conduction, and muscle contraction (Ref. 7).

Sodium requirements vary with age, physical activity, environmental factors, and pregnancy status. Estimates have been made for safe minimum daily requirements for sodium in healthy persons taking into account wide variations in climate and physical activity but not including an allowance for large or prolonged sweat losses. These estimates range from approximately 300 milligrams (mg) per day for children 2 through 5 years of age to 500 mg per day for adults over 18 years of age (Ref. 63). In the United States, sodium is generally consumed well in excess of bodily needs. Dietary intake estimates range from 3,000 to 6,000 mg per day (refs. 18, 34, 35, and 43).

3. Relationship Between Sodium and Hypertension

An association of salt intake with high blood pressure was first observed in 1904 (Ref. 1). Since then, considerable experimental evidence linking sodium intake to hypertension has accumulated (Ref. 14). This increasing body of evidence resulted in public health concerns about the high levels of sodium intake in the U.S. population (Refs. 3, 9, 11, 22, 43, 62, 63, and 85). Consequently, a series of recommendations for Americans to moderate or reduce their sodium consumption have been made (Refs. 43, 62, 63, and 85).

Despite widely accepted recommendations to reduce or moderate sodium intake, estimating the

effectiveness of sodium restriction in reducing blood pressure has proven difficult because high blood pressure has many causes, and blood pressure levels are affected by many factors. The 1990 amendments require FDA to review and evaluate the data on sodium and hypertension to determine whether health claims on this topic are appropriate.

C. Sodium: Regulatory History

Sodium and salt have long regulatory histories. Salt (sodium chloride) has been regulated as an ingredient (21 CFR 100.140) and a flavoring (21 CFR 101.22). It has traditionally and historically been regarded as a generally recognized as safe (GRAS) substance (21 CFR 182.1). Sodium has been regulated as an essential nutrient (21 CFR 107.10, 21 CFR 107.100, and current 21 CFR 101.9). However, in the early 1980's, concern over high sodium consumption led to the GRAS safety review of sodium chloride (June 18, 1982, 47 FR 26590) and to FDA regulations (June 18, 1982, 47 FR 26580; April 18, 1984, 49 FR 15510) to include sodium content information on nutrition labels (current 21 CFR 101.9), to define descriptive terms for "low sodium" and "reduced sodium" foods (current 21 CFR 101.13), and to permit sodium labeling without full nutrition labeling on foods used to regulate sodium intake (21 CFR 105.69).

The intent of these regulations was to provide guidelines for sodium and salt labeling on foods, to establish definitions for descriptor terms useful in labeling foods low in sodium and salt, and to encourage manufacturers to provide a greater number and variety of low sodium foods. The emphasis was on developing and maintaining policies appropriate for the general public so that consumers could structure their diets to meet individual health needs, and so that medical professionals could better manage those patients requiring control of dietary sodium intake. Two quotes summarize the agency position in 1982 to 1984. The first refers to the general public:

> Adult intake of sodium in the United States is in excess of physiological needs, and it would be prudent for the general population to reduce sodium intake whenever possible. The role of excess dietary sodium in the development of hypertension needs to be defined more clearly, but there is no evidence that a moderate reduction in sodium intake for the general public would have any adverse effects, and there is a strong indication that such a reduction would be beneficial to a large segment of the population. (47 FR 26580 at 26581.)

The second quote refers to that portion of the U.S. population predisposed to hypertension:

> Although many epidemiological studies indicate a relationship between sodium intake and the prevalence of hypertension, the evidence that sodium consumption is a major factor in causing hypertension is not fully conclusive. Nevertheless, the evidence is strong enough for most members of the medical and scientific community to conclude that a substantial portion of the U.S. population which is predisposed to hypertension would benefit from a reduction in dietary sodium. (47 FR 26580 at 26581.)

In the **Federal Register** of June 18, 1982 (47 FR 26590), FDA reviewed the GRAS status of sodium chloride. Regulatory action was deferred until the agency could assess the impact of sodium descriptor and labeling regulations and voluntary efforts of manufacturers to reduce the salt and sodium content of their products. It was recognized that salt occupies a unique place in the food supply because it occurs naturally in foods, has a wide variety of manufacturing uses, and has a long history of direct consumer use in food preparation and at the table. In addition, the level of dietary sodium recommended for different individuals varies widely, from severe sodium restriction for some hypertensive patients, to moderate restriction for others, to general recommendations to reduce sodium intake for the general public. FDA concluded that it would be impractical to set upper safe limits for salt in individual foods, and that it was more appropriate to provide sodium content information than to try to restrict sodium use. In the years following the sodium labeling initiatives, FDA has taken no further action on the GRAS status of salt.

Consideration of health claims for a sodium and hypertension relationship was first proposed by FDA in a reproposed rule on health messages published on February 13, 1990 (55 FR 5176). Sodium and hypertension was proposed as one of six possible topics most likely to be suitable for health claims.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a supplementary proposal on mandatory nutrition labeling, Reference Daily Intakes (RDI's), and Daily Reference Values (DRV's) for nutrients. The proposed DRV for sodium is 2,400 mg. Also in this issue of the **Federal Register**, FDA is proposing a revision of nutrient content claims that include sodium content claims.

D. Evidence Considered in Reaching the Decision

The agency has reviewed relevant scientific evidence on sodium and hypertension. Federal government documents considered include the Surgeon General's Report on "Nutrition and Health" (Ref. 43), the U.S. Department of Agriculture's (USDA) and the Department of Health and Human Services, (DHHS) "Nutrition and Your Health—Dietary Guidelines for Americans" (Ref. 85), the National Institute of Health (NIH), National Heart, Lung, and Blood Institute's (NHLBI) "The 1988 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure" (Ref. 38), and the NIH/NHLBI Hypertension Workshop (Ref. 103).

The agency also reviewed additional documents prepared by recognized scientific bodies: The National Academy of Sciences/National Research Council's (NAS/NRC) "Diet and Health—Implications for Reducing Chronic Disease Risk" (Ref. 62), and the NAS/NRC "Recommended Dietary Allowances" (Ref. 63). FDA recently contracted with the Federation of American Societies for Experimental Biology (FASEB), Life Sciences Research Office (LSRO) to prepare an independent evaluation of the available scientific evidence on the relationship between sodium and hypertension. The agency has also considered the results of this "Sodium and Hypertension" review (Ref. 108). These reports considered the weight of the publicly available scientific evidence up until their publication, and they provided a foundation for studies published subsequently. The agency considered the results of animal studies to the extent that they clarified human studies or suggested possible mechanisms of action. FDA updated the evidence in these documents by reviewing relevant human studies that have become available since 1988. The agency evaluated one major, multinational investigation (Ref. 37), four clinical trials (Refs. 44, 70, 79, and 109), and three meta-analyses (Refs. 100, 106, and 107).

To ensure that its review of relevant evidence was complete, FDA requested, in the **Federal Register** of March 28, 1991 (56 FR 12932), scientific data and information on the 10 specific topic areas identified in section 3(b)(1)(A) of the 1990 amendments. The topic of sodium and hypertension was among the 10 subjects on which the agency requested information.

E. Comments Received in Response to FDA Request for Scientific Data and Information

FDA received 13 comments in response to the **Federal Register** request for data and information about the relationship between sodium and hypertension (56 FR 12932). One comment was a request for an extension for additional time for comments, and this request was denied because of the limited time available. Several provided comments about the general process of writing health claims. Others expressed opinions in support of or in opposition to sodium reduction or health claims for sodium and hypertension. Among those taking positions, a manufacturer and a trade association opposed reducing sodium intake and sodium/hypertension health claims. Reduced sodium intake and sodium/hypertension health claims were supported by a professional health association, a distributor of health foods, and a foreign government.

Comments from a trade association stated that health claims were inconsistent with the statutory requirements of the act. However, this comment was contained in a letter that was written before the enactment of the 1990 amendments which explicitly authorize health claims.

Comments from a State department of health, an association of State and territorial public health nutrition directors, a trade association, and a distributor of health foods included support for the 1990 amendments and the Surgeon General's report (Ref. 43). The comments favored requiring significant scientific agreement as a precondition to a health claim and suggested that FDA should authorize such claims only if other nutrient levels do not contradict the health benefits from the substance. These comments said that such claims should emphasize the total diet rather than individual foods, supplementation, or fortification. Some expressed concern that industry could abuse health claims or that the general public could misinterpret them. One suggested that FDA should do a literature search to obtain an impartial selection of data for review. Another emphasized that the public should continue to rely on modern medicine for the cure and mitigation of diseases. FDA believes that the proposed rule is responsive to these concerns.

Comments from a health food distributor and a professional health association made recommendations about levels of daily sodium intake. The health food distributor advised that adult sodium intake should not exceed 1,600 mg per day, while the professional health association recommended that adult sodium intake should not exceed 3 grams (g) (3,000 mg) per day. In this issue of the **Federal Register**, as stated above, FDA is proposing a DRV of 2,400 mg of sodium per day. Comments concerning recommended daily sodium intakes are more appropriately discussed in response to the establishment of a DRV for sodium. Copies of these two comments have been placed under Docket No. 90N-0134.

A distributor of health foods recommended a two-tiered approach to establishing the maximum amount of sodium that a food could contain and still bear a health claim. It suggested an absolute value (less than 100 mg of sodium per 100 calories) and recommended a secondary criteria based on the naturally occurring sodium levels in the various food categories. The health food distributor emphasized the importance of maintaining standard levels of other important nutrients and suggested that sodium/hypertension health claims would be misleading on low sodium foods if other ingredients in the food caused increased hypertension. These issues have been addressed in the proposed regulation on general requirements for health claims published elsewhere in this issue of the **Federal Register**.

Comments from a trade association suggested that health claims should be national in scope and uniform nationwide, and that FDA should not proceed without the resources to adequately enforce any new regulations. Under the 1990 amendments, regulations established by FDA on health claims are national in scope. FDA is required to prepare appropriate regulations in response to the congressional mandate. The agency will enforce the food labeling regulations to the best of its ability with the resources available.

Comments from a trade association suggested that model label statements should be created by expert advisory committees, evaluated through consumer testing, and published in the **Federal Register** for public comment. Manufacturers will have the latitude to develop claims that meet the requirements of the rule. FDA has tentatively decided that, under the act, the appropriate course is for the agency to determine the requirements that a health claim must meet. In this and other documents, FDA is proposing to authorize health claims and is proposing a model claim. FDA is inviting public comment on that model claim as well as on the proposed rule.

Comments from both a State health department and a health food distributor suggested that health claims should recognize the populations affected, refer to other factors that contribute to the disease, and emphasize the overall diet and lifestyle and not overstate the effectiveness of the nutrient or allow short descriptive statements separate from the total health claim. As discussed below and in the document on general principles for health claims, FDA's proposal is responsive to these concerns.

Several organizations sent in references for scientific studies. All recent and pertinent studies and comments concerning the scientific evaluation are included in the scientific review and summary elsewhere in this document.

A comment from a trade association included detailed objections to the Surgeon General's report (Ref. 43) and the NAS report (Ref. 62) and suggested that the documents were outdated, incorrect, incomplete, and biased. The comment concluded that the reports should not be given special consideration. FDA disagrees with these comments and believes that the documents are appropriate for consideration.

The Canadian Government also submitted a comment, outlining its position on the relationship of diet and nutrients to disease. The position reflects the work of the Canadian Scientific Review Committee (the Committee) (Ref. 84). The Committee reviewed the scientific data and recommended that the sodium content of the Canadian diet should be reduced. The report stated that there were insufficient data to support a quantitative recommendation. However, it concluded that a reduction in current sodium intakes of the Canadian population would involve no risk. Canada also pointed out that its Food and Drug Act expressly prohibits the sale or advertisement of foods represented to treat, prevent, or cure hypertension and other diseases.

II. Review of the Scientific Evidence

A. Introduction

Definitions of hypertension are related to both contracting, or systolic, blood pressure (SBP) and resting, or diastolic, blood pressure (DBP) measurements, are based on correlations with risk of heart disease and stroke, and differ by organization and purpose (Refs. 4, 17, 27, and 38). Currently, individuals with SBP greater than or equal to 140 millimeters of mercury (mm Hg) or DBP greater than or equal to 90 mm Hg or currently taking

antihypertensive medication are considered hypertensive. Those with SBP less than 140 mm Hg and DBP less than 90 mm Hg are considered normotensive (Refs. 17, 38, and 83). "High normal" DBP is defined as DBP between 85 and 89 mm Hg. All definitions are currently under review by the NIH/NHLBI Joint National Committee.

In considering the scientific evidence on the relationship between dietary sodium intake and hypertension, FDA reviewed three Federal government documents (Refs. 38, 43, and 85), a Federal government workshop (Ref. 103), and three other documents from recognized scientific bodies (Refs. 62, 63, and 108). FDA also reviewed the human studies that have become available since these documents were written. The agency included in its review English language reports of primary human studies involving sodium and hypertension specifically. FDA considered review articles and issues involving hypertension or other nutrients only as they related to the primary relationship between sodium and hypertension.

B. Federal Government Documents

1. "The 1988 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure"

"The 1988 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure" (Ref. 32) noted that research on hypertension prevention was in progress, and that recommendations for ways to prevent hypertension could not yet be made. It concluded that population studies suggest that low sodium intake, weight reduction, and moderation of alcohol consumption may contribute to prevention of age-related increases of blood pressure. The report noted that "high sodium intake plays a critical role in maintaining the elevated blood pressure of some hypertensive patients and in limiting the effectiveness of certain antihypertensive drugs," and that "some patients with mild or moderate blood pressure elevation may achieve control through moderate sodium restriction." The report observed that there is no easy way to identify specific individuals who would profit from sodium restriction and indicated that moderate sodium intake (approximately 1,500 to 2,500 mg per day) produced no serious adverse consequences.

2. "The Surgeon General's Report on Nutrition and Health," 1988

"The Surgeon General's Report on Nutrition and Health" (Ref. 43) observed that epidemiological studies have shown that, in populations with low sodium intake, blood pressure does not rise with age, and that populations with low blood pressure do not generally consume much salt. The report noted that the correlation between salt intake and blood pressure is not consistent in population studies, and that the associations among individuals within a population have been less consistent, which may be due to methodological reasons.

The report observed that long-term clinical studies have shown that 40 percent of hypertensive patients and 30 percent of mildly hypertensive patients could control their blood pressures by reducing sodium intake below 1,150 and 1,720 mg per day, respectively. It further noted that the effect of sodium restriction has been less well studied in normotensive populations as compared to hypertensive populations. There are fewer studies of normotensive individuals, and the studies have been small in size and short in duration. A few studies have indicated that dietary sodium restriction in normotensive adults or infants can result in small blood pressure decreases.

The report observed that intervention studies have suggested that sodium restriction and weight control can be beneficial in helping control hypertension in mildly hypertensive individuals who have discontinued their antihypertension medication.

The Surgeon General's Report on Nutrition and Health" concluded that "[d]ietary factors that clearly contribute to high blood pressure include obesity and excessive intake of sodium and alcohol," and that "[s]tudies indicate a relationship between a high sodium intake and the occurrence of high blood pressure and stroke."

The report observed that the average sodium consumption by U.S. adults (4,000 to 6,000 mg per day) significantly exceeds the range that NRC estimated in 1980 as would be a safe and adequate daily intake (1,100 to 3,300 mg). It noted that there is no easy way to identify individuals who would profit from sodium restriction, and that some individuals appear to respond to sodium restriction and are considered "salt-sensitive" and others do not respond and are considered "salt-resistant." The report observed that there is no practical way of distinguishing the two groups other than by measuring the blood pressure response itself. It concluded that moderate reduction of dietary sodium would not be harmful and might be of significant benefit to that portion of the population at risk of developing hypertension. The report suggested that most Americans should consider reducing their sodium intake by choosing foods with less sodium, using less sodium in food preparation, and adding less sodium at the table.

3. "Nutrition and Your Health—Dietary Guidelines for Americans," 1990

In 1990, "Nutrition and Your Health—Dietary Guidelines for Americans" (Ref. 85) made seven nutrition recommendations for the U.S. population. Among other suggestions, it stated that Americans should "[u]se salt and sodium in moderation" and recommended that Americans choose foods with less sodium, use less sodium in food preparation, and add less sodium at the table.

4. Summary

These three Federal government documents acknowledged a relationship between sodium intake in excess of physiological need and the prevalence of hypertension. There was agreement that limiting dietary sodium may benefit a portion of the population with elevated blood pressures, i.e., be of benefit for some hypertensive individuals. Dietary Guidelines and the Surgeon General's report also indicated that in addition to benefitting individuals identified as hypertensive, moderation of dietary sodium might also benefit the portion of the normotensive population at risk of developing hypertension.

C. Federal Government "Workshop on Salt and Blood Pressure," 1989

On November 1 and 2, 1989, NHLBI sponsored a "Workshop on Salt and Blood Pressure" to review the scientific evidence on the relationship between sodium and blood pressure, to consider the variability in human response, to review research findings relative to clinical and public health policies, and to provide recommendations for future research (Ref. 103). Three articles that resulted from this workshop (Refs. 109, 111, and 114) are discussed elsewhere in this document. Positions and opinions expressed at the meeting were highly polarized on the value of salt restriction. A wide range of topics was presented, and the scientific discussions reflected the controversy surrounding this topic. Some participants at the conference supported reducing sodium intake and argued that the relationship is scientifically supported (Refs. 94, 97, and

113), that many hypertensives are "salt-sensitive" (Ref. 95), that there are no negative consequences of decreased sodium intake (Ref. 98), and that since the target population cannot be identified easily or cheaply (Ref. 104), a population approach, which is often used for nutrition policies (Ref. 99), is necessary (Ref. 104). Some indicated that reductions in sodium intake are possible because interventions have been successful and have made significant contributions to treatment and prevention (Ref. 98). Others contended that only expensive, labor-intensive interventions with highly motivated participants have been successful (Ref. 105), and that the most pragmatic approach would be to alter the sodium content of the entire food supply (Refs. 102 and 105).

Other participants opposed reducing sodium intake and contended that more research is necessary because electrolytes other than sodium may affect hypertension (Ref. 110). Some indicated that sodium restriction affects people in very different ways, and that some individuals might be closer to a critical deficit of extracellular fluid or might have more difficulty reconstituting losses after acute salt-depleting stress. They argued that sodium reduction should be used only for individuals at risk and for those in whom it has proven effective (Ref. 112). Some asserted that long-term, substantial reductions in sodium intake have not been successfully achieved in comparative trials (Ref. 113).

D. Other Documents and Statements

1. "Diet and Health—Implications for Reducing Chronic Disease Risk," 1989

The NAS "Diet and Health—Implications for Reducing Chronic Disease Risk" (Ref. 62) observed that cross-cultural, epidemiological studies show that blood pressure does not increase with age, and that there is a low prevalence of hypertension in populations with low sodium intake. However, the relationship between low sodium intake and low blood pressure or low incidence of hypertension has been less consistent in epidemiological studies within individual cultures. The report noted that INTERSALT, a large, multinational, pooled study, showed both a small but significant positive correlation between sodium excretion and mean SBP and also a significant positive correlation between sodium excretion and increases in blood pressure that occur with age (Ref. 37).

The report observed that small, short-term clinical studies suggest that sodium restriction is related to reductions in blood pressure in normotensive individuals. However, these results have not been confirmed in long-term, prospective, controlled trials in normotensive populations.

The report noted that animal studies support the conclusions from human studies. High salt intake appears to promote the development of high blood pressure in some animal models, especially when renal defects reduce the ability of the kidney to excrete salt. The report noted that these findings suggest that high-salt diets in combination with reduced sodium excretion may be related to the development of hypertension in humans. It further noted that, once high blood pressure is induced by high sodium intake, it cannot necessarily be reversed by resumption of a moderately low intake, due probably to irreversible changes in the kidney.

"Diet and Health—Implications for Reducing Chronic Disease Risk" concluded that: "[b]lood pressure levels are strongly and positively correlated with the habitual intake of salt," and that "the weight of evidence supports the contention that intake of sodium is an important factor in the occurrence of hypertension." The report recommended that total daily salt intake should be not greater than 6 g (2,400 mg sodium), with a possible future goal of 4.5 g salt (1,800 mg sodium). It suggested reducing salt and sodium intake by choosing low sodium foods and using less sodium in food preparation and at the table. The report observed that there is a wide variability in genetic susceptibility to salt-induced hypertension, that some people are more salt-responsive ("salt-sensitive") than others, and that there is no reliable way to identify individuals in the population who would benefit from sodium restriction. It concluded that limiting dietary sodium may be of significant benefit to that portion of the population at risk of developing hypertension and noted that the recommended intake levels would not be harmful to the general public.

2. "Recommended Dietary Allowances," 1989

"Recommended Dietary Allowances," 10th Edition (Ref. 63) noted that: "[s]ustained overconsumption of sodium, particularly as salt, has been related to development of hypertension in sensitive individuals." It supported the recommendation of the NAS Report to limit daily sodium intake to 2,400 mg. It noted that 500 mg sodium per day is a safe minimum intake for adults, and that there is no known advantage in consuming large amounts of sodium.

3. "Dietary Sodium Chloride and Blood Pressure," 1991

FASEB recently prepared an independent evaluation of the available scientific evidence on the relationship between sodium and hypertension (Ref. 108). The FASEB report concluded that the association between increased sodium or salt intake and increased blood pressure is due to sodium and chloride in combination, and that the increase is mitigated by the presence of potassium and calcium ions. It indicated that the most convincing evidence comes both from studies across populations and from controlled clinical trials which have shown a small, significant positive correlation between dietary sodium chloride intake and blood pressure for hypertensive and normotensive individuals.

The FASEB report noted that studies within populations have been inconclusive or have shown a low correlation. The report noted that there was little long term information about the effect of dietary sodium intake on the development of hypertension, and that the available data have been inconclusive. The report concluded that observational data and intervention trials document a small, but consistent effect of dietary sodium chloride on blood pressure.

4. Summary

There is general agreement among the three authoritative documents that there is a relationship between sodium intake and hypertension.

E. Review of the Scientific Evidence Since the Authoritative Reports

1. INTERSALT, 1988

INTERSALT (Ref. 37) was a large, multinational investigation of the relationship between electrolytes, including sodium, and blood pressure (Table 1). The intent was to apply highly standardized methods across varied populations, to examine the major confounding factors, and to evaluate the relationships in individuals (Ref. 64). The study involved 10,079 adults in 52 population centers around the world (Refs. 37, 50 through 54, 58, 59, and 64). Within-individual variability in sodium excretion was estimated using data from a random sampling (8 percent) of individuals who provided two 24-hour urine collections. The within-center data were pooled, and a statistically significant relationship between sodium intake and increased SBP was reported. A relationship between sodium intake and DBP was significant under some analysis conditions and not others.

Similar results were found when the data were analyzed by gender and by age (Ref. 51), and when the normotensive population was considered independently (Ref. 50).

The across-center data analysis considered relationships between sodium intake and blood pressure and between sodium intake and trends in blood pressure with age. The data were analyzed with and without four isolated population centers, two Brazilian Indian (Yanomamo and Xingu), the Papua New Guinean, and the Kenyan. These four centers had exceptionally low median sodium intakes (ranging from 5 to 1,180 mg per 24 hours) and the lowest average blood pressures of all 52 centers (SBP of 103 mm Hg, DBP of 63 mm Hg) (Ref. 58). The relationship between sodium intake and blood pressure, across centers, was strongly dependent on the inclusion or exclusion of these four populations. When these populations were included, the relationship between sodium intake and blood pressure was positive and significant. Results were negative and significant or inconclusive when these four populations were excluded from the analysis. The relationship between sodium intake and trends in blood pressure with age was positive and significant under all analysis conditions. The four centers with exceptionally low sodium intakes had little or no upward slope of blood pressure with age and low prevalence of hypertension (5 percent in Kenya, absent in remaining three centers) (Ref. 58). The Yanomanu Indians consumed as little as 1 mg of sodium in 24 hours and appeared healthy and physically active with no evidence of malnutrition or protein deficiency (Ref. 59).

The INTERSALT Cooperative Research Group analysis included adjustments for age, sex, potassium excretion, body mass index, and alcohol intake. The group estimated that an average sodium reduction of 100 millimole (mmol) per day (2,300 mg sodium) would correspond to an average reduction in SBP and DBP of 2.2 mm Hg and 0.1 mm Hg, respectively, on a population basis. In addition, assuming a cumulative effect over time, the group estimated the difference that this 2,300 mg reduction in sodium would have on the age-related increase in blood pressure that is characteristic of Western populations. It calculated that the average blood pressure would increase more slowly and, after 30 years (from 25 to 55 years of age), would be 9.0 mm Hg (SBP) and 4.5 mm Hg (DBP) lower than it would have been with a diet higher in sodium. The INTERSALT Cooperative Research Group concluded that even these small changes in blood pressure could result in important public health benefits when applied to the population as a whole.

In recent years, there have been many published opinions on the INTERSALT findings. In reviewing the totality of publicly available scientific evidence, FDA also included these articles and considered the INTERSALT findings in this total context. The arguments were similar to those expressed at the government workshop discussed above. Several authors supported sodium restriction and emphasized the predicted benefits on a population basis (Refs. 52, 60, 69, 75, 111, and 114). Two authors objected to sodium restriction, contended that it is unclear whether the relationship is nonexistent or small with negligible benefit, and expressed concern about potential adverse effects of sodium restriction (Refs. 90 and 120).

The Stamlers, et al. (Refs. 69 and 114) used the INTERSALT data (Ref. 37) to estimate that the 2.2 mm Hg reduction in SBP would correspond to a 4 percent reduction in coronary mortality and a 6 percent reduction in stroke mortality, or 12,000 fewer U.S. deaths each year for people in the age range from 45 to 64. They estimated that the 9 mm Hg reduction in the expected increase in blood pressure from age 25 to 55 would correspond to a 16 percent reduction in deaths from coronary heart disease (CHD) and a 23 percent reduction in deaths from stroke. R. Stamler estimated that 85 percent of the American population have some risk for mortality associated with blood pressure levels (Ref. 114).

2. Clinical Trials (Table 2)

Many of the studies considered involved hypertensive subjects. Dustan and Kirk (Ref. 121) investigated sodium depletion (210 mg sodium per day) and loading (varied by body weight, added 90 mg sodium per kilogram (kg) per day) in 31 hypertensive and 84 normotensive subjects. The authors reported that in hypertensives and some normotensives, mean arterial blood pressure fell with sodium depletion and rose with sodium loading. In other normotensives, blood pressure remained stable throughout. The study phase was very short (4 days sodium depletion, and 3 days sodium loading), and the sodium loading was administered intravenously which introduced additional uncontrolled variability. In addition, the sodium depletion regime was very extreme, allowing only 210 mg sodium per day.

Lasaridis et al. (Ref. 55) studied the responses of 18 (10 male, 8 female) hypertensive patients to controlled diets low (1,150 mg per day) and high (4,600 mg per day) in sodium. Average supine blood pressure rose significantly (6.7 mm Hg). Average standing blood pressure rose (5.0 mm Hg), but the increase was not significant. The study size (18 subjects) was small.

The Australian National Health and Medical Research Council Dietary Salt Study Management Committee (Ref. 44) conducted an 8-week, double blind, placebo-controlled intervention study with 103 (86 male, 17 female) mildly hypertensive subjects (DBP: 90 to 100 mm Hg). Lower and statistically significant decreases in SBP (average decrease of 6.1 versus 0.6 mm Hg) and DBP (average decrease of 3.7 versus 0.9 mm Hg) were observed in the low sodium intake group (1,840 mg sodium per day) as compared to the normal sodium intake group (3,680 mg sodium per day). A large range of variation in individual response was observed but not confirmed.

The Australian National Health and Medical Research Council Dietary Salt Study Management Committee (Ref. 45) continued the intervention study into a crossover design. Eighty eight (73 male, 15 female) subjects continued into the second phase of the study. Similar decreases in SBP (average decrease of 6.0 versus 0.1 mm Hg) and DBP (average decrease of 4.1 versus 0.4) were observed for the low and high sodium intake groups when the data were analyzed as a parallel design identical to that of the first study (Ref. 44). When individual response was considered in accordance with the crossover design of this second study, the average reduction was 3.6 mm Hg (SBP) and 2.1 mm Hg (DBP) in the placebo phase (1,840 mg dietary sodium per day) versus the diet phase (1,840 mg dietary sodium plus 1,840 mg sodium chloride tablets per day).

Koopman et al. (Ref. 76) conducted an intervention trial in 28 mild to moderate hypertensives (average initial SBP of 144.5 mm Hg and DBP of 95.4 mm Hg) to encourage reduced sodium diets through dietary counseling and feedback from results from urinary sodium excretion. At the end of 18 months, the average sodium had decreased by 510 mg per 24 hours (from 3,590 to 3,080 mg), accompanying average decreases in SBP of 3.7 mm Hg and in DBP of 4.0 mm Hg. In general, over the 18 months, the sodium intake and blood pressure decreased over the first 6 months and then remained at the lower levels for the rest of the trial period. Four subjects dropped out because of high blood pressure. This was a small study (18 subjects) with no untreated control group (CG).

In another study of mildly hypertensive subjects, Luft et al. (Ref. 79) used a placebo controlled, crossover study design to investigate sodium effects on blood pressure of 10 mildly hypertensive (SBP > 140 mm Hg or DBP > 90 mm Hg) and 10 normotensive (SBP < 140 mm Hg and DBP < 90 mm Hg) subjects (10 male, 10 female) (10 black, 10 white). Sodium chloride (1,810 mg sodium per day) or sodium bicarbonate (1,810 mg sodium per day) supplements were supplied with a controlled basal diet (1,380 mg sodium per day). During the sodium chloride intake period, no statistically significant change in blood pressure was observed in either the mildly hypertensive or the normotensive group. The SBP of the mildly hypertensive group was decreased by 5 mm Hg during the sodium bicarbonate intake period. The population size was small (2 groups of 10 subjects).

In another study involving 20 (11 male, 9 female) (5 black, 15 white) mild hypertensives (DBP: 90 to 110 mm Hg), MacGregor et al. (Ref. 122) investigated blood pressure response in a crossover study involving three levels of sodium intake determined by urinary excretion (1,130 mg, 2,480 mg, and 4,370 mg sodium per 24 hours). Blood pressure increased stepwise with sodium intake (SBP: 147, 155, and 163 mm Hg, DBP: 91, 95, and 100 mm Hg). The differences were statistically significant and were not affected by the order of sodium intake.

Several studies involved normotensive subjects. In addition to the two studies considered above (Refs. 79 and 121), Mascioli et al. (Ref. 109) conducted a double blind, placebo controlled, crossover study involving 48 (79 percent male) (1 black, 47 white) normotensive (SBP < 150 mm Hg; DBP: 80 to 89 mm Hg; not on antihypertensive medication or diagnosed as hypertensive) subjects, randomized into two groups, ingesting sodium capsules (2,210 mg sodium per day) or a placebo in addition to a low sodium diet (monitored as less than 805 mg sodium per 8-hour overnight urine collection). In 65 percent of the participants, SBP was higher during the sodium chloride intake period than during the placebo period (Group 1: 4.3 mm Hg higher, 126.4 versus 122.1 mm Hg; Group 2: 2.8 mm Hg higher, 121.4 versus 118.5 mm Hg). In 69 percent of the participants, DBP was higher during the sodium chloride intake period than during the placebo period (Group 1: 2.7 mm Hg higher, 78.8 versus 76.1 mm Hg; Group 2: 1.8 mm Hg higher, 78.5 versus 76.6 mm Hg). The study used timed, overnight, 8-hour urine excretion to assess adherence to low sodium diet.

Mtabaji et al. (Ref. 80) investigated blood pressure response to salt intake in 30 normotensive, black male Tanzanians. In the group on the low sodium diet (1,200 mg per 24 hours), the average mean arterial blood pressure decreased from 87 to 81 mm Hg, whereas, in the group on the high sodium diet (7,750 mg per 24 hours), the average mean arterial blood pressure increased from 86 to 89 mm Hg. The high sodium diet phase was excessively high in sodium (7,750 mg per day).

Three studies, from Scotland (Ref. 41), Japan (Ref. 71), and Belgium (Ref. 42), were cross sectional. The Scottish heart health study (Ref. 41) investigated the relationship of blood pressure to sodium in 7,354 (3,754 male, 3,600 female) free-living subjects from 22 districts in Scotland. The study concluded that there was a weak, positive correlation between sodium and SBP (males: 0.025, females: 0.055) and between sodium and DBP (males: 0.026, females: 0.052) in both sexes. Sodium intake was not independently significant after multivariant analysis. Single sodium measurements in cross sectional studies do not assess previous or habitual sodium intake habits.

Takemori et al. (Ref. 71) considered sodium intake and blood pressure response in 7,441 Japanese females from 88 urban (3933 subjects) and 81 rural (3,508 subjects) municipalities including all prefectures in Japan. The authors concluded that an increase of 2,300 mg sodium per day was related to an increase in SBP of 4.5 mm Hg (urban: 4.1 mm Hg; rural: 4.9 mm Hg) and to an increase in DBP of 1.6 mm Hg (urban: 1.2 mm Hg; rural: 2.0 mm Hg). Spot urine and predictive equations were used to estimate 24-hour sodium which added uncertainty to the results.

Staessen et al. (Ref. 42) conducted a 5-year, cross sectional, intervention trial in two Belgian towns (12,000 and 9,000 inhabitants). A mass media campaign to avoid salt was implemented in one of the two towns, and the second town received no information and served as a control. Data from a random sampling of 777 males and 733 females were analyzed. There were decreases in average urinary sodium, SBP, and DBP for men in the intervention town, and the trends in the control town were not significantly different. In women, sodium decreased in the intervention town and increased in the control town; whereas SBP and DBP decreased similarly in both towns. No conclusions about the relationship between sodium intake and blood pressure could be made. There was a large range of variability in the results, and no independent assessment was made of what information was available to inhabitants in the control town.

Three of the studies were intervention trials. Stamler et al. (Ref. 70) conducted a 5-year, dietary, multiple intervention trial involving 201 subjects with high normal blood pressure (DBP: 80 to 89 mm Hg). The intervention group (IG) was encouraged to reduce alcohol and sodium intakes (goal: 1,800 mg sodium per day or less), reduce weight, and increase physical activity. The intervention group significantly modified their behavior in three of these four categories relative to the control group (CG), increased frequent, moderate physical activity, weight reduction, and sodium reduction (IG: drop of 25 percent from 3980 to 3040 mg sodium per day; CG: drop of 6 percent from 4,300 to 4,060 mg sodium per day). Both groups showed similar reductions in alcohol consumption. After 5 years, the incidence of hypertension (IG: 9 percent; CG: 19 percent), the average SBP (IG: decrease of 2.6 mm Hg from 122.5 to 119.8 mm Hg; CG: decrease of 1.3 mm Hg from 122.7 to 121.5 mm Hg), and the average DBP (IG: decrease of 1.3 mm Hg from 82.5 to 81.2 mm Hg; CG: decrease of 0.1 mm Hg from 82.6 to 82.5 mm Hg) were significantly lower in the IG as compared to the CG. After multiple regression analysis, the independent effect of reduced sodium intake on lowering blood pressure was not statistically significant. Appropriate statistical tools were used to assess the effect; however, the analysis was complicated due to the four simultaneous interventions.

The Hypertension Prevention Trial Research Group (Ref. 124) conducted a dietary counseling intervention involving 841 subjects randomized into four intervention groups and a control. The four interventions involved dietary counseling to encourage reduced calories, reduced sodium, reduced sodium and calories in combination, and reduced sodium and increased potassium. Sodium and blood pressure were reduced in all groups, including the control group. In the sodium only intervention group, sodium was reduced significantly at 6 months and marginally at 3 years. Blood pressure was generally lower in the sodium only intervention group than in the control group, but the decreases were not statistically significant.

The Trials of Hypertension Prevention (TOHP) Collaborative Research Group (Ref. 123) investigated seven nonpharmacological interventions (weight loss and exercise; sodium restriction; stress management; and

supplementation with four nutrients: calcium, magnesium, potassium, and fish oil) relative to a control population, in 2,182 subjects with high normal blood pressure (DBP: 80 to 89 mm Hg). After 18 months, there was a 39 percent reduction in sodium in the sodium restriction population, and SBP and DBP were reduced by 1.5 and 0.8 mm Hg, respectively. The authors concluded that weight loss and sodium restriction were the most promising nonpharmacological interventions.

3. Meta-Analyses

FDA evaluated five meta-analyses (Refs. 94, 97, 100, 106, and 107) which analyzed the effect of sodium intake on blood pressure (table 3). Meta-analyses combine data collected using a wide variety of methodologies, and this complicates data analysis and assessment.

Cutler et al. (Ref. 94) considered 23 randomized clinical trials involving 1536 subjects. Net reductions in sodium ranged from 370 to 3,910 mg sodium, and average pooled reductions in blood pressure were 2.9 mm Hg (SBP) and 1.6 mm Hg (DBP). When hypertensive and normotensive subjects were considered separately, the reductions were larger for the hypertensive subjects (SBP: 4.9 mm Hg; DBP: 2.6 mm Hg) and smaller for the normotensive subjects (SBP: 1.7 mm Hg; DBB: 1.0 mm Hg). The results were statistically significant except for DBP results in normotensive subjects after including adjustments for inverse variance weights.

Elliott et al. investigated the combined results of 14 observational studies involving 12,503 (7,099 male, 6,136 female) subjects in 16 populations. The authors concluded that an average reduction of 2,300 mg sodium per day was related to average reductions in SBP and DBP of 3.7 and 2.0 mm Hg, respectively. Regression coefficients were somewhat larger in women than in men.

Three meta-analyses from one group (Refs. 100, 106, and 107) considered the relationship of sodium intake to blood pressure among populations, within populations, and from clinical trials of salt reduction. In the analysis among populations (47,000 subjects) (Ref. 106), 12 economically undeveloped and 12 economically developed communities were considered separately. The authors developed a model to analyze the relationship of blood pressure to sodium intake. The variability in blood pressure increases with age was controlled by age-stratified analysis. On a population basis, the analysis showed small but consistent increases in blood pressure with increases in sodium intake for both economically developed and undeveloped populations. The magnitude of the increase was greater for older people and for those with higher initial blood pressures. A difference of sodium intake of 100 mmol per day (2,300 mg) was associated with an average change in SBP of 5 mm Hg (ranging from 3 to 7 mm Hg) for those 15 to 19 years of age and of 10 mm Hg (ranging from 6 to 15 mm Hg) for those 60 to 69 years of age. The magnitude of the change was greatest for those with higher initial blood pressure. Smaller changes were observed for those with lower initial blood pressure, but some change was observed in even the lowest blood pressure range.

The within-population analysis of 14 studies (Ref. 100) tested the model developed in the first paper. Using a concept previously applied to 24-hour dietary recall data (Ref. 5), the analysis demonstrated that there is considerable day-to-day variability in sodium intake, determined that a single 24-hour excretion study underestimates the true variance, and used two studies of daily variation to estimate the magnitude of the bias. After adjustment for bias, the magnitude of the correlation between blood pressure and sodium excretion for the within population data agreed with the estimates of the correlation for the among population data in the first paper.

The authors noted that for a small effect, such as the change in blood pressure with sodium intake, very large sample sizes are required to produce statistically significant results because of the substantial random error in measuring sodium intake and the wide range of blood pressures associated with each level of sodium intake. The authors estimated that a study would need to include 400 hypertensive subjects and 400 normotensive subjects to have a 50 percent probability of detecting such a small effect. Doubling the sample size would increase the probability to 80 percent. The authors concluded that, when estimates of the correlation of sodium intake and blood pressure are based on 24-hour dietary intake data, the estimates of the true correlation are too low, and the relationship is stronger than previously reported.

The third analysis included data from 68 crossover trials and 10 randomized controlled trials (Ref. 107). The authors concluded that lower sodium intake was associated with reduced blood pressure in those with high and normal initial blood pressure levels. The authors estimated that, in people between 50 and 59 years of age, a 50 mmol per day (1,150 mg) reduction in sodium intake would lower SBP by an average of 5 mm Hg in the total population and by 7 mm Hg in those with initially high blood pressures. They also estimated that these lower blood pressure levels for the entire population would result in a 26 percent reduction in stroke and a 15 percent reduction in heart disease in Western populations.

Sodium intake was associated with blood pressure. Studies of 4 weeks or less showed smaller differences than studies that lasted 5 weeks or longer.

Taken together, the three meta-analyses concluded that the correlation between sodium intake and blood pressure is stronger than previously estimated, and that the INTERSALT study, among others, underestimated the magnitude of the correlation. The meta-analyses supported the conclusion that modest sodium intake is related to lower blood pressure on a population basis and suggested a beneficial effect on an individual basis, the magnitude depending on the age and the existing blood pressure of the individual.

4. Summary

FDA reviewed the totality of available human studies published since the authoritative documents. One of the studies showed a decrease in blood pressure with increased sodium bicarbonate intake in 10 mildly hypertensive subjects (Ref. 79). For the other subjects in the study and for all subjects during the sodium chloride intake period, the results were inconclusive. The results of the 5-year study involving four simultaneous interventions, the results of the 5-year intervention in two Belgian towns, and the results of the 3-year dietary counseling intervention were also inconclusive (Refs. 42, 70, and 124). However, the large, multinational INTERSALT study (10,079 subjects) (Ref. 37), 11 other recent studies (Refs. 41, 44, 45, 55, 71, 76, 80, 109, 121, 122, and 123), and 5 meta-analyses (Refs. 94, 97, 100, 106, and 107) supported the relationship between sodium intake and blood pressure levels.

F. Summary and Conclusions

There was significant scientific consensus among the three Federal government documents (Refs. 38, 43, and 85), most of the position papers presented at the Federal government workshop (Ref. 103), and the other documents of recognized scientific bodies (Refs. 62, 63, and 108) that high dietary sodium intake, particularly as sodium chloride, is related to the prevalence of hypertension, and that diets that are low in sodium will be

associated with low occurrences of hypertension.

FDA updated the evidence in the documents described above by reviewing the totality of available human studies published since these documents. One study (Ref. 79) was negative in mildly hypertensive subjects, and four studies (Refs. 42, 70, 79, and 124) showed no effect or were inconclusive with respect to a relationship between sodium intake and blood pressure. The other studies (Refs. 37, 41, 44, 45, 55, 71, 76, 80, 94, 97, 100, 106, 107, 109, 121, 122, and 123) supported the conclusions reached in earlier government and authoritative reviews which recognized a link between sodium intake and hypertension. Based on its review, FDA tentatively concludes that the contradictory or inconclusive studies are insufficient to affect the consensus among the government documents and other reviews discussed above.

In summary, the effect of changes in dietary sodium on blood pressure is small but statistically significant. Changes in sodium intake are associated with changes in blood pressure across a wide range of normotensive and hypertensive blood pressures. Thus, reductions in sodium intake have broad applicability. The magnitude of the effect varies widely, with benefit for some but not for all individuals. This variability is typical of nutrient and chronic disease relationships. The responsiveness of some individuals is thought to be the result of a "salt sensitivity"; however, the difficulty in identifying these individuals makes it impractical to predict those individuals most likely to benefit by moderation or reduction in sodium intake. There is some indication that different sodium salts may produce different blood pressure responses, and thus, increasing emphasis is being placed on the potential importance of the chloride ion in combination with the sodium ion in producing blood pressure increases. Additional research is needed in this area. However, because most sodium in foods is in the form of sodium chloride, this issue has little practical impact on public health policies.

G. Tentative Decision To Authorize a Health Claim Relating Sodium and Hypertension

FDA reviewed the publicly available scientific data and authoritative documents on the association between dietary sodium intake and hypertension. On the basis of this review, the agency tentatively concludes that there is significant scientific agreement among experts who by training and experience are qualified to evaluate such evidence to support health claims that high sodium intake is related to the prevalence of hypertension. The basis for this decision is threefold: (1) The strength and the scientific evidence relating high sodium intakes to the prevalence of hypertension; (2) the extent and significance of the likely public health benefit; and (3) the safety of expected dietary changes.

1. Scientific Evidence Is Sufficient to Support the Relationship

Proposed § 101.14(c) states that a health claim may be made if the Secretary determines, "based on the totality of publicly available scientific evidence (including evidence from well designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by the evidence." A companion document, published elsewhere in this issue of the **Federal Register**, considered this requirement and is proposing this standard for health claims for both conventional foods and dietary supplements.

In the case of sodium and hypertension, the "totality of publicly available scientific evidence" included three Federal government documents derived through consensus-building processes (Refs. 38, 43, and 85), a Federal government workshop (Ref. 103), three other documents prepared by recognized scientific bodies (Refs. 62, 63, and 108), one major international epidemiological investigation (Ref. 37), 17 clinical trials (Refs. 41, 42, 44, 45, 55, 70, 71, 76, 79, 80, 94, 97, 109, 121 through 124), and five meta-analyses (Refs. 94, 97, 100, 106, and 107).

In determining whether there was "significant scientific agreement," FDA first looked for consistency in the conclusions and recommendations of the relevant, Federal government documents. The agency then considered the contribution of the Federal government workshop, other recent authoritative documents, and all pertinent human studies available since 1988. In considering the value of particular studies and assessing the quality of the research that produced the data, FDA took into consideration the relevance of study objectives for examining the relationship of sodium to hypertension, the experimental design of the study, the treatment of resultant data, and the statistical significance of the conclusions.

In reviewing the recent primary research, the agency looked for general agreement or disagreement with the conclusions and policy of the Federal government and other comprehensive, authoritative documents and evaluated whether inconsistencies in results from newer studies were sufficient to cause the agency to reverse or modify the conclusions reached in those earlier review documents.

Throughout its evaluation, FDA focused primarily on human studies because the public health issue is hypertension in humans, and especially in Americans. In addition, FDA concentrated on the relationship between the nutrient, sodium, and the disease, hypertension. FDA is aware that a wide range of variables, in addition to sodium intake, have been reported to affect hypertension. Among others, these include chloride, calcium, and magnesium ions; chemical forms of sodium other than sodium chloride; the ratio of serum sodium to serum potassium; alcohol consumption; and obesity. Given the severe time constraints and other specific requirements of the 1990 amendments, FDA limited its evaluation of the scientific data to, the relationship between "sodium" and "hypertension." The agency considered these other issues to be peripheral, and they were addressed only if they related directly to interpretation of the relationship between sodium and hypertension.

In general, the Federal government documents (Refs. 38, 43, and 85), the Federal government workshop (Ref. 103), and the other documents (Refs. 62, 63, and 108) were in agreement that sodium intake specified as sodium chloride in the FASEB document) is related to the prevalence of hypertension. While the effect of the average change in blood pressure in response to sodium restriction is "small" in magnitude, much larger benefit can be expected for persons at greater risk because of already elevated blood pressure levels or because of a predisposition or sensitivity to the adverse effects of salt. Many of the documents noted that there is some indication that, in addition to benefiting many hypertensive individuals, reduced sodium levels may reduce blood pressures and associated risks in some normotensive individuals as well.

In research published subsequent to the documents described above, a few of the human studies showed no effect. However, most of the studies supported the previous conclusions of a link between sodium and hypertension. Thus, the more recent studies were

generally consistent with the conclusions reached by earlier government and authoritative reviews.

FDA tentatively concludes that, having reviewed the relevant, publicly available, scientific evidence, there is significant scientific agreement among experts qualified by scientific training and experience to evaluate claims on a relationship between sodium and hypertension that such claims are supported by the evidence.

2. Public Health Impact

The prevalence of hypertension in the U.S. population is very high, with about one in three adults classified as hypertensive (Ref. 85). As many as 58 million people in the United States have elevated blood pressure (SBP equal to or greater than 140 mm Hg and/or DBP equal to or greater than 90 mm Hg) (Refs. 23 and 38), and only one-quarter to one-third of these individuals have their blood pressure under control (Ref. 74).

Uncontrolled high blood pressure is a serious public health problem because it is associated with mortality from heart disease and stroke, which were ranked as the first and third leading causes of death respectively in the United States in 1987 (Ref. 43). In 1988, 35.3 percent of all deaths were attributable to heart disease and 7.0 percent to stroke (Ref. 82). Individuals with uncontrolled high blood pressure have seven times the risk of developing a stroke and three to four times the risk of developing CHD as persons with normal blood pressure levels (Ref. 74).

Though mortality risk is greatest for hypertensives, normotensives are also at risk, and the higher the blood pressure, the greater the risk (Refs. 69 and 114). A recent, followup, surveillance study of the men screened for the Multiple Risk Factor Intervention Trial (Refs. 68 and 114) showed age-standardized death rate among middle-aged (35 to 57 years of age) U.S. men to be directly proportional to SBP across all blood pressure ranges. Not only did hypertension appear to be a risk factor for premature death, but below average blood pressure appeared to have a beneficial effect on survival. The death rate among hypertensive men (SBP greater than 160 mm Hg) was 41.7 deaths per 1,000; the death rate among those with high normal blood pressure (SBP from 135 to 139 mm Hg) was 20.5 deaths per 1,000; and the death rate among those with low normal blood pressure (SBP from 115 to 119 mm Hg) was 14.9 deaths per 1,000. Because there is a continuum of risk across all blood pressure levels, reducing blood pressure has the potential to benefit the entire population.

In the adult U.S. population, the prevalence of hypertension varies with age, gender, and race (Refs. 27, 43, 57, and 62). High blood pressure and related risks increase sharply with age. Less than 1 percent of individuals under 18 years of age are hypertensive, whereas 23 percent of those from 45 to 64 years of age and 38 percent of those over 65 years of age are hypertensive (Ref. 81). Hypertension commonly occurs in males at a younger age than in females. However, as people age, the prevalence of hypertension increases more rapidly in women and eventually surpasses that of men (Ref. 57). The group with the highest prevalence of hypertension is non-Hispanic blacks, and both males and females are at risk (Refs. 27 and 57). In those over 65 years of age, 52 percent of blacks and 37 percent of whites are hypertensive (Ref. 81).

Changes over time in mean blood pressure and in the prevalence of hypertension have been estimated using data from three large national health surveys. These changes were estimated using an earlier definition of hypertension: SBP equal to or greater than 160 mm Hg and/or DBP equal to or greater than 95 mm Hg and/or currently taking antihypertensive medication (Ref. 27). Although the data from these surveys show that, between 1960 and 1980, the prevalence of hypertension among black adults decreased from 34 to 29 percent, this difference was not statistically significant. There was no decrease of hypertension among white adults during the 20-year period. Average SBP decreased by 5 and 10 mm Hg in white and black adults, respectively. The greatest improvement was among older adults. The data suggest a trend toward lower average blood pressure in the U.S. population that has been attributed to increased public awareness, diagnosis, and treatment. The prevalence of undiagnosed hypertension decreased from 52 to 29 percent, medical treatment of hypertension increased from 30 to 45 percent, and the proportion of individuals with hypertension whose condition was medically controlled increased from 39 to 52 percent.

Recognition of the continuum of mortality risk across all blood pressures prompted recent changes in the clinical definition of hypertension. The current definition identifies hypertension as SBP greater than 140 mm Hg or DBP greater than 90 mm Hg or currently taking antihypertensive medication. Based on this definition, DHHS, in its "Year 2000 Health Objectives for the Nation" (Ref. 74), established a goal for reducing uncontrolled high blood pressure such that at least 50 percent of people with high blood pressure would have their blood pressure under control, a 108 percent increase. Achievement of this goal is expected to have a major effect on reducing the number of deaths from CHD and stroke, two other Year 2000 objectives.

Blood pressure is regulated by a complex process involving multiple factors that are not well understood. Sodium intake, alcohol consumption, and obesity are considered the major dietary factors that influence the development of hypertension in genetically susceptible individuals (Refs. 38, 43, and 62). Nonpharmacological approaches to controlling hypertension have included sodium restriction, alcohol restriction, and weight control (Ref. 29). Thirty to 60 percent of hypertensives and 15 to 45 percent of normotensive individuals respond to sodium reduction and are considered "salt sensitive" (Ref. 116).

The most common source of dietary sodium in the U.S. food supply is sodium chloride or common table salt. The terms "salt" and "sodium" have frequently been used interchangeably although salt (sodium chloride) is only 39 percent sodium by weight. Additional food sources of sodium include sodium bicarbonate or baking soda, baking powder, monosodium glutamate, sodium nitrite, and sodium citrate. Additional sources of sodium include drinking water and sodium-containing drugs (Ref. 16).

In addition to providing sodium to meet nutrient needs of individuals, salt has important uses in foods. Salt is added to a wide variety of foods to enhance and improve flavor. In pickling brines and salted meats, salt helps retard spoilage by inhibiting bacterial growth. In food processing, sodium salts promote curd formation in cheeses, serve as leavening agents in chemically-leavened baked goods, control the growth of yeast in yeast-leavened baked goods, and help to solubilize muscle proteins in some processed meat products (Refs. 6, 7, 8, and 10). Some of the sodium used for these functions can be reduced without unduly affecting the final food product (Ref. 13).

Sodium intake is a small, but significant risk factor for high blood pressure. It has been estimated that reducing sodium intake by 100 mmol per day (2,300 mg) would correspond to an average reduction in SBP and DBP of 2.2 mm Hg and 0.1 mm Hg respectively, on a population basis (Ref. 37), resulting in a 4 percent reduction in CHD mortality

and a 6 percent reduction in stroke mortality each year (Refs. 69 and 114). Assuming a cumulative effect over time, it has been estimated that reducing sodium intake by 100 mmol per day (2,300 mg), from the age of 25 to 55, would correspond to a 16 percent reduction in CHD mortality and a 23 percent reduction in stroke mortality (Refs. 69 and 114). Other estimates suggest that a 50 mmol per day (1,150 mg) reduction in sodium intake, from the age of 50 to 59, would result in a 15 percent reduction in heart disease and a 26 percent reduction in stroke (Ref. 107).

Based on the weight of the evidence that high dietary sodium intake increases the prevalence of high blood pressure, several authoritative groups have recently recommended that Americans reduce or moderate their sodium intake: "Nutrition and Your Health—Dietary Guidelines for Americans" (Ref. 85), "The Surgeon General's Report on Nutrition and Health" (Ref. 43), and "Diet and Health—Implications for Reducing Chronic Disease Risk" (Ref. 62). "Diet and Health—Implications for Reducing Chronic Disease Risk" recommended limiting daily salt intake to 6 g or less (2,400 mg sodium). This recommendation serves as the basis for the proposed DRV for sodium in the proposal on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. Current consumption is estimated at between 3,000 and 6,000 mg sodium per day (Refs. 18, 34, 35, and 43), approximately 25 to 150 percent above the maximum level recommended.

It has been estimated that 90 percent of the sodium in foods is from added salt (75 percent added during processing and manufacturing and 15 percent added during preparation and consumption). Therefore, only 10 percent of dietary sodium is attributable to the natural salt and sodium content of foods (Refs. 34 and 35). Because approximately 90 percent of the sodium in foods is added, reduction in sodium consumption is an achievable goal.

FDA has long recognized that sodium is a risk factor contributing to high blood pressure, and the agency first outlined its position concerning sodium and hypertension in 1982 to 1984 in the proposed sodium claim and labeling regulation (47 FR 26580) and in the discussion on the GRAS status of salt (47 FR 26590). FDA concluded that sodium consumption should be reduced in the general population because sodium intake was in excess of biological requirements, that moderate sodium intake would have no adverse effects, and that a large portion of the population would benefit. The agency emphasized that the policy was intended for the general public so that consumers could make informed decisions about their diets.

FDA has monitored sodium labeling since the first Food Label and Package Survey (FLAPS) in 1976 to 1978 (Ref. 25), and sodium education initiatives were included as part of The National High Blood Pressure Education Program, begun in 1981 by FDA and NHLBI (Ref. 47). The labeling and education initiatives resulted in more sodium content labeling on foods (an increase of nearly 60 percent between 1978 and 1988) (Ref. 46), the introduction of more products with lower sodium levels by manufacturers (Ref. 56), greater public awareness of the relationship between sodium and hypertension (up from 12 to 34 percent between 1979 and 1982) (Refs. 47 and 56), an increase in the number of consumers who have seen sodium reduced products and in the number who have purchased such products (Ref. 56), lower sales of table salt (down by 13 percent) (Ref. 47), and an increase in sodium avoidance dieting (practiced by approximately 40 percent of survey population) (Ref. 78).

In conjunction with sodium content in the nutrition label and the use of sodium content claims, the sodium/hypertension health claims, described in this proposal, will provide additional assistance to consumers in implementing the dietary guidelines and in understanding the nature of the relationship between sodium and hypertension. These regulations will be supplemented by extensive, educational initiatives. Such efforts have proven effective in the past in encouraging responsive actions by manufacturers (Refs. 46 and 56), in increasing consumer awareness (Refs. 47 and 56), and in affecting consumer s purchasing habits and behaviors (Refs. 56 and 78).

In summary, because high sodium intake is related to the prevalence of high blood pressure, and because high blood pressure is related to increased risk of heart disease and stroke, reduction and moderation in sodium intake have the potential for having a significant impact on the health of the general U.S. population. Although average changes in salt and sodium intake are associated with changes in average blood pressure that are small in magnitude, the overall potential effect on health care costs and morbidity and mortality rates is quite significant. Persons who are sensitive to sodium would be expected to benefit significantly, and at the recommended levels, there is no apparent risk for those who are not sensitive to sodium Reductions in sodium intake are feasible within current dietary patterns, both through potential changes in food formulations and through the potential for altered consumer awareness and behavior in food selection and in decreased use of discretionary salt.

3. Safety

Minimum average adult requirements for sodium, under conditions of maximum adaptation and without active sweating, have been estimated to be 115 mg per day (Ref. 63). A safe minimum intake has been estimated to be 500 mg per day (Ref. 63), more than three times the minimum requirements. This estimate takes into account wide variations in patterns of physical activity and climatic exposure but does not include an allowance for large amounts of sodium loss from sweating. Current sodium intakes in the U.S. population are thought to be 5 to 10 times higher, well in excess of physiological needs (Refs. 18, 34, 35, and 43).

The DRV proposed for sodium (2,400 mg per day) represents a 20 to 60 percent reduction below current estimates of sodium intake (3,000 to 6,000 mg per day) (Refs. 18, 34, 35, and 43). The DRV is well in excess of the safe minimum intake, and NAS has noted that there is no known advantage in consuming large amounts of sodium (Ref. 63). Reductions in sodium intake, in response to Dietary Guidelines to use salt and sodium in moderation (Ref. 85), to the proposed DRV for sodium, or to sodium/hypertension health claims in this proposed rule, are unlikely to pose a safety risk given the large gap between current intakes (3,000 mg to 6,000 mg sodium per day) and minimum safe levels (500 mg sodium per day) and the wide margin between the proposed goal (2,400 mg sodium per day) and the minimum safe intake levels (500 mg sodium per day).

Sodium is naturally present in many foods, albeit frequently in small amounts. A diet that includes a variety of foods is likely to remain above the minimum safe intake level even without additional salt or sodium being added. Moderate sodium intake; below current consumption levels, is a reasonable public health objective for the general population. This policy would benefit a large segment of the population and would maintain adequate sodium intake for biological functions.

Recommendations to reduce sodium intake are likely to result in reduced chloride intake because sodium chloride, or "salt," is the most common

form of dietary sodium. Reduced chloride intake is not likely to pose a safety concern because dietary chloride deficiencies do not occur under normal circumstances, and the safe minimum intake of chloride was formulated jointly with sodium and salt minimum intakes (Ref. 63).

Of some concern is the loss of sodium as salt during periods of heavy sweating from high temperatures or vigorous physical activity (Ref. 30). Sodium losses can be significant under such conditions and tend to be more severe in individuals who are not acclimated to the temperature or conditioned to the level of activity (Refs. 20 and 30).

Illness can result from heat exhaustion, primarily as a result of salt depletion, and if accompanied by unreplaced fluid losses, can lead to potentially fatal heatstroke (Ref. 30). The concerns over excessive sweat losses led to recent experiments investigating the impact of dietary sodium on the adaptation of soldiers to high temperatures and vigorous exercise (Refs. 117, 118, and 119). Subjects consumed either 4 g salt (1,600 mg sodium) or 8 g salt (3,200 mg sodium) per day, and fluid losses were replaced frequently. Heat acclimation was safely achieved by all subjects, though subjects on the lower salt diet reported more symptoms of heat illness during the first few days, and Johnson (Ref. 118) recommended that higher sodium intakes may be beneficial during the first few days of heat acclimation.

Reports of heat exhaustion tend to involve isolated situations with excessive temperatures or extreme activity levels (Ref. 30). When making health policy recommendations, FDA must balance concerns about hypertension, which affects one third of the U.S. population, against safety concerns under conditions of extreme sweat losses. Heat acclimation was safely achieved on the controlled, low salt diet (1,600 mg sodium per day), and FDA is recommending a DRV for sodium (2,400 mg per day) that is well in excess of 1,600 mg per day. FDA's policy to encourage moderation in sodium intake provides for a wide safety margin. It is the agency's position that concerns about excessive sweat losses should be part of educational efforts aimed at groups that experience heavy physical exertion and especially at those who work with people under conditions of high temperature or vigorous exercise, such as military personnel, sports coaches, and officials involved in exercise programs in hot regions of the nation.

A few studies suggest that some individuals may respond to sodium reduction with blood pressure increases instead of decreases (Refs. 33 and 72). As with many physiological measurements, a heterogeneous distribution may be the result of random variation, especially because the magnitude of the blood pressure lowering effect is small. Additional studies are needed under controlled conditions to determine whether these results are significant and reproducible.

There are a few studies in which plasma lipids were associated with increased sodium restriction (Refs. 40, 49, and 89) and another study that was inconclusive (Ref. 2). The intervention periods in these studies were very short (1 week or less), and the sodium restriction was extreme (460 mg and 780 mg as compared with the 2,400 mg DRV recommended by FDA). FDA believes that these studies are so few in number, so short in duration and conducted under such extremely restricted conditions that they have no bearing on public health recommendations for the general public.

Between 1982 and 1984, FDA concluded that moderate sodium intake would not have any adverse effects on the general public (47 FR 26580). After reviewing the scientific evidence related to sodium and hypertension and the safety issues relevant to moderate dietary sodium, FDA reaffirms that moderate sodium intake is unlikely to pose a safety concern in the U.S. population. Recommendations to moderate sodium intake have been part of public health policy guidelines for more than 10 years (Refs. 9, 22, and 85) with no adverse effects. There is significant agreement among the authoritative documents that moderate sodium intake would not be harmful (Refs. 38, 43, and 62), and serious problems have not been observed in populations that traditionally consume low amounts of salt (Ref. 69). In addition, the review of the scientific evidence indicates that high sodium intakes pose a significant health risk to a large number of people (Refs. 43 and 62).

FDA welcomes any additional information or data on the safety of sodium and salt intake and will continue to monitor the safety implications of all public policy recommendations.

III. Provisional Requirements for Health Claims

A. Relationship

FDA is proposing in § 101.74 to authorize health claims on the relationship of dietary sodium and hypertension on food labels and labeling. The agency has identified several key points that it considers essential for helping consumers to understand this relationship. These points are made in § 101.74(a).

The definition of hypertension used in § 101.74(a) is taken from U.S. DHHS/PHS/NIH reports (Refs. 23 and 38). It defines hypertension as SBP of more than 140 mm HG or DBP of more than 90 mm HG. The regulation also distinguishes sodium from salt.

Proposed § 101.74(a) describes the relationship between sodium and hypertension. Based on its review of the available scientific evidence, FDA states that high sodium intake is related to the prevalence of hypertension and to the increase of blood pressure with age. The agency also states that low sodium intake is related to low prevalence of hypertension and to a low rise or no increase of blood pressure with age.

A substantial amount of human and animal data indicate that high potassium intake may be related to reduced blood pressure levels (Refs. 38, 43, and 62). In addition, high sodium-potassium ratios have been positively correlated with blood pressure levels (Refs. 43 and 62), and NAS (Ref. 62) noted that low sodium intake in combination with high potassium intake "is associated with the lowest blood pressure levels and the lowest frequency of stroke in individuals and populations." FDA considered including potassium intake information in sodium/hypertension health claims. However, because of time and resource constraints, the lack of evidence for a quantitative ratio, and safety concerns involving potassium supplementation and fortification (21 CFR 201.306), FDA at this time has limited the relationship statement to sodium and hypertension. This is the topic that FDA was directed to address in section 3(b)(1)(A)(vi) of the 1990 amendments.

B. Significance

In summarizing the significance of reductions and moderation in sodium intake relative to the reduction in the prevalence of hypertension in the general U.S. population and within the total dietary context, FDA has identified in proposed § 101.74(b) several key points that it considers essential for helping consumers in understanding this nutrient and disease relationship.

This section states that hypertension is a public health concern because it is a risk factor for CHD and stroke. This statement is based on the Surgeon General's Report (Ref. 43) and the NAS Report (Ref. 62). The recognition that there is a continuum of risk across the range of blood pressures, which is reflected in this provision, was

documented in the followup surveillance study of the men screened for the Multiple Risk Factor Intervention Trial (Refs. 68 and 114). The agency has included a statement from Dietary Guidelines on the prevalence of high blood pressure in the United States in this section to provide some indication of the magnitude of the problem and the number of Americans currently affected (Ref. 85).

Based on FDA's evaluation of the scientific evidence, proposed § 101.74(b) goes on to state that reduced sodium intake may benefit some but not all hypertensives and possibly some but not all normotensives. The range of percentages in § 101.74(b) of responsive hypertensive and normotensive individuals that respond to sodium reduction was taken from the Sullivan review (Ref. 116). The regulation recognizes, however, based on the Surgeon General's report (Ref. 43), the NAS report (Ref. 62), and "Dietary Guidelines" (Ref. 85) that there are no practical biological markers for identifying responsive individuals.

The regulation goes on to list the populations most at risk for hypertension and most likely to benefit from sodium reduction. These populations were identified in the Surgeon General's report (Ref. 43), the NAS report (Ref. 62), and the National Health and Nutrition Examination Survey (Ref. 27). It then lists the risk factors for hypertension other than sodium intake. These factors are mentioned in the Surgeon General's report (Ref. 43) and the NAS report (Ref. 62). The statement that the magnitude of the effect is "small" but statistically significant is based on FDA's evaluation of the scientific evidence, which is summarized in section II. of this document. Proposed § 101.74(b) goes on to cite the estimated magnitude of the change in blood pressure in response to a change in dietary sodium intake. The agency took this information from the conclusions of the INTERSALT study (Ref. 37). The estimated reductions in mortality cited in proposed § 101.74(b) were taken from the Stamler's analysis of the impact that the change in blood pressure would have on a population-wide basis (Refs. 69 and 114). This section concludes with recommendations for ways to reduce sodium intake, which were taken from "Dietary Guidelines" (Ref. 85), the Surgeon General's report (Ref. 43), and the NAS report (Ref. 62).

In discussing the magnitude of the effect of a change in sodium intake, the agency uses the words "estimate" and "approximate" to indicate that the values cited are based on the best information available and are close to but not identical to the actual and true values. FDA would consider changing these estimates only if newer estimates that were based on better data and that were significantly different from these values were presented to it.

C. General Requirements

In § 101.74(c)(1), FDA is requiring that for a food to bear a health claim on the topic of sodium and hypertension, it must meet the general requirements for health claims set forth in proposed § 101.14, published elsewhere in this issue of the **Federal Register**. Under this regulation, a sodium/hypertension health claim is prohibited if any of the specified disqualifying nutrient levels are exceeded. This requirement assures that sodium/hypertension health claims may not appear on foods and food products that contain 11.5 g or more of fat per reference amount commonly consumed, per label serving size, or per 100 g, 4 g or more of saturated fat per reference amount commonly consumed, per label serving size, or per 100 g, and 45 mg or more of cholesterol per reference amount commonly consumed, per label serving size, or per 100 g. There are also disqualifying criteria for sodium: 360 mg or more of sodium per reference amount commonly consumed, per label serving size, or per 100 g. However, to qualify to make a sodium/hypertension health claim under proposed § 101.74(c)(2), it must contain 140 mg or less of sodium per serving and per 100 g. A more thorough discussion of the criteria for identifying risk nutrients and the levels of these nutrients allowed in foods that bear health claims is included in the document on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

The requirement that a food must meet the "low sodium" definition to bear a sodium/hypertension health claim assures that such claims will appear only on foods and food products that contain 140 mg or less of sodium per serving and per 100 g. A more thorough discussion of the "low sodium" criteria and the rationale for the established sodium content levels is presented in the adjectival descriptor document published elsewhere in this issue of the **Federal Register**. Should additional considerations or evidence prompt the establishment of a different definition for "low sodium," only the descriptor document will require revision.

FDA used the qualifying criteria and the disqualifying criteria, described above, to identify foods that would likely be allowed to bear sodium/hypertension health claims (Ref. 93). Examples of foods qualifying for sodium/hypertension health claims include tuna and salmon without added salt; most fruits and vegetables, except for canned and frozen vegetables processed with salt; lowfat milk (2 percent or less fat), evaporated milk, lowfat yogurt with fruit, cottage cheese, ice milk, sherbet, and nondairy dessert toppings and cream substitutes; most flours, meals, grains, and pastas (except for egg pastas); and breakfast cereals such as shredded wheat, low sodium corn flakes, frosted shredded (mini-sized) wheat, puffed rice, sugar crisp, wheat germ, and many prepared cereals such as cream of wheat, cream of rice, and grits. In addition to these types of foods, several other food types would qualify for sodium/hypertension health claims including beverages such as carbonated soft drinks, coffee, tea, some fruit juices, drinks, and punches; some candies, cookies, baked goods, and icings; jams, jellies, and other sweeteners; and margarines and salad dressings without added salt. Given the minimal nutrition value of many of these foods, FDA requests comments as to whether they should be allowed to bear a health claim.

D. Relationship Statement

In the companion document on general principles for health claims published elsewhere in this issue of the **Federal Register**, FDA is proposing to require that claims present an accurate representation of the nutrient/disease relationship. Consequently, based on the scientific evidence regarding the relationship between sodium and hypertension, in § 101.74(c)(2), FDA is proposing that sodium/hypertension health claims must state that a low sodium diet is associated with lower blood pressure in some people, or that a high sodium diet is associated with higher blood pressure in some people. Because sodium reduction helps lower blood pressure in some but not all individuals, FDA is proposing that health claims acknowledge this fact. It is the agency's position that, without such an acknowledgement, the health claim would be misleading to those people whose blood pressures do not respond to sodium reduction.

E. Populations at Greatest Risk and Dietary Risk Factors

In § 101.74(c) (3), FDA is proposing to require that health claims acknowledge that many factors are associated with the development of high blood pressure. Thus, under this proposal, claims will be required to identify high risk populations

and dietary risk factors associated with hypertension. Those most at risk of developing hypertension, and consequently most likely to benefit from sodium restriction, include the elderly and those with family histories of high blood pressure, which may encompass individuals in specific racial or gender groups (Refs. 27, 43, 57, and 62). In addition to dietary sodium intake, alcohol consumption and obesity are identified, modifiable, dietary risk factors for hypertension (Refs. 43 and 62). Consequently, achieving weight control and reducing alcohol consumption have been recommended to assist in lowering blood pressure levels in the general population (Ref. 85). This additional information on populations and risk factors provides a broader context for the nutrient/disease relationship. Presentation of this information will ensure that consumers are aware that, in addition to sodium intake, there are many other factors that contribute to the development and control of hypertension.

IV. Optional Health Claim Information

A. Sodium as an Essential Nutrient

Sodium is an essential nutrient, and it is important that consumers include sodium in their total diets. On the other hand, NAS has recommended a safe, minimum level of 500 mg sodium per day (Ref. 63) and an upper limit of 2,400 mg sodium per day (Ref. 62). Elsewhere, in this issue of the **Federal Register**, FDA is proposing to establish a DRV for sodium of 2,400 mg per day for use in nutrition labeling. Yet, while some sodium is required for good health, excessive intake of sodium is unnecessary and may be harmful. For consumers to understand the significance of the sodium contained in a food that is qualified to bear a sodium/hypertension health claim in relation to the total daily intake goal, FDA considered requiring that sodium/hypertension health claims state that adults should consume at least 500 mg but not more than 2,400 mg sodium per day. However, in an attempt to keep health claims short and not overwhelm consumers with information, FDA is tentatively proposing in § 101.74(d) (1) to allow, but not to require, quantitative limits for sodium intake. The agency requests comments on whether this additional information will be beneficial to consumers, and whether it should be required on health claims or remain optional.

B. Consultation of Physicians

Many people are now aware of the dangers of high blood pressure (Ref. 56). With the ready availability of "do it yourself" machines to measure blood pressure levels in grocery stores and shopping malls and the common practice of having blood pressure levels checked each time an individual visits a physician or health professional, many people now know what their blood pressure levels are. FDA is concerned that some individuals may attempt to use the ready-availability of sodium labeling, and in particular sodium/hypertension health claims, to self-medicate or treat their hypertension without consulting a physician. For this reason, the agency considered requiring that health claims state that individuals with high blood pressure should consult their physician for specific medical advice and guidance.

Health claims that result from this regulation are intended for the general healthy public, however. Hypertension is a serious medical condition. It is FDA's view that any individual with an identified medical problem should be under the care of a physician, and that health claims are not intended as a substitute for individual patient/doctor care and especially not for individuals with identified medical diseases or health-related conditions. The agency has tentatively decided to include this information as an optional element, § 101.74(d) (2), and requests comments.

C. Sodium and Salt

FDA is proposing in § 101.74(d) (3), to allow manufacturers to use the term "salt" in addition to the term "sodium," both of which have been incorporated into "Dietary Guidelines" to use salt and sodium in moderation. Salt, which is 39 percent sodium by weight, is the most common source of dietary sodium and is a more familiar term to the general public than sodium. A recent FDA survey found that approximately 70 percent of the survey population generally understood that sodium and salt are related (Ref. 1982). Respondents frequently used "sodium" and "salt" interchangeably, which is technically incorrect but functionally effective because reducing salt intake also reduces sodium intake. The available evidence suggests, however, that sodium is the nutrient most clearly implicated in hypertension. Furthermore, in the proposed nutrition labeling document published elsewhere in this issue of the **Federal Register**, FDA is proposing to use the term "sodium" in the nutrition label to inform consumers of the sodium content of a food. Therefore, allowing use of the term "salt" in a sodium/hypertension health claim, rather than the term "sodium," would be potentially confusing to consumers because it would be inconsistent both with the nutrition label and with the strongest scientific evidence for linking dietary factors to hypertension. Conversely, using the term "salt" in addition to the term "sodium" would seem less likely to be misleading and may actually be useful to those consumers who are unfamiliar with the more technical term but who wish to reduce their sodium intake. Therefore, the agency is proposing to allow the use of the term "salt" if the term "sodium" is also used.

The agency is aware that a few recent studies and reviews suggest that the chloride ion, rather than or in addition to the sodium ion, may be important in the development of high blood pressure (Refs. 31, 48, 79, 87, and 92). Early studies with sodium chloride attributed blood pressure increases to the chloride ion; however, in the 1950's the sodium ion was considered to be more important (Refs. 14 and 43). Because many of the studies that investigated the relationship between sodium and hypertension used sodium chloride as the source of dietary sodium, these studies do not distinguish the effects of sodium from the effects of sodium chloride.

In the early and mid-1980's, studies with various sodium salts found that while sodium chloride raised blood pressure levels in sensitive individuals and animals, other sodium salts had no effect (Refs. 31 and 43). The recent studies (Refs. 79 and 87) are inconclusive with respect to chloride or indicate that the sodium and chloride ions have different roles. Recent reviews (Refs. 48 and 92) suggest that sodium and chloride together produce larger blood pressure changes, and that the ion that is associated with the sodium may greatly influence the subsequent blood pressure response. To date, the studies involving humans have been few in number and small in size. Consequently, at this time, there is insufficient information available for drawing substantive conclusions or for changing public health policy recommendations. Nonetheless, these results raise important questions, and FDA encourages additional research to determine the independent and combined effect of sodium and of chloride on blood pressure.

Sodium chloride is the major source of dietary sodium. Because FDA's policy of encouraging sodium reduction will also result in chloride reduction, the policy remains prudent regardless of whether sodium, chloride, or sodium chloride is determined to be important in relationship to hypertension. In addition, compliance is simplified because sodium content is identified on the labeling and

verification would involve detection of sodium alone. The agency requests data and comments on the appropriateness of selecting sodium rather than sodium chloride as the specified nutrient and on the appropriateness of allowing the term "salt" in addition to the term "sodium" on sodium/hypertention health claims.

D. High Blood Pressure and Hypertension

In § 101.74(d)(4), FDA is proposing to allow manufacturers to use the term "hypertension" in addition to the term "high blood pressure." Hypertension is a broader term which encompasses persons with untreated high blood pressure levels as well as persons with "normal" levels as a result of effective treatment. Hypertension is also the disease specified in section 3(b)(1)(A)(vi) of the 1990 amendments. The term "high blood pressure" means nearly the same thing as hypertension and individuals with controlled high blood pressure are frequently considered to have high blood pressure even though, technically, the blood pressure levels are in the normal range. The term "high blood pressure" is less technical and more familiar to consumers since blood pressure measurement is included in routine physical examinations, and blood pressure response is used to monitor the treatment of hypertension. Because simple, uncomplicated terminology is useful for assuring that health claims are clear and understandable to consumers, FDA is proposing to require the use of the term "high blood pressure" and to allow for the optional addition of the term "hypertension." The agency requests comments on the appropriateness of this proposed usage.

E. Additional Information

In § 101.74(d)(5), FDA is proposing to allow manufacturers to develop sodium/hypertension health claims that provide factual information about hypertension, including information contained in the "Relationship" and "Significance" statements included as part of the regulation and estimates of the number of people in the United States who are affected with high blood pressure or hypertension. It is FDA's policy that one of the purposes of health claims is to inform and educate the general public. Consequently, manufacturers should be allowed to include accurate, factual information in their health claims about the prevalence and seriousness of hypertension for the U.S. population. FDA is proposing to limit the additional information allowed to that contained in these statements because they are based on FDA's review of the scientific evidence concerning sodium and hypertension. By using an approximate estimate of prevalence, such as "one in three" adults, updating this estimate is likely to be less of a problem than if a more precise estimate were used.

F. Model Health Claim

FDA is including in proposed § 101.74(c) a model health claim on sodium and hypertension. The agency is including this model to assist manufacturers in formulating an appropriate claim.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

VII. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

Appendix to the Preamble—Consumer Health Message Summary—Sodium and High Blood Pressure

The following Appendix is a proposed consumer summary on sodium and hypertension. FDA solicits comments on this document as explained in the proposal on the general requirements for health claims published elsewhere in this issue of the **Federal Register**.

Appendix—Consumer Summary on Sodium and High Blood Pressure

Sodium and High Blood Pressure

Under the provisions of the recent Nutrition Labeling and Education Act of 1990, manufacturers may put clear information on the food label about the relationship between a nutrient, such as sodium, and a disease or health-related condition, such as hypertension. To prevent consumers from being misled, FDA allows only truthful label statements about diet and health relationships that are firmly supported by the current scientific evidence. There is agreement that the scientific evidence is strong enough to allow health claims about the relationship between sodium in the diet and hypertension.

Many consumers have said that health claims on food labels could be useful to them in making improvements in their diets. However, label space is often limited. Therefore, the label statement may refer to an attached pamphlet, or other adjacent labeling that provides additional information about the health claims that appear on the label of the food product itself.

In addition to allowing health claims about the relationship between sodium and hypertension, FDA is allowing health claims about the relationship between calcium and osteoporosis, saturated fat and cholesterol and cardiovascular disease, and fat and cancer. For information about these other diet and health relationships, write to: (to be supplied by manufacturer).

What is Hypertension?

Hypertension means high blood pressure, a condition in which your blood pressure goes up and stays above a normal level. Blood pressure measures the force of blood against the artery walls as the heart pumps blood through the body.

When you get your blood pressure checked, you are given two numbers. The first number (systolic pressure) is the force of blood against the artery walls when the heart beats. The second number (diastolic pressure) is the force on the artery walls when the heart relaxes between beats. Currently, people with systolic blood pressure of 140 or more millimeters of mercury (mm Hg) and/or diastolic blood pressure of 90 or more mm Hg are considered to have high blood pressure.

Why is There Concern About Hypertension?

In the United States, about one in three adults has high blood pressure. The disease affects approximately 58 million people and is a public health concern primarily because it is a major risk factor for death from coronary heart disease and stroke. Risk of death increases steadily as blood pressure increases. People with high blood pressure levels are at greatest risk, and the lower the blood pressure the lower the risk.

Hypertension occurs more frequently among persons with a family history of high blood pressure, elderly men and women of all races, black men and women, and men at an earlier age than women. In the U.S., hypertension and its related risks increase with age. Less than 1 percent of people below age 18, about 23 percent of people between ages 45 through 64, and about 38 percent of people over 65 have hypertension.

Primarily because of increased public awareness and treatment of the disease, hypertension has decreased somewhat in the U.S. population in recent years; nevertheless it remains a serious public health concern.

What Is the Cause of Hypertension?

In most people with high blood pressure the cause is unknown. Regulation of blood pressure by the body is a complex process that is not completely understood. Probably a variety of factors influence the development of hypertension in people whose heredity makes them susceptible to the disease.

Currently, scientists generally agree that three major diet-related factors have an effect on blood pressure—obesity or being overweight, excessive sodium in the diet, and excessive alcohol consumption.

The terms "salt" and "sodium" often are used interchangeably, although salt (which is sodium chloride) is only part sodium. Salt is our most common source of dietary sodium.

Studies of populations around the world provide the primary basis for associating dietary sodium with hypertension. In populations that have diets low in sodium, high blood pressure is less common than in populations with diets high in sodium. Scientists believe that dietary sodium is related to hypertension, and that diets which are lower in sodium will be associated with lower frequency of hypertension.

These studies also indicate, that in populations with diets low in sodium, blood pressure increases less rapidly or does not increase at all with age. This contrasts sharply with the blood pressure increases with age that are seen in the U.S. Less salt in the diet may be particularly appropriate for people who are at increased risk for developing hypertension in later life, such as blacks and those with either a family history of high blood pressure or current high normal blood pressure levels. The blood pressure of some—but not all—people will be lowered by decreasing dietary sodium. Persons whose blood pressure is decreased by lowering sodium are considered "salt sensitive." There is no practical way to identify the "salt-sensitive" people in the population, to predict who might develop high blood pressure, or to determine who will benefit from reducing dietary sodium. Authorities currently recommend that most people use salt and sodium only in moderation. Reduction in sodium will benefit those people whose blood pressure rises with high salt intake. No harmful effect is known to occur from moderately reducing dietary sodium.

Do Most People Eat Too Much Salt and Sodium?

Sodium is an essential nutrient that is required by the body. The National Academy of Sciences has set a minimum safe amount for adults of 500 milligrams (mg) per day under normal temperature and activity conditions. People who lose a lot of sodium and water through sweat need to drink extra water and in rare cases replace the lost salt. The Academy has stated that there is no known advantage in consuming large amounts of sodium in excess of body needs. Most Americans consume several times the minimum amount of sodium needed.

The U.S. Public Health Service has set a national health goal for the public to use salt and sodium in moderation. To do this, people are encouraged to prepare foods without adding salt, to avoid salt at the table, and to make a habit of purchasing foods that are low in sodium or modified to lower sodium content.

Which Foods Are Sources of Sodium?

Sodium in the diet comes from many sources. Small amounts of sodium are found naturally in many foods, so if you eat a variety of foods, you'll easily get the minimum safe amount.

However, your salt intake can increase dramatically depending on the choices you make. Salt is added for flavoring and preserving during processing of many foods, but products are often available in a "low sodium" version as well. Salt may also be added during cooking at home, or by yourself at the table. In addition to table salt, many substances added to foods, such as baking soda, baking powder, sodium nitrite, and monosodium glutamate (MSG), contain sodium.

A good way to learn about the amount of sodium in foods is to read nutrition labels. Most foods now have nutrition information on their labels. The amount of sodium in a serving of food is listed in milligrams. FDA has established "Daily Values" for several nutrients, including sodium, that are important in diet and health relationships. The daily value is intended to help consumers determine how a single serving of a food contributes to the total amount of nutrient for the day. The daily value for sodium is 2,400 mg, based on a report from the National Academy of Science. Therefore, a food that contains 600 mg sodium per serving would provide about one-quarter of the daily recommended value for sodium. When you add up the sodium from all the foods you eat in a day, it should total less than 2,400 mg.

What Do Label Claims About Sodium Mean?

In addition to the amount of sodium per serving on the nutrition label, you may see other kinds of claims about sodium on some food packages. There are two kinds of label claims—nutrient content claims and health claims.

Nutrient content claims may be made about the amount of sodium the food contains. For example, a food that contains 35 mg sodium or less per serving may be labeled "very low sodium." Foods that contain 5 mg or less of sodium per serving may be labeled "sodium free" or "no sodium," and foods that contain 140 mg sodium or less per serving may be labeled "low sodium." A reduced sodium claim on a food label indicates that the sodium content has been reduced by 50 percent or more compared to the regular product.

Some foods that are low in sodium may contain one or more nutrients that may increase the risk of a diet-related disease other than high blood pressure. For example, a low sodium food could be high in saturated fat which has a relationship to elevated blood cholesterol and heart disease. A content claim about sodium cannot be made on such foods without indicating the presence of the other nutrient, for example, "Low, sodium; see nutrition label for saturated fat content."

Health claims are those made about the relationship between the nutrient, sodium, and the disease, hypertension. Health claims of this type may appear only on foods that qualify as "low sodium." In addition, the food must not contain any other nutrient that FDA has determined increases the risk of a diet-

related disease or health condition other than hypertension. For example, a health claim could not appear on a "low sodium" food that contains a high amount of saturated fat, because saturated fat has a relationship to heart disease.

Many foods are eligible to make sodium and hypertension claims. For example, at least some products in each of the following categories of foods can make such claims: Fruits and vegetables; fruit juices and drinks; milk and dairy products; breakfast cereals; cereal grains (such as rice); pasta products (such as spaghetti); flours; legumes (peas and beans); nuts and seeds; and seafood.

Other Diet-Related Risk Factors for Hypertension

In addition to sodium, there are at least two other diet-related factors for hypertension over which a person has control—body weight and alcohol consumption. Increased body weight is related to increased blood pressure, and blood pressure falls when weight is reduced. Weight loss is recommended for all overweight persons, particularly those with hypertension. People who regularly consume large amounts of alcohol have higher blood pressure than people who don't drink or who drink only in moderation. Authorities recommend maintaining a healthy weight and drinking alcoholic beverages in moderation, if at all.

Facts to Keep in Mind

It's the total combination of foods that you eat regularly— both the kinds and the amounts—that's important in terms of good nutrition. Eating particular foods or one specific food isn't a magic key that will assure you have a more healthy diet.

Eating a healthy diet, in itself, doesn't guarantee good health. A healthy diet, however, is an important part of a healthy lifestyle that includes, for example, regular physical exercise, not smoking, not drinking alcoholic beverages to excess, and not abusing drugs.

In addition to what you eat, many factors may affect your own chance of developing a particular disease. Among these are your heredity, your environment, and the health care you receive. Our knowledge about most diet-health relationships is incomplete and will improve as scientific knowledge increases. However, enough is known today about some of these relationships to encourage specific dietary practices that are believed to be beneficial.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Ambard, L., and E. Beaujard, "Causes de L'hypertension Arterielle," *Archives Generales de Medicine*, 1:520–533 (1904).

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3. Select Committee on Nutrition and Human Needs, "Dietary Goals for the United States," 2d ed., U.S. Senate, 95th Cong., 1st sess., U.S. Government Printing Office, Washington, 1977.

4. World Health Organization, "Arterial Hypertension," Report of a WHO Expert Committee, Technical Report Series 628, World Health Organization, Geneva, 1978.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR Part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. Section 101.74 is added to subpart E to read as follows:

§ 101.74 Health claims: sodium and high blood pressure.

(a) *Relationship between sodium and high blood pressure.*

As used here, hypertension, or high blood pressure, means systolic blood pressure of greater than 140 millimeters of mercury (mm Hg) or diastolic blood pressure of greater than 90 mm Hg. Normotension, or normal blood pressure, is a systolic blood pressure below 140 mm Hg and diastolic blood pressure below 90 mm Hg. Sodium is specified here as the chemical entity or mineral "sodium" and is distinguished from sodium chloride or salt, which is 39 percent sodium by weight. The scientific evidence from epidemiological, clinical, and animal data establishes that high sodium intake is related to the prevalence of hypertension or high blood pressure and to the increase of blood pressure with age, and that low sodium intake is related to low prevalence of hypertension or high blood pressure and to a low rise or no increase of blood pressure with age.

(b) *Significance of sodium in affecting high blood pressure.* High blood pressure is a public health concern primarily because it is a major risk factor for mortality from coronary heart disease and stroke. There is a continuum of mortality risk that increases as blood pressures rise. Individuals with high blood pressure are at greatest risk, and individuals with moderately high, high normal, and normal blood pressure are at steadily decreasing risk. The 1990 "Dietary Guidelines for Americans" states that: "In the United States, about one in three adults has high blood pressure." The scientific evidence from clinical data indicates that reducing sodium intake lowers blood pressure and associated risks in some but not all hypertensive individuals; approximately 30 to 60 percent respond to sodium reduction. There is some evidence that reducing sodium intake lowers blood pressure and associated risks in many but not all normotensive individuals as well: approximately 15 to 45 percent respond to sodium reduction. There are no practical genetic markers to identify responsive individuals. The populations at greatest risk for high blood pressure, and those most likely to benefit from sodium reduction, include those with family histories of high blood pressure, the elderly of all genders and races, males because they develop hypertension earlier in life, and black males and females. Sodium intake, alcohol consumption, and obesity are identified risk factors for high blood pressure. On a population-wide basis, the indications from epidemiological and clinical data are that reducing the average sodium intake would have a small but statistically significant effect on reducing the average blood pressure. Estimates suggest that reducing sodium intake by 100 millimoles (mmol) per day (2,300 mg of sodium or approximately one rounded teaspoon of salt) would correspond to an average lowering of blood pressure of approximately 2.2 mm Hg systolic and 0.1 mm Hg diastolic. Because these are population-wide estimates, the magnitude of the effect for sensitive individuals would be greater. Estimates suggest that, for the age range from 25 to 55, a 100 mmol per day (2,300 milligrams (mg) per day) lower lifetime intake of sodium would correspond to a reduction in mortality rates of approximately 16 percent for coronary heart disease and 23 percent for stroke. In order to reduce sodium intake, individuals can choose foods with less sodium and salt, reduce the amount of sodium and salt used in food preparation and cooking, and reduce the amount of salt added at the table.

(c) *Specific requirements.* A food label or labeling may contain a sodium/hypertension health claim provided that:

(1) The health claim for a food or food product meets all the general requirements of § 101.14 for health claims.

(2) The health claim states that a low sodium diet is associated with or related to lower blood pressure in some people. Alternatively, the health claim can state that a high sodium diet is associated with or related to higher blood pressure in some people.

(3) The health claim identifies the populations at greatest risk of developing high blood pressure as being the elderly and those with family histories of high blood pressure and states that other dietary risk factors associated with high blood pressure include alcohol consumption and excess weight.

(d) *Optional information.* Sodium/hypertension in health claims may provide additional information:

(1) The health claim may state that sodium is an essential nutrient or necessary for good health, and that the total intake of sodium should be at least 500 mg per day but not more than 2,400 mg per day.

(2) The health claim may state that individuals with high blood pressure should consult their physicians for medical advice and treatment.

(3) In specifying the nutrient, the health claim may include the term "salt" in addition to the term "sodium".

(4) In specifying the disease, the health claim may include the term "hypertension" in addition to the term "high blood pressure".

(5) The health claim may include information from paragraphs (a) and (b)

of this section, which include summaries of the relationship between sodium and high blood pressure and of the significance of sodium reduction in affecting high blood pressure.

(e) *Sample health claim.* High blood pressure is associated with many factors, including a family history of the disease, growing older, being overweight, drinking too much alcohol, and diets high in sodium. A low sodium diet is associated with lower blood pressure in some people.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

TABLE 1.—INTERSALT STUDIES

Reference	Study design and duration	Subjects	Base diet	Other factors	Results	Assessment and comments
INTERSALT Cooperative Research Group (1988). (Ref. 37)	Cross sectional study. Sodium (Na) intake determined by single 24-hour urine collection blood pressure determined by average of 2 seated measurements. Repeated urine collections for 8% of subjects to estimate within-individual variability.	10,079 subjects from 52 population centers in 32 countries. (5,045 males, 5,034 females). (Goal of 200 at each center, 25 in each of 8 age and sex groups).	Normal diets ranging from 5 mg Na per day to 5,560 mg Na per day.	Single Na measurement does not assess previous or habitual Na intake habits. Subjects on antihypertensive medication included thereby reducing the effect of Na on blood pressure. Urine collection probably not complete in all subjects. Confounding factors: age, sex, body mass index, alcohol intake, and potassium intake. Significance sometimes lost after adjustment for confounding factors.	Within centers: Na significantly related to SBP and DBP. Across 52 centers Na significantly related to SBP, to DBP, and to changes in SBP and DBP with age. Across 48 centers: Na significantly related to change in DBP with age and significantly and negatively related to DBP. Estimated that 2300 mg less Na per day corresponds to lower SBP (2.2 mm Hg), lower DBP (0.1 mm Hg), and lower change of SBP (9.0 mm Hg) and DBP (4.5 mm Hg) with age from 25 to 45 years of age.	Large scale International Standard assessments Little data loss (approximately 3%). Study methods consistent within and across populations. Within center relationships and across center changes in relationships with age were consistent. Across center relationships depended on inclusion or exclusion of 4 population centers.
Elliott (1989) (Ref. 50)	INTERSALT study design. Analysis of normotensive subjects.	Normotensive subjects from INTERSALT population (SBP < 140 mm Hg, DBP < 90 mm Hg, not on antihypertensive medication).	Normal diets	Multiple regression analysis adjusted for age, sex, potassium intake, alcohol intake, and body mass index. Corrected for individual variability of Na excretion ("reliability") (see below).	Na intake significantly related to blood pressure: 2300 mg change in Na intake corresponded to - 2.10 mm Hg change in SBP after multiple regression analysis to adjust for confounding factors.	Regression coefficient similar to findings with the total INTERSALT population. Total population: 2300 mg change in Na intake corresponded to 2.17 mm Hg change in SBP.
Elliott (1989) (Ref. 51)	INTERSALT study design. Analysis of all INTERSALT data by age and sex.	10,079 subjects: (5045 males, 5034 females). (Goal of 100 males and 100 females from each of 52 centers, 25 in each age category: 20–29, 30–39, 40–49, and 50–59).	Same as INTERSALT	Multiple linear regression analyses in 52 centers, pooled, weighted, adjusted for potassium intake, alcohol intake, and body mass index, and adjusted for age or sex as appropriate. Corrected for individual variability of Na excretion ("reliability") by estimating the degree of regression dilution using data from 8% of subjects who returned and provided second set of data.	Within centers: Average Na intake related to SBP and DBP in men and in women, to SBP for men and women combined in 4 age categories, and to DBP in only the oldest age category. Across centers associations influenced by 4 centers with low Na intake.	Associations stronger for women than for men and for the older age categories.
Elliott (1989) (Ref. 52)	INTERSALT study design. Main results and implications for public health policy.	Same as INTERSALT	Same as INTERSALT	Some subjects were on antihypertensive medication which would give artificially low blood measurements and underestimate any effect of Na on blood pressure. Only simple adjustments were used to correct for bias toward zero. Some populations had been subjected to health campaigns to reduce Na intake which would underestimate current blood pressure effects due to previous habits.	The higher the center's median Na excretion, the steeper the slope of blood pressure with age.	Authors suggest that small clinical changes could result in large benefits to a population, especially in the cumulative effects over a lifetime. Authors conclude that the study gave "powerful *qualitative* tests . . . poor *quantitative* estimates of the size of these relationships."
Elliott (1989) (Ref. 53)	INTERSALT study design. Analysis of data from three United Kingdom centers (Belfast, Birmingham, and South Wales). Data collection in 1985.	598 subjects: (299 men, 299 women)	Normal diets Na ranging from 730 mg to 9,040 mg per 24 hours. Averages: Belfast: 3,470 mg Na per 24 hours. Birmingham: 3520 mg Na per 24 hours. South Wales: 3500 mg Na per 24 hours.	43 subjects excluded (41 for incomplete urine collection and 2 for pregnancy).	SBP positive and significantly related to Na in 2 of 3 centers ($p<0.05$) (Belfast, South Wales) and inconclusive in third. DBP relationship inconclusive in 3 centers.	Authors recommend modest increase in K and reductions in Na, obesity, and heavy alcohol drinking and suggest these lifestyle changes could result in downward shift of population blood pressure and prevalence of hypertension.

Hashimoto (1989)... (Ref. 54)	INTERSALT study design. Analysis of data from three Japanese centers (urban Osaka, rural Tochigi, semi-rural Toyama).	591 subjects: (295 men, 296 women)	Normal diets Average Na of 4,300 mg per 24 hours Averages: Osaka: 3,870 mg Na per 24 hours. Tochigi: 4,150 mg Na per 24 hours. Toyama: 4,890 mg Na per 24 hours.	9 subjects excluded for incomplete data. High within-individual variation. Public health campaigns to reduce Na intake resulted in declines in Na consumption, Blood Pressure, prevalence of hypertension, and stroke mortality. 16.7 normotensives and 47.4 hypertensives receiving medical treatment reported reducing salt intake.	SBP negative and significantly related to Na in 1 center ($p<0.001$). (Osaka), positive and significantly related to Na in 1 center ($p<0.05$). (Toyama) and inconclusive in third DBP negative and significantly related to Na in 1 center ($p<0.01$). (Osaka) and inconclusive in other two.	Authors recommend further reductions in Na, increases in K, and reductions in heavy drinking.
Mancilla-Carvalho (1989). (Ref. 58)	INTERSALT study design. Analysis of data from four remote populations with low ??? (NaCl) intake. (Yanomano and Xingu Indians in Brazil, rural Kenya, and rural Papua New Guinea).	731 subjects: Yanomano Indians: 195 subjects. Xingu Indians: 198 subjects. Papua New Guinea: 162 subjects Kenya: 176 subjects	Normal diets Median Na: tanomano Indians: 5 mg Na per 24 hours. Xingu Indians: 130 mg Na per 24 hours. Papua New Guinea: 620 mg Na per 24 hours. Kenya: 1,180 mg Na per 24 hours.	Average body weight low relative to other 48 centers. No or low average alcohol intake. Group variability largest in Kenya population. Authors noted that within-center association between Na and blood pressure was unlikely due to small variations in average Na and blood pressure. Adults were physically active and healthy with no signs of malnutrition or protein deficiency.	Four populations had lowest average blood pressure compared to other 48 centers (SBP of 103 mm Hg vs 120 mm Hg, DBP of 63 mm Hg vs 74 mm Hg). Four populations had little or no upward slope of blood pressure with age. Hypertension in 5% of Kenyan population and absent in other populations. Four populations had low average Na relative to other 48 centers (1-3 grams NaCl vs 9 grams NaCl).	Authors noted that when other centers had low average body weights and alcohol intake, but high Na intake (2,760 to 4,830 mg), the prevalence of hypertension ranged from 8 to 19%.
Mancilla-Carvalho (1989). (Ref. 59)	INTERSALT study design. Analysis of data from Yanomano Indians, a seminomadic population from the Brazilian, Amazon rainforests. Data collected July 1986.	195 subjects: (99 males, 96 females)	Normal diets Average Na of 21 mg per 24 hours. Range from 1 mg to 614 mg per 24 hours. Diet of local crops and game supplemented by wild fruits and insects. Banana and manioc staple foods. Little salt, refined sugar, alcohol, milk or dairy products in diet.	Low average body mass index, calcium intake, total fat and saturated fat. High K intake, fiber. No alcohol intake. Almost no obesity. Relatively high physical activity and endurance. No physical signs of evident malnutrition or protein deficiency. Na not considered in correlation analysis because nonnormal distribution made it inappropriate. May have eaten some food from investigators.	Average SBP 96.0 mm Hg (range from 78 to 128 mm Hg). Average DBP 60.6 mm Hg (range from 37 to 86 mm Hg). Low average blood pressure. No hypertension. No increases of blood pressure with age.	
Rose (1989) (Ref. 64)	INTERSALT study design. Summary of background, methods, and main results. Designed to apply highly standardized methods across varied populations, to examine major confounding factors, and to evaluate the relationships in individuals.	INTERSALT populations	Same as INTERSALT	Planned study to be large enough to observe an effect. Planned standardized methods to allow for appropriate pooling of results. Planned analysis methodology to deal with confounding factors. Planned random repeat urine collections to estimate within-individual variability ("reliability").	Na excretion significantly related to blood pressure in individuals and to rise of blood pressure with age.	2 years for planning, funding, and recruitment of centers. Regional training meetings in 1984-1985. Field work and laboratory analyses completed in 1987.

TABLE 2.—SODIUM/HYPERTENSION STUDIES

Reference	Study design and duration	Subjects	Treatment or intervention	Intake of test material	Base diet	Other factors	Results	Assessment and comments
Australian National Health and Medical Research Council Dietary Salt Study Management Committee (1989a). (Ref. 44).....	Double blind, placebo controlled, clinical intervention trial. 6 weeks: run-in phase. 8 weeks: diet phase. Subjects seen every 2 weeks and 24-hr urine provided at each visit. During diet phase, all subjects monitored and counseled to keep dietary Na intake to below 1840 mg Na per day. NaCl or placebo added to low Na base diet.	103 mildly hypertensive subjects (DBP: 90–100 mm Hg). (86 male, 17 female). (Average age: 58.4 years). Randomized into two groups.	Study population: 8 (10 mmol) slow release NaCl tablets per day. Control population: 8 placebo tablets per day.	1840 mg Na per day.	Low Na diet (< 1840 mg Na per day monitored by 24-hr urine collection and dietary counseling).	2 centers..... 8 subjects dropped out. Large range of individual variation SBP of study and control populations approached same value near end of study DBP of study and control populations approached each other but remained distinct at end of study. Confounding factors: age, sex, weight, initial blood pressure, center.	Blood pressure of low Na group reduced an average 6.1 (SBP) and 3.7 (DBP) mm Hg in the study population relative to 0.6 (SBP) and 0.9 (DBP) mm Hg reduction in the control population ($p<0.005$). Results remained significant after multi-variant analysis to adjust for age, weight, and initial blood pressure.	Sound methodology Skewed sex ratio, but approximately equal distribution to each group Dietary Na restriction produced heterogeneous response in individuals, but confirmatory studies in "responder" and "nonresponder" populations have not been done.
Australian National Health and Medical Research Council Dietary Salt Study Management Committee (1989b). (Ref. 45).....	Double blind, placebo controlled, clinical intervention trial. Continuation of previous study and study design to include crossover phase. 6 weeks: run-in phase. 8 weeks: diet phase 1. 8 weeks: diet phase 2.	88 mildly hypertensive subjects (DBP: 90–100 mm Hg). (73 male, 15 female). (Average age: 58.6 years). Randomized into two groups.	Study population: 8 (10mmol) slow release NaCl tablets per day. Control population: 8 placebo tablets per day.	1840 mg Na per day.	Low Na diet (< 1840 mg Na per day monitored by 24-hr urine collection and dietary counseling).	2 centers..... 15 subjects dropped out between two diet phases. 79 subjects completed study. Confounding factors: age, sex, weight, initial blood pressure, center, order of treatment.	Blood pressure of low Na group reduced an average 6.0 (SBP) and 4.1 (DBP) mm Hg in the study population relative to 0.1 (SBP) and 0.4 (DBP) mm Hg reduction in the control population ($p<0.001$). Blood pressure reduced an average 3.6 (SBP) and 2.1 (DBP) mm Hg in the NaCl diet phase vs the placebo diet phase. Differences independent of order of treatment. Statistical significance greater for DBP than for SBP.	Sound methodology.

TABLE 2.—SODIUM/HYPERTENSION STUDIES—Continued

Reference	Study design and duration	Subjects	Treatment or intervention	Intake of test material	Base diet	Other factors	Results	Assessment and comments
Dustan (1989). (Ref. 121)	Clinical intervention trial. Protocol 1: 3 days: Control phase, 4 days: Na depletion phase, 3 days: Na loading phase. Protocol 2: 3 days: Control phase, 3 days: Na loading phase, 4 days: Na depletion phase. Na determined by 24-hour urine excretion blood pressure determined 4 times per day.	Protocol 1: 69 normotensives and 21 hypertensives. Protocol 2: 27 normotensives and 19 hypertensives. 12 normotensives and 9 hypertensives participated in both protocols. Hypertensives were either untreated or had not received antihypertensive medication for at least 1 month.	Na depletion phase: Furosemide (1 mg per kg) taken as 2 divided doses. Na loading phase: Isotonic saline (3.88 mM NaCl per kg per day) supplied intravenously over 4 hrs.	Na loading phase: 90 mg Na per kg per day.	Controlled diets. Control phase: 3450 mg Na per day (assumed as diet since was not clear). Na depletion and loading phases: 210 mg Na per day.	Only Na loading performed intravenously which introduces variability. Low Na phase was extreme: Only 210 mg per day.	Protocol 1: Mean arterial blood pressure in hypertensives fell and rose with Na (116 to 104 to 110 mm Hg). Mean arterial blood pressure in normotensives remained stable throughout (84 to 83 to 81 mm Hg). Protocol 2: Mean arterial blood pressure in hypertensives and some normotensives rose and fell with Na (107 to 111 to 98 mm Hg and 83 to 87 to 82 mm Hg). Separate analysis of subjects who participated in both protocols suggested that sequence was not important.	Short study Low Na diet was extreme Population differed between two protocols. Means of administering Na differed between different phases.
Hypertension Prevention Trial Research Group (1990). (Ref. 124)	Intervention trial (parallel design) 3 years. Na determined by timed, overnight, urine collection blood pressure determined as average of 2 measurements Individuals received dietary counseling (once a week for 10 weeks, then every other week for 4 weeks, then every other month for the duration of the study).	841 subjects (DBP: 78–89 mm Hg) (no antihypertensive medication or evidence of cardiovascular disease) (65.3% male) (82.2% white) (Average age: 38.6 years) Randomized into 5 groups.	4 intervention groups and a control. 5 groups: 1) Reduce calories, 2) Reduce Na, 3) Reduce calories and Na, 4) Reduce Na and increase K, 5) Control.	N/A	Group goal of 50% reduction in average dietary NA Individual goal of less than 1610 mg/d.	Multipliers used to estimate 24-hour Na from timed, overnight, urine collections. All groups, including the control, had reductions in Na excretion and in blood pressure during follow-up. Largest sustained reduction in Na occurred on the group encouraged to reduce both NA and calories. Intervention populations blood pressure levels were lower than those of the control population.	Na reduction statistically significant at 6 months ($p = 0.002$) and marginal at 3 years ($p = 0.053$) blood pressure reductions generally below those of control population, but changes were not statistically significant.	Authors note that maintaining dietary changes in free-living populations is difficult.

TABLE 2.—SODIUM/HYPERTENSION STUDIES—Continued

Reference	Study design and duration	Subjects	Treatment or intervention	Intake of test material	Base diet	Other factors	Results	Assessment and comments
Koopman (1990). (Ref. 76)	Clinical intervention trial. Dietary counseling and feedback, follow-up from 3 to 18 months. Na determined monthly by 24-hr excretion blood pressure determined monthly. Participants asked to return for evaluation at 18 months.	28 mild to moderate hypertensives (average initial SBP: 144.5 mm Hg; average initial DBP: 95.4 mm Hg).	Dietary counseling and feedback monthly. Dietary counseling and Na and blood pressure measurements ended at 12 months.	N/A	Low Na diets encouraged.	7 subjects dropped out (4 for high DBP, 2 for suspected angina, and 1 for stroke). During 1st 3 months of study; participants had been divided into an intervention and a control group. Control group participants received dietary counseling from 3 to 12 months. Intervention group participants received counseling from 0 to 12 months.	Average Na decrease of 510 mg per 24 hrs ($p<0.05$). Average decrease in SBP of 3.7 mm Hg ($p<0.05$). Average decrease in DBP of 4.0 mm Hg ($p<0.01$). Na and blood pressure decrease during first 6 months then leveled off at lower values.	Small study. No untreated control group followed throughout.
Lasaridis (1989). (Ref. 55)	Clinical intervention trial. 2 days: adaptation period. 5 days: low Na diet. 5 days: high Na diet. Blood pressure (supine and standing) determined 3 times per day. Na determined by 24-hr urine excretion.	18 hypertensive patients. (10 males, 8 females). (Average age: 47.3 years). (Age range: 30–64 years of age).	N/A	N/A	Controlled low Na diet: 1150 mg Na per day. Controlled high Na diet: 4600 mg Na per day.	Blood pressure determined by automated device. Patients on high Na diet had an average increase in body weight of 1.3 kg ($p<0.01$). "Responders" (8 patients with a change in mean supine blood pressure >8 mm Hg). Low-renin patients (6 patients with plasma renin activity <3 ng/ml per hr during Na deprivation). "Responders" were virtually all low-renin patients.	Average Na rose from 1180 to 4440 mg Na per day ($p<0.001$). Average supine blood pressure rose 6.7 mm Hg (from 102.7 to 109.4 mm Hg) ($p<0.001$). Average standing blood pressure rose 5.0 mm Hg (from 107.6 to 112.6 mm Hg) (not significant).	Small study Not clear if patients were receiving or had received antihypertensive medication. Low-renin patients appeared to respond better to changes in Na.
Luft (1990). (Ref. 79)	Placebo controlled crossover trial. Phase 1: 4 days: low Na diet. 7 days: low Na diet plus mineral water with NaCl or NaHCO3. Phase 2: 4 days: low Na diet. 7 days: low Na diet plus mineral water with NaHCO3 or NaCl. All urine collected. Phase 1 and Phase 2 conducted a month apart.	10 mildly hypertensive subjects (blood pressure >140/90 mm Hg) and 10 normotensive subjects (blood pressure <140/90 mm Hg) (10 male, 10 female) (10 black, 10 white) (Average age: 36 years) Randomized into two groups.	NaHCO3 Phase: 3 liters per day of mineral water containing NaHCO3 (26.2 mmol/l Na, 33.03 mmol/l HCO3, and 4.23 mmol/l (Cl). NaCl Phase: 3 liters per day of mineral water containing NaCl (26.2 mmol/l Na and 36.07 mmol/l Cl).	1810 mg Na per day.	Controlled low Na diet containing 1380 mg Na per day. All foods prepared and eaten at research center. Same food eaten for each meal every day during both phases of study.	Blood pressure determined by automated device. NaHCO3 mineral water contained 12.69 mmol Cl per day. Base diet contained 60 mmol Cl per day. NaCl increased calcium excretion whereas NaHCO3 did not.	NaCl intake period: Blood pressure did not change in hypertensive or normotensive subjects. NaCHO3 intake period: SBP decreased by 5 mm Hg in hypertensive subjects ($p<0.05$). SBP did not change in normotensive subjects. DPB did not change in hypertensive or normotensive subjects.	Small sample size NaCl and NaCHO3 may differ in their effects on blood pressure.

TABLE 2.—SODIUM/HYPERTENSION STUDIES—Continued

Reference	Study design and duration	Subjects	Treatment or intervention	Intake of test material	Base diet	Other factors	Results	Assessment and comments
MacGregor (1989). (Ref. 122)	Double blind, placebo controlled, crossover trial. 2 months: observation, 4 weeks: low Na diet phase, 1 month: 1st diet phase, 1 month: 2nd diet phase, 1 month: 3rd diet phase, 12 months: follow up. Diet phases included total daily diets of 1150, 2300, and 4600 mg Na. Blood pressure determined as average of 5 measurements. Na determined as average of 2 24-hr urine collections.	20 subjects with mild hypertension (DBP: 90–110). (11 men, 9 women). (15 whites, 5 blacks). (Average age: 57 years). (Age range: 42–72 years).	1150 mg Na phase: 16 placebo tablets per day. 2300 mg Na phase: 7 (10 mmol) slow release NaCl tablets plus 9 placebo tablets per day. 4600 mg Na phase: 16 (10 mmol) slow release NaCl tablets per day.	1150 mg Na phase: 0 mg Na per day. 2300 mg Na phase: 1610 mg Na per day. 4600 mg Na phase: 3680 mg Na per day.	Low Na diet (690–1150 mg Na per day) monitored by 24-hr urine collection and dietary counseling.	Excluded patients with renal failure, ischaemic heart disease, cerebrovascular disease, and those taking oral contraceptives or other drugs. Weight increased as Na increased, but change was not significant. 16 to 20 (1 moved, 3 medicated) controlled blood pressure by salt restriction alone for the year following the study (Na of 1420 mg per 24 hr, SBP of 142 mm Hg, DBP of 87 mm Hg).	Na in 3 phases was 1130, 2480, and 4370 mg per 24-hr. SBP in 3 phases was 147, 155, and 163 mm Hg. DBP in 3 phases was 91, 95, and 100 mm Hg. Average change in blood pressure from lowest to highest Na intake was 16 mm Hg SBP and 9 mm Hg DBP ($p<0.001$).	Blood pressure differences were not affected by the order in which the Na intake was altered. Necessary to have some salt-free products (i.e. salt-free bread) in order to reach the dietary Na intake of 690–1150 mg Na per day.
Mascioli (1991). (Ref. 109)	Double blind, placebo controlled, crossover trial. Phase 1: 4 weeks: NaCl or placebo capsules. Phase 2: 4 weeks: placebo or NaCl capsules. Phase 1 preceded by 2 weeks of testing and 8 weeks of dietary counseling to achieve low Na diet. 2 week washout period (placebo capsules) between phases. Low Na diet continued throughout.	48 normotensive subjects. (SBP<150 mm Hg, DBP: 80–89). (47 white, 1 black). (79% male)..... (Average age: 52 years) Randomized into two groups.	Intervention phase: 6 (16 meq) NaCl capsules per day Control Phase: 6 placebo capsules per day.	2210 mg Na per day.	Low Na diet (<805 mg Na per timed overnight, 8-hr urine excretion assessed prior to Phase 1 by 5 consecutive overnight urine collections below 805 mg Na).	23% of initial participants excluded for high urine NA levels. 2 subjects dropped out. Blood pressure measured every 2 weeks (twice at each visit) 8-hr urine measured at beginning of Phase 1 and at end of each phase. Subjects lost weight and blood pressure dropping during diet only phase.	Average SBP 3.6 mm Hg higher during NaCl treatment period as compared with placebo period ($p<0.001$). Average DBP 2.3 mm Hg higher during NaCl treatment period as compared with placebo period ($p<0.005$). 65% and 69% of participants experienced an increase of SBP and DBP, respectively, when on NaCl capsules as compared with placebo capsules.	Sound methodology Estimated 3–6 mm Hg increase in SBP and 2–4 mm Hg increase in DBP associated with 2300 mg increase in Na intake.

TABLE 2.—SODIUM/HYPERTENSION STUDIES—Continued

Reference	Study design and duration	Subjects	Treatment or intervention	Intake of test material	Base diet	Other factors	Results	Assessment and comments
Mtabaji (1990). (Ref. 80)	Clinical intervention trial. 3 days: control phase. 7 days: diet phase. One group on low Na diet, other on normal diet plus Na as consomme soup. Blood pressure determined daily. Na determined by 24-hr Na excretion.	30 normotensive Tanzanian black male subjects Randomized into two groups.	High Na group: 250mmol NaCl per day as consomme soup.	High Na group: 5750 mg Na.	Control phase: Diet of unspecified Na content. Low Na group: 1150 mg Na per day. High Na group: Normal diet of unspecified Na content.	Blood pressure determined by automated device. Ages of participants not specified.	Significant difference between two groups within 4–5 days ($p<0.001$). Low Na group: Na of 1200 mg per day. Mean arterial blood pressure fell from 87 to 81 mm Hg. High Na group: Na of 7750 mg per day. Mean arterial blood pressure rose from 86 to 89 mm Hg.	Control diet and normal diet of unknown Na content. Single population: High Na diet phase was excessively high in NA (7750 mg per day).
Smith (1988). (Ref. 41)	Cross sectional study. Part of Scottish heart health study. Data collected from 1984–1986. Na intake determined by single 24-hr urine collection. Blood pressure determined by average of 2 measurements.	7354 subjects from 22 districts in Scotland (3754 males, 3600 females). (Age range: 40–59 years) Subjects chosen at random.	N/A	N/A	Normal diets	Single Na measurement does not assess previous or habitual Na intake habits. 74% response rate, 17.5% excluded (generally for failure to provide urine). 1.6% excluded due to antihypertensive medication. Confounding factors: age, body mass index, pulse rate, alcohol consumption, potassium intake.	Weak, positive correlation between Na and blood pressure in both sexes. Na correlation with SBP 0.025 for males and 0.055 for females. Na correlation with DBP 0.026 for males and 0.052 for females. Na not independently significant after multivariant analysis.	Large study population. Single community (Scotland).

TABLE 2.—SODIUM/HYPERTENSION STUDIES—Continued

Reference	Study design and duration	Subjects	Treatment or intervention	Intake of test material	Base diet	Other factors	Results	Assessment and comments
Staessen (1988). (Ref. 42)	Cross sectional intervention trial. 5 years (1979–1985). Mass media campaign to avoid salt directed mainly at women in one town. Control town was observed. Urinary NA excretion and blood pressure determined at beginning and end of intervention.	Intervention town of 12,000 and control town of 9,000 Belgian inhabitants. 2211 subjects examined (5 and 10% random sample at baseline in control and intervention town, respectively; doubled at follow-up). Previous participants excluded from follow-up. Data from 1697 subjects analyzed. (777 males, 733 females) with and without 187 subjects on antihypertensive medication.	Intervention town (IT): Leaflets sent to all homes, posters displayed, radio and newspaper ads run. Active support from Town Council, local health officials and practitioners, and insurance organizations. Local bakers and restaurants asked to prepare low-salt foods. Women's clubs, health education courses, and children's homework targeted. Control town (CT): Salt not mentioned as a health hazard.	N/A	Normal diets	Data from teens excluded (464 subjects). Data excluded if urine volume or creatinine excretion outside limits (50 subjects). Blood pressure determined as average of 10 measurements collected at 2 home visits 2–5 weeks apart. Na determined by 24-hr urine extraction. Baseline and follow-up data taken on different subjects.	The trends in Na, SBP, and DBP in men and women were similar between the two towns except for Na in women which was significantly lower in the IT than in the CT. Na changes ranged from +180 mg in females in CT to −410 mg in females in IT. SBP changes ranged from −4.4 mm Hg in males in CT to −9.1 mm Hg in females in IT. DBP changes ranged from +1.8 mm Hg in males in CT to −2.8 in females in IT.	Large range of variation in results affects interpretation (eg.: change in Na in females in control town was + 180 ±210 mg). No independent assessment of information available to subjects in control town between 1979 and 1985 regarding Na and health hazards. Inconclusive.
Stamler, R. (1989). (Ref. 70)	Intervention trial 5 years. Intervention subjects: Extensive dietary and lifestyle counseling varying from 2 visits per week initially to 4 visits per year. Control subjects: 2 visits per year Blood pressure measured 2 times per year Na from urinary excretion measured 1 time per year.	201 hypertension prone subjects (high normal DBP: 85–89 mm Hg) or (high normal DBP: 80–84 plus 10–49% overweight) and/or (rapid resting pulse rate >80 beats per min). Randomized into two groups (102 intervention subjects and 99 control subjects).	Intervention goals: 1) Reduce daily NA intake, 2) Reduce alcohol intake, 3) Reduce overweight, 4) Increase moderate physical activity.	N/A	Goal of <1800 mg Na per day. 13% of intervention subjects achieved Na intervention goal. Average Na intake reduced by 24% in intervention group (drop from 3980 mg/day to 3040 mg/day) vs 6% in control group (drop from 4300 mg/day to 4060 mg/day)($p<0.001$).	Multiple interventions. Blood pressure measure at worksite and at office and worksite measurements used for comparison. 24-hr NA estimated from timed, 8-hr Na excretion and multipliers. Statistically significant changes in 3 of 4 interventions: NA intake, alcohol intake, and weight reduction. Statistically significant relationship with blood pressure in one of 4 interventions: weight reduction.	19% of control subjects and 9% of intervention subjects developed hypertension (DBP >90 mm Hg or medication). SBP: Reduction of 2.6 mm Hg (from 122.5 to 119.8 mm Hg) in intervention group vs 1.3 mm Hg in control group (from 122.7 to 121.5 mm Hg). DBP: Reduction of 1.3 mm Hg (from 82.5 to 81.2) in intervention group vs 0.1 in control group (from 82.6 to 82.5 mm Hg). Relationship between Na and blood pressure not independently significant.	Appropriate statistical tools used. Low dropout rate: 87% participating at least 4 years.

TABLE 2.—SODIUM/HYPERTENSION STUDIES—Continued

Reference	Study design and duration	Subjects	Treatment or intervention	Intake of test material	Base diet	Other factors	Results	Assessment and comments
Takemori (1989). (Ref. 71)	Cross sectional study Na intake determined by spot urine. Blood pressure determined by single measurement. Data collected in 1985.	7,441 Japanese females from 88 urban and 81 rural municipalities including all prefectures in Japan. (3933 urban subjects, 3508 rural subjects). (3 age groups between 40 and 69 years of age).	N/A	N/A	Normal diet averaging 3720 mg Na per day.	History of being hypertensive or on antihypertensive medicine not considered. Confounding factors: age, height, weight, potassium.	Increase of 2300 mg Na per day related to increase of 4.5 mm Hg SBP (urban: 4.1 mm Hg, rural: 4.9 mm Hg) and an increase of 1.6 mm Hg DBP (urban: 1.2 mm Hg, rural: 2.0 mm Hg).	Spot urine and predictive equations used to estimate 24-hr Na adds to uncertainty of results. Single population.
Trials of Hypertension Prevention (TOHP) Collaborative Research Group (Abstract) (1991). (Ref. 123)	Clinical intervention trial. Investigation of 7 nonpharmacological interventions in persons with high normal blood pressure. Checked at 6, 12, and 18 months into study.	2182 subjects with high normal blood pressure. (DBP: 80-89 mm Hg). (Age range: 30-54 years) randomized to 1 of 8 groups.	7 interventions (3 lifestyle changes for 18 months, 4 nutrition supplements for 6 months) and 1 control). 1) weight loss and exercise, 2) NA restriction, 3) stress management, 4) calcium supplementation, 5) magnesium supplementation, 6) potassium supplementation, 7) fish oil supplementation, 8) control.	None	None	None	39% reduction in Na at 18 months. SBP 1.5 mm Hg lower at 18 months (p=0.05). DBP 0.8 mm Hg lower at 18 months (p=0.07).	Authors suggest that weight loss and Na restriction are the most promising nonpharmacological interventions for hypertension control.

TABLE 3.—SODIUM/HYPERTENSION META-ANALYSES

Reference	Study design and duration	Subjects	Other factors	Results	Assessment and comments
Cutler (1991) (Ref. 94)	Meta-analysis of 23 randomized clinical trials published before January 1990. Analyzed separately for hypertensives, normotensives, and total subjects.	Total: 23 trials with 1536 subjects. Data for hypertensive and normotensive subjects analyzed separately and together.	Excluded trials with confounded designs. Excluded 2 trials for Na intake outside the usual ranges for Na. Magnitude of results was reduced slightly when inverse variance weights were included. All results statistically significant except for DBP in normotensives after including an adjustment for inverse variance weights.	Hypertensives: Net reductions in Na ranged from 1290 to 2410 mg. Average pooled reductions in blood pressure were 4.9 mm Hg (SBP) and 2.6 mm Hg (DBP). Normotensives: Net reductions in Na ranged from 370 to 3910 mg. Average pooled reductions in blood pressure were 1.7 mm Hg (SBP) and 1.0 mm Hg (DBP). Totals: Net reductions in Na ranged from 370 to 3910 mg. Average pooled reductions in blood pressure were 2.9 mm Hg (SBP) and 1.6 mm Hg (DBP).	Studies used a variety of different methodologies (unstandardized). Selected only randomized trials which eliminates selection bias. Authors indicate there is evidence for a dose-response relationship between Na and blood pressure.
Elliott (1991) (Ref. 97)	Meta-analysis of 14 observational studies in 16 populations. Only studies that provided 24-hr urine and blood pressure data and published quantitative regression or correlation estimates.	12,503 subjects (7099 men, 6136 women)	Excluded studies that compared hypertensives with normotensives. Excluded studies that just reported significance without quantification. Data corrected for within-individual variability in Na ("reliability") using INTERSALT estimate. 2 studies of only men, 1 study of only women, 2 studies of only combined data for women and men combined.	Reduction of 2300 mg Na related to reduction in SBP of 3.7 mm Hg and in DBP of 2.0 mm Hg. Regression coefficients somewhat larger in women than in men.	Variety of study designs (unstandardized methodology).
Frost (1991) (Ref. 100)	Meta-analysis of 14 published studies of blood pressure and Na intake. 24 hour Na excretion. One blood pressure measurement. 24 hour intake of NA adjusted due to common underestimation.	12,773 people from Europe, Asia, and the United States.	None	2 mm Hg decrease in blood pressure for every 100 mmol decrease in 24 hour NA intake. Weak effect within populations—reduced Na intake reduced blood pressure slightly. Unclear how study controlled for confounding factors. One of three studies suggesting that Na reduction reduces SBP and the risk of mortality due to hypertension.	Variety of study methodologies (unstandardized).
Law (1991a) (Ref. 106)	Meta-analysis: 12 developing 12 developed communities Cross sectional studies	47,000 people from 24 communities.	Developed versus developing communities. Confounders: Potassium, alcohol, and body mass linked to Na. These varied between, but not within, the two groups. Blacks excluded from study because blood pressure in these communities were higher than for communities with similar Na intake. The effect was measured in both developing and developed communities.	Blood pressure varied according to intake. The change in blood pressure was relative to the age and existing blood pressure. It appeared that there was not a lower Na threshold below which no effect was measured.	Variety of study methodologies (unstandardized).
Law (1991b) (Ref. 107)	Meta-analysis of 78 published studies that recorded the effect of salt restriction on blood pressure. Variable duration: Researchers subdivided the data from studies that recruited both subjects with high blood pressure and subjects with normal blood pressure to allow separate assessment of the effect of salt restriction for each category.	Not stated	Some of the trials were not randomized which could introduce bias.	Salt reduction lowered blood pressure in persons with high blood pressure and in those with normal blood pressure. In people aged 50–59, a reduction in daily Na intake of 50 mmol (about 3 g salt), after a few weeks, lowered SBP by an average of 5 mm Hg and by 7 mm Hg in those with high blood pressure DBP was lowered by about half this amount.	Variety of study methodologies (unstandardized). Authors suggest that the effect of moderate dietary salt reduction on mortality from stroke and ischemic heart disease would be substantial. Authors concluded that the effect of salt reduction on blood pressure was larger than previously reported. Unclear exactly how authors controlled for confounding factors in this study.

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21 CFR Parts 5, 20, 100, 101, 105, and 130

[Docket No. 91N-0219]

RIN 0905-AD08

Regulatory Impact Analysis of the Proposed Rules to Amend the Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Regulatory impact analysis statement.

SUMMARY: The Food and Drug Administration (FDA) is publishing herein the regulatory impact analysis (RIA) that it has prepared under Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354) on the costs and benefits of the food labeling regulations that FDA is currently proposing to amend. FDA is issuing these proposals (published elsewhere in this issue of the **Federal Register**) in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and as part of the Secretary of Health and Human Services' (the Secretary's) food labeling reform initiative. The agency has prepared this comprehensive RIA document for these proposals because, when taken together, they constitute a major rule.

DATES: Written comments by February 25, 1992.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Richard A. Williams, Jr., Center for Food Safety and Applied Nutrition (HFF-303), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0271.

SUPPLEMENTARY INFORMATION: FDA is publishing herein its RIA of the proposed rules to amend the food labeling regulations. This document analyzes both the costs and the benefits, including the impact on small businesses, of FDA's proposals (published elsewhere in this issue of the **Federal Register**) to reform the food label in response to the 1990 amendments and the Secretary's food labeling initiative. This analysis was prepared by the Economics Section of the Office of Compliance in FDA's Center for Food Safety and Applied Nutrition (CFSAN).

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has developed one comprehensive RIA that presents the costs and benefits of all of the food labeling proposals taken together. FDA requests comments on the RIA.

I. Introduction

The 1990 amendments amend the Federal Food, Drug, and Cosmetic Act (the act) to expand the coverage of nutrition labeling to all food products (except meat and poultry), produce more ingredient labeling, regulate health claims, and standardize nutrient content claim definitions and serving sizes. The 1990 amendments require that the nutrition information on both the food label and on eating establishment menus be readily understandable by the public. These changes to the food label are the most comprehensive changes to be proposed in 53 years. FDA has proposed implementing regulations for the 1990 amendments and estimated the costs and benefits of the proposed changes and regulatory options within the act. However, even before the 1990 amendments were enacted FDA believed that the food label could be improved and was engaged in proposing a series of similar regulations.

In order to evaluate the need for Federal intervention, FDA examined the market for food label information and found that less than the optimal amount of nutrition information was being produced because consumers cannot, independently, determine the nutritional quality of food, thus leading to insufficient incentives for manufacturers to reveal the nutrient content of their products or produce nutritious food. FDA undertook two studies to determine the costs and benefits of these proposed regulations, by engaging a contractor, Research Triangle Institute (RTI). These studies were done over a period of 3 years under the direction of the Economics Section of CFSAN.

A. Costs of the 1990 Amendments

The cost study consisted of both interviews with food manufacturers and a mailed survey. The result was a generic model which can be applied to any regulation mandating a label change. Categories of costs include administrative, analytical, printing, inventory, and reformulation. Administrative costs are management costs which are often high because of the prominence of the food label as an advertising tool for packaged foods. Analytical costs are costs of testing products for nutrient composition to comply with labeling provisions. Printing costs are the costs of printing new labels which may be either glue-on labels or the food package itself. These costs may include redesign costs where extensive labeling changes are undertaken. In the model, estimates of printing costs take into account normal firm relabeling.

Inventory costs are the costs of disposal of existing labels where firms have inventories that outlast the compliance period, i.e., the period of time between issuance of a final rule and its effective date. Inventories of labels, both glue-on labels and packages, range from only a few months to well over 10 years in the food industry. The last cost category reformulation includes the costs of reformulating products and introducing new ones in response to labeling regulations and market testing those products. No estimate of these costs is given because they depend on marketing decisions and are impossible to predict. Moreover, they do not result directly from these proposed rules. Regardless, FDA expects a substantial benefit to be derived from such reformulations, which are likely to make foods more nutritious. In all cost categories, except administrative costs, the costs of relabeling products produced and labeled in foreign countries cannot be separated from those produced and labeled domestically. Thus, administrative costs considered are domestic costs only, and printing, inventory, and analytical costs are considered multinational.

FDA estimates that about 17,000 domestic food manufacturers and 257,000 labels will be affected by the regulations promulgated in response to the 1990 amendments. In addition, approximately 96,000 food service firms might be required to alter their menus if they are not in compliance with health claims or descriptors regulations. The majority of the costs will occur in the first year. Recurring costs are assumed to continue 20 years into the future and are discounted back to the present at a rate of 5 percent.

The individual regulations may be divided into the following separable categories: (1) Mandatory ingredient labeling for standardized foods and certified colors; (2) "voluntary" (see section III.E. of this document) labeling

of raw fruit, vegetables, and fish; and (3) all other labeling regulations including mandatory nutrition labeling. The first category, mandatory ingredient labeling for standardized foods and certified colors, is separable from the other actions because it will take effect almost 2 years prior to mandatory nutrition labeling. Costs for these provisions, as proposed, are $128 million.

Voluntary labeling of raw fruit, vegetables, and fish is separable from all other provisions of the 1990 amendments because it affects supermarkets, not food manufacturers. Costs have been estimated to be between $117 to $155 million for this provision.

All other labeling regulations will become effective at the same time including percent juice labeling, mandatory nutrition labeling, nutrient content claims definition, health claim labeling, format changes and others. These costs to food manufacturers are estimated to be as high as $1.3 billion, depending on the compliance period chosen.

In addition, there could be costs to some restaurants and other food service establishments to reprint menus not in conformance with nutrient content and/or health claim regulations. For those firms wishing to continue use of these statements following publication of the final rules for these regulations, there could be additional costs of analytical testing and, possibly, nutrition information printing. These costs have been preliminarily estimated to be $116 million.

Total costs of the 1990 amendments, excluding the voluntary supermarket labeling, are approximately $1.5 billion. If the agency opted to allow an additional 6 months or an additional year to the compliance period provided for by the statute, total costs would decrease to $.8 billion and $.6 billion, respectively.

B. Benefits of the 1990 Amendments

The benefits of the 1990 amendments include decreased rates of cancer, coronary heart disease (CHD), osteoporosis, obesity, hypertension, and allergic reactions to food. As consumers are given more informative labeling in a better format, uncertainty over the ingredient and nutrient content of the foods they now eat will decrease and some consumers will select more nutritious, healthier foods. Also, with creation of consistent metrics and definitions such as standardized serving sizes and adjectival nutrient content claim definitions by which consumers can judge the nutritional aspects of foods, manufacturers will compete to reformulate their products into healthier foods. Thus, even those consumers who may be unaware of the diet/health revolution may inadvertently eat a better diet.

The model chosen to estimate these benefits focused on the two largest health problems, cancer and CHD (Ref. 24). This model involved the following three-step estimation process:

(1) Estimate changes in consumer purchase behavior and resulting changes in nutrient intakes as a result of receiving new nutrient information about foods.

(2) Estimate the changes in health states that would result from consumers' changes in nutrient intakes, particularly for reduced incidence of cancer and CHD.

(3) Estimate the value of changes in health states in terms of life-years gained, number of cases and deaths avoided and the dollar value of such benefits.

The estimate of benefits was obtained from the Special Dietary Alert program (SDA) (Ref. 1), a special program done by FDA in conjunction with Giant Food, Inc., which measures actual consumer response to new nutrition information. Reductions in the amount of cancer cases and early deaths were estimated to occur as a result of reduced total fat intake after a lag of 10 years. CHD reductions were estimated to result from lowered serum cholesterol as a result of decreases in saturated fat and cholesterol intake. Over the 20-year period the regulation is estimated to prevent about 39,100 cases of cancer and heart disease, of which, 12,900 would have resulted in death, yielding 80,900 life-years gained. The monetary value of the benefits (number of life-years saved) of this regulation is estimated to be $3.6 billion (discounted at 5 percent over a 20-year period). Valuing benefits based on the number of lives saved would raise this value to $21 billion (discounted at 5 percent over a 20-year period).

To put these estimates into perspective, the maximum health changes resulting from "perfect" diets were estimated by comparing the average nutrient intake of men and women in the U.S. with Daily Reference Values (DRVs). These numbers were then adjusted to reflect only FDA regulated foods. This estimate is a measure of all potential benefits to be derived from consumers eating a healthier diet while maintaining their current consumption of meat and poultry. The results indicate that if all consumers were to adopt "perfect diets" from FDA-regulated foods, 500,000 cases of CHD and cancer resulting in 213,000 premature deaths would be avoided over the next 20 years.

FDA has determined that these proposed rules are major rules as defined by Executive Order 12291, and have significant effect on a substantial number of small entities as defined by the Regulatory Flexibility Act.

II. Purpose of the Regulatory Impact Analysis

The purpose of this RIA is to determine the economic effects of the proposed rules to amend the food labeling regulations in 21 CFR parts 5, 100, 101, 105, and 130. This analysis is intended to satisfy the requirements of an RIA as specified in Executive Order 12291 as well as the requirements for a Regulatory Flexibility Analysis as specified in the Regulatory Flexibility Act.

Guidance for determining whether these actions constitute a "major" impact under Executive Order 12291 includes the criteria in Section 1b of the Executive Order itself, and informal supplementary guidance provided by The Department of Health and Human Services's (DHHS) Handbook on Developing Low Burden and Low Cost Regulatory Proposals, dated February 1984. Guidance for determining whether this action creates "a significant impact on a substantial number of small entities" includes definitions in section 601 of the Regulatory Flexibility Act (Pub. L. 96-354) and informal supplementary guidance provided by the DHHS Handbook.

FDA requests comments concerning the various considerations and conclusions it used in determining the quantitative or qualitative costs and benefits for this proposed regulation.

III. Description of the Proposed Action

FDA is responding to the 1990 amendments to amend the act. The 1990 amendments provide FDA specific authority to issue regulations concerning food labeling. The rulemaking actions analyzed in this document are as follows:

A. Mandatory Status of Nutrition Labeling and Nutrient Content Revision

These actions require nutrition labeling on most foods that are meaningful sources of nutrients and revise the list of required nutrients and the conditions for listing nutrients in nutrition labeling. The 1990 amendments specify that nutrition labeling shall include information on:

(1) The total number of calories derived from any source, and the number of calories derived from fat;

(2) The amount of total fat, saturated fat (i.e., saturated fatty acids), cholesterol, total carbohydrate, complex carbohydrate, sugars, dietary fiber, total protein, and sodium; and,

(3) Any vitamin, mineral, or other nutrient required to be placed on the label before October 1, 1990:

In response to a Citizen's petition, the agency is also proposing to allow the use of the protein digestibility-corrected amino acid scoring method for foods intended for persons of all ages, except infants.

FDA is further proposing that, when a food contains insignificant amounts of more than one-half the required nutrients, a simplified format shall be used.

B. Revision of Reference Daily Intakes and Daily Reference Values

This action updates the U.S. Recommended Daily Allowances (RDA's) used in food labeling and replaces the term U.S. RDA with Reference Daily Intake (RDI). The agency is also proposing a separate set of DRV's for fat, fatty acids, cholesterol, carbohydrate, fiber, sodium and potassium, substances for which RDAs have not been set.

C. Declaration of Ingredients

FDA is proposing the following changes in regard to the label declaration of ingredients:

(1) Require label declaration of certified food colors;

(2) Require label declaration of all ingredients in standardized foods;

(3) Require that when more than one sweetener is used in a product, all sweeteners be declared together by common or usual names in descending order of predominance by weight, in parentheses in the list of ingredients, following the collective term "sweeteners;"

(4) Require the declaration of all protein hydrolysates by their common or usual name, including the identification of the food source;

(5) Require identification of a caseinate as a milk derivative in foods labeled as nondairy foods; and,

(6) Require that labels bear an explanatory statement that the list of ingredients is in descending order of predominance.

FDA is also proposing two voluntary provisions including:

(1) Provide a uniform format for voluntary declaration of percentage ingredient information, and

(2) Permit inclusion of the food source in the names of several of the sweeteners prescribed by food standards.

The agency is also responding to comments by advising sellers that wax or resin coatings on fresh fruit must be labeled with the specific wax (currently required) name or the proposed collective names. This language emphasizes regulatory enforcement of an existing requirement. FDA advises that the information must be placed in a conspicuous place where the produce is displayed in bulk but retailers are allowed sufficient flexibility to choose the specific location. Producers or distributors are required to supply the information to retailers through labeling accompanying the produce. In the case of resins, a statement of function must appear in the labeling. The 1990 amendments exempt produce sold in small open containers.

D. Percent Juice Labeling

The agency is proposing to:

(1) Require declaration of the total percentage of juice and the percentage of each represented juice on both single and multiple juice beverages;

(2) Require percentages of juice to be expressed in one percent increments. For multiple juice beverages, if manufacturers declare one or more individual juices or picture them on the vignette, or represent their presence in any other way, the percent of these individual juices will have to be identified. If major modifications (i.e., changes in the color, taste, or other organoleptic properties) have been made to a juice to the extent that the original juice is not recognizable, or if its nutrient profile has been diminished, then the juice may not count toward the total percent of juice. FDA believes it is appropriate to include juices with minor modifications such as acid-reduced orange juice. If the beverage contains no fruit or vegetable juices, and either fruit or vegetables are pictured on the vignette or the labeling, or the color or flavor of the product implies that a juice is present, then it must be labeled as containing zero percent juice;

(3) Describe where the percentage label statement must be on the container; and

(4) Provide directions on how to name various classes of juices and juice beverages, e.g., "diluted grape juice beverage."

E. Labeling of Raw Fruit, Vegetables, and Fish

The 1990 amendments require that FDA:

(1) Develop guidelines for food retailers for the "voluntary" nutrition labeling of raw agricultural commodities and raw fish;

(2) Identify the 20 varieties of raw fruit, vegetables, and fish most frequently consumed to which the guidelines apply; and

(3) Define substantial compliance with respect to adherence by food retailers to the guidelines.

F. Serving Sizes

This action will ensure that serving sizes are standardized to reflect the amount of the food customarily consumed. In this action FDA will establish mandatory declarations of serving sizes to be used on the nutrition panel which will reflect either the customary amount consumed, e.g., 6 ounces (oz) or the customary unit of consumption, e.g., a slice of bread.

G. Nutrient Content Claims

This action establishes definitions for and proper conditions for use of terms describing cholesterol content, fat content, sodium content, calorie content, and other nutrient content claims on packaged food labels and on food service establishment menus and menu boards. Also, FDA will establish a procedure for handling petitions for inclusion of a claim in a brand name through informal rulemaking.

H. Nutrition Label Format

The 1990 amendments state that implementing regulations "shall require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet." FDA will propose to revise the nutrition label format.

I. Health Claims

FDA is proposing general procedures that cover the regulation of health claims on both packaged food labels and on food service establishment menus and menu boards. The 1990 amendments require that the agency issue regulations in 10 diet/health topic areas determining whether health claims may be made in conjunction with specific food components. In addition, FDA will establish a procedure for handling petitions for new claims.

IV. Market Failure

The *Regulatory Program of the United States Government—1990 to 1991* (Ref. 40) notes that agencies must evaluate the existence of a "market failure" which will be addressed by Government action. According to Leftwich, "A market failure is said to occur when either quantity or quality of a good

produced in an unregulated market differs from what is purported to be the social optimum" (Ref. 2). Because there is no objective standard by which the performance of markets may be compared, it may be more instructive to present a comparison of how freely operating markets respond to various interventions and contrast the respective levels of transactions costs. This "comparative institution approach" (Ref. 3) utilizes a positive analysis to predict the outcomes of different institutional sets of property rights (Ref. 4). In this approach, both the unattenuated market and administrative institutions have strengths and weaknesses. Markets are assumed to be low cost transmitters of information to coordinate economic activity between producers and consumers, thereby lowering "identification" costs. The strength of administrative solutions lies in taking advantage of scale economies to enforce difficult or ambiguous property rights.

When "a large number of people are involved and * * * the costs of handling the problem through the market or the firm are high, governmental administrative regulation should lead to an improvement in economic efficiency" (Ref. 5). That is, "* * * a particular good or service may be available at a fixed cost which, if borne by all of those who benefit from it, would cost no more than each beneficiary would be willing to pay. However, if the beneficiaries are so numerous that coordination among them is expensive, either in terms of locating and exacting payment from class members or in terms of measuring relative benefits and, hence, relative charges to each, then potential buyers may forego, wholly or in part, an otherwise desirable good or service" (Ref. 6). In short, when the transaction costs of effecting a purchase or sale are high, the market may produce costly misallocations and redistributions of social resources. When this occurs, government intervention may produce a superior outcome to the market outcome (Ref. 7).

A more probable market failure in food labeling, however, is the problem of asymmetric information that characterizes a market for "lemons" (Ref. 8). Since consumers cannot judge nutritional quality for themselves, manufacturers are unable to charge a premium for high "quality foods" so that only the foods with the lowest nutritional value are produced and marketed.

V. Economic Impact Analysis

A. Costs of the Proposed Actions

This section describes and estimates the costs of the 1990 amendments. The discussion of costs includes a discussion of sources of data, industries affected, and quantitative estimates of the various requirements. Although most costs are a direct result of specific provisions of the legislation and may not be changed, FDA has cost altering options with respect to the time firms have to comply with mandatory nutrition labeling, whether or not eating and drinking establishments are affected by the regulation, and other, lesser options.

1. Sources of Information

The anticipated cost to manufacturers covered by these regulations was estimated using a compliance cost model for food labeling created for FDA by RTI (Ref. 9). RTI conducted their study of food labeling costs in two phases. In the first phase, RTI discussed actual and hypothetical labeling policies with 30 firms of various sizes and four-digit standard industrial classifications (SICs).

Firms were encouraged to estimate the effort (resource use) and, when possible, the cost to complete different compliance activities. From the information gained in the first phase, RTI was able to produce a model of the cost of food labeling. The first phase also produced information on administrative activities.

In the second phase of the project, RTI and FDA surveyed over 350 firms to collect more printing and label inventory data. The sampling frame defined each target population as all firms within a given industry. Within each target population, the sample was stratified to reflect proportional allocation among four firm size categories: Small (less than (<) 10 employees), medium (10 to 99 employees), large (greater than (>) 99 employees), and unknown size. Firms were strongly encouraged to respond to the survey, but participation was voluntary. RTI used the survey data to update and improve the parameter estimates for the compliance cost model developed during the interview phase of the project.

The source for the estimate of the number of food processing firms is Dun and Bradstreet's Electronic Yellow Pages, which is a comprehensive data base of U.S. businesses. Food manufacturers were identified using the SIC on a four-digit level. These firms were further categorized to exclude those producing only foods regulated by the U.S. Department of Agriculture (USDA) to estimate the number of firms producing food products subject to FDA regulations. Precautions were taken in order to avoid double counting. FDA found there were some problems using this data base, such as a lack of frequent updates. However, the alternative, which is Census data, counts establishments rather than firms. Also, very small firms are not included in the Census. Therefore, FDA found the Dun and Bradstreet data base to be the better choice.

The estimate of the number of products (77,000) was derived from A.C. Nielsen sales data obtained from sampling 21,000 grocery stores with annual sales of more than $4 million each. These stores account for approximately 80 percent of the sales of packaged foods. This estimate of total food products was refined in order to include only those food products affected by FDA regulations (USDA-regulated foods were removed from the estimate). This estimate includes both domestic and foreign products for sale on U.S. grocery shelves. Although food product labels are required to list either the address of the distributor or manufacturer of the food, it is impossible to determine the location (foreign or domestic) of the manufacturer who will bear the four costs (administrative, printing, inventory, and analytical), or some portion of them. The estimate of the number of food labels (defined as stock keeping units (SKUs)) (257,000) was also derived using the data from the A.C. Nielsen data base. This estimate also includes both domestic and foreign labels for sale on U.S. grocery shelves. A separate label is applied to each brand of food in a specific size which may be further divided by flavor, color, etc. Products are also differentiated by distinct recipes and manufacturers. In other words, if a manufacturer produces a strawberry jelly and a grape jelly, he produces two products. If the jellies are each sold in two sizes (32 oz and 16 oz jars), the manufacturer has four distinct labels SKUs. In order to estimate SKUs, it was necessary to estimate the number of both branded and private labels. The latter was accomplished by estimating the relationship between the number of private brand labels and sales of private labeled products.

2. Costs of Compliance

The costs of a labeling regulation are those associated with: (1) Administrative activities, (2) analytical testing, (3) label printing, (4) label inventory disposal, and (5) reformulation (including market testing).

These costs depend on the attributes of the regulation itself and on the characteristics of the industry being regulated. Relevant attributes of the regulation include the scope of the regulation, the intricacy of the regulation, the complexity of the expected label change, and the length of the compliance period. The characteristics of the particular industry that affect the magnitude of the costs include:

(1) Firm size
(2) Label type
(3) Printing process(es)
(4) Normal label redesign frequency
(5) Average label inventory
(6) Average label order and its cost
(7) Number of products

a. *Scope of the regulation.* All food processing industries will be affected in whole or in part by these actions. Table 1, which follows, indicates which industries are affected by the various actions.

An internal review of labeling of standardized foods using the Food Packaging and Labeling Survey (FLAPS) (Ref. 15), showed that in all likelihood, all standardized foods already contain full ingredient labeling. Therefore, for cost estimation purposes, only those products which contain artificial colors will be affected by the ingredient labeling requirements (effective in November, 1991). However, cheese (SIC 2022), ice cream (SIC 2024), and milk (SIC 2026) are exempt from labeling colors.

TABLE 1.—INDUSTRIES AFFECTED BY LABELING REGULATIONS

		(Phase I regulations)			(Phase II regulations)
SIC	Industry name	Standard foods, ingredients, and colors labeling	Percent juice labeling	Raw fruit, vegetables, and fish labeling	Mandatory nutrition labeling, format, nutrient content claims
2021	Creamery butter				X
2022	Cheese, natural and processed				X
2023	Dry, condensed and evaporated milk products.	X			X
2024	Ice cream and frozen desserts				X
2026	Fluid milk				X
2032	Canned specialties				X
2033	Canned fruits and vegetables	X	X		X
2034	Dehydrated fruits, vegetables, and soups	X			X
2035	Pickles, sauces, and salad dressings	X			X
2037	Frozen fruits and vegetables	X	X		X
2038	Frozen specialties	X			X
2041	Flour and other grain mill products	X			X
2043	Cereal and breakfast foods	X			X
2044	Milled rice and byproducts				X
2045	Flour mixes and refrigerated doughs	X			X
2046	Wet corn milling				X
2051	Bread, cake, and related products	X			X
2052	Cookies and crackers	X			X
2053	Frozen bakery products except bread	X			X
2061	Sugar cane mill products and byproducts				X
2062	Refined cane sugar and byproducts				X
2063	Beet sugar				X
2064	Candy and other confectionery products	X			X
2066	Chocolate and cocoa products				X
2067	Chewing gum	X			X
2068	Nuts and seeds				X
2075	Soybean oil mills				X
2079	Edible fats and oils, nec [1]	X			X
2083	Malt and malt byproducts				X
2086	Bottled and canned soft drinks	X	X		X
2087	Flavoring extracts and syrups	X			X
2091	Canned and cured fish and other seafoods				X
2092	Fresh or frozen prepared fish and other seafood.	X			X
2095	Roasted coffee				X
2096	Potato chips and similar products	X			X
2098	Macaroni and spaghetti				X
2099	Food preparations, nec [1] dietary supplements grocery stores.	X		X	X

[1] Not elsewhere classified.

All products which purport to contain fruit or vegetable juices are affected by the percentage juice labeling requirements.

The 1990 amendments specifically exempt certain products from nutrition labeling but not from health claim regulations:

(1) Foods that contain insignificant amounts of all the nutrients and food components required within nutrition labeling (insignificant is defined as that amount which allows a declaration of zero in nutrition labeling);

(2) Foods sold by businesses having annual gross sales of not more than $500,000 or annual gross sales of food of not more than $50,000;

(3) Foods served in restaurants or similar food service establishments and foods that are principally processed and prepared in a retail establishment and are ready for consumption; (FDA may choose to require nutrition labeling with a nutrient content or health claim.)

(4) Foods sold by grocery stores that are offered for sale from self-service salad bars and deli or bakery counters; (FDA may choose to require nutrition labeling with a health claim.)

(5) Foods in small packages (must provide nutrition labeling at point-of-purchase);

(6) Medical foods;

(7) Infant formula;

(8) Foods shipped in bulk form; and

(9) Foods supplied for institutional food service use only.

The 1990 amendments specifically exclude restaurant foods from the requirement for nutrition labeling. However, the agency believes it has the authority to issue regulations requiring restaurants that choose to make health claims or nutrient content claims to adhere to the requirements for such claims, including nutrition labeling. In 1989, there were a total of 536,796 commercial food service establishments (CFEs), as illustrated in table 2 (Refs. 10 and 11). In addition, there were 172,131 institutional and 1,256 military food service establishments. Institutional establishments include employee food service, school and hospital cafeterias, penal institutions, nursing homes, and transportation food service. However, only institutional establishments which actually sell food are potentially affected such that prisons, for example, would not be covered.

TABLE 2.—FOOD SERVICE ESTABLISHMENTS

Eating places	331,926
Drinking places	37,227
Lodging places	27,199
Retail hosts	106,397
Food contractors	15,739
Recreation and sports food service	12, 414
Other (vending/catering/mobile)	5,894
Total commercial food service	536,796
Institutional feeding	172,131
Military feeding	1,256
Total food service establishments	710,183

Nutrient content and health claims regulations applicable to food service establishments would apply to all forms of labeling in those establishments: Menus, signs, and posters. FDA believes that posters and other types of menu boards in restaurants are generally changed frequently, at least every 6 months. FDA requests input as to the validity of this assumption. Assuming menu boards are changed frequently, the cost of changing these items will not be considered in this assessment. This analysis will therefore consider only the cost of the currently proposed regulations on changing printed menus and lighted menu boards using preprinted plastic strips to indicate menu items, and the cost of any implied nutrition testing. Approximately 294,051 CFEs may be assumed to have some sort of commercially printed menu, as indicated in table 3. Not all categories of food service establishments can be assumed to have written menus as many establishments may use menu boards and signs. Although there are no data on the number of food service establishments using written menus, a rough estimate of this number may be generated by listing only those establishments in categories for which it seems reasonable to assume written menus. This has been done in table 2. The number of establishments in each category are taken from "The Food Service Industry: 1989 in Review (Ref. 10). Note that the agency assumes only 36 percent of the total number of limited menu restaurants in 1989 have written menus. This corresponds to the portion of all limited menu restaurants falling into one of the following three categories in 1987:

(1) Table, booth, counter seat with waiter/waitress service;

(2) Take out or drive through; and

(3) Other (Ref. 11).

TABLE 3.—ESTIMATED TOTAL NUMBER OF NONINSTITUTIONAL AND NONMILITARY COMMERCIAL FOOD SERVICE ESTABLISHMENTS HAVING PRINTED MENUS

Restaurants and lunchrooms	160,859
Limited menu restaurants (incl. fast food)	52,658
Bars and taverns	37,727
Lodging places	27,199
Store restaurants	16,108
Total	294,051

One of the most significant developments in the restaurant industry has been the shift toward healthier options on the menu. For example, in 1990, the National Restaurant Association (NRA) found 34 percent of the menus submitted to its annual menu contest have "light and healthy" menu sections, compared to only 12 percent in 1985 (Ref. 12). Similarly, in a survey of its members, the NRA found that 55 percent of respondents "featured or promoted items because of their specific health or nutrition benefit (Ref. 13)." Any nutrient content claim or health claim not in compliance would require a change in the printed menu. If it is conservatively assumed that none are in compliance, then 55 percent is an approximation of the proportion of the total number of menus likely to be affected by the current proposal. There are several potential problems encountered with using this survey to estimate the current use of health claims and nutrient content claims. First, the survey was not designed to be a representative sample of the entire industry, only of the membership of the NRA. Secondly, this approach will not reveal where a single respondent may have had such nutrient content claims or health claims on more than one menu, i.e., on both lunch and dinner menus. Thirdly, it will not reveal which CFEs currently using such terms will be in compliance with regulations governing those claims and nutrient content claims.

Finally, there is no way to determine from the survey which restaurants currently using nutrient content claims and health claims will continue to do so following publication of the final rules. Firms may discontinue use of these terms both because many recipes and types of nutrient content claims will not qualify under the proposed guidelines, and because of the additional costs of analytical testing. Those firms choosing not to continue to use these terms will have to change their menus, but may not have to undergo nutrient analysis.

Under the preceding assumptions, an estimated 161,728 CFEs will be affected potentially. Assuming, further, that 30 percent of the CFEs under consideration would normally change their printed menus within the time allowed by the regulation, 113,210 CFEs will have to change their menus involuntarily as a result of the current regulations. FDA recognizes that the above assumptions are speculative and FDA requests information regarding these issues.

To generate a more accurate assessment of the number of firms affected, FDA requests information concerning the proportion of firms using health claims or nutrient content claims with respect to nonmeat and nonpoultry dishes, the number of menus affected, and the number of such firms that are already in compliance with FDA regulations governing those claims and nutrient content claims.

In addition, a certain proportion of those CFEs not using printed menus, but using menu boards, will also be affected. Since these menu boards typically do not contain as much information as

printed menus, the agency assumes that a smaller proportion of these establishments use nutrient content and/or health claims. As an example, FDA assumes 5 percent of CFEs using menu boards (i.e., not assumed to have printed menus), or 12,137, use health claims or nutrient content claims.

Although nutrition labeling for fresh produce and fish is "voluntary," it will become mandatory if FDA determines that "substantial compliance" has not been met. Because FDA has determined that it is not necessary that all firms comply for substantial compliance to be achieved, some "free riding" may occur. That is, firms may attempt to rely on their competitors to label, which would lead to a low overall compliance rate. However, because: (1) The grocery industry may wish to avoid mandatory regulations, (2) there is a low minimum compliance cost per firm, and (3) firms may have to label to be competitive, full compliance may occur.

b. *Effective dates.* The 1990 amendments require that final regulations become effective 6 months after the date of promulgation of all final regulations. If no final regulations have issued by November 8, 1992, the proposals are statutorily mandated to be considered final rules on November 8, 1992, with an effective date of May 8, 1993. The 1990 amendments allow the Secretary to delay the effective date of some of the provisions for up to 1 year if he finds that compliance with the new provisions of the act would cause undue economic hardship.

FDA is proposing to make certain of the provisions of the ingredient labeling regulations effective on the same date as the nutrition labeling rule. The exception to this is the provisions for the listing of all ingredients in standardized food and the listing of all FDA-certified colors which must take effect November 8, 1991 (Pub. L. 102–108). Under the provisions of Pub. L. 102–108, those firms whose inventory is depleted between July 1, 1991 and May 8, 1993 are required to revise such labels for their products consistent with the proposal in the **Federal Register** of June 21, 1991 (56 FR 28592). Such firms will bear administrative costs and redesign costs to include color and standardized food ingredient information. There will be no analytical costs, inventory costs or printing costs outside of redesign costs as this additional printing is not prompted by requirements of this regulation.

Table 4 shows the separable proposed regulations for enactment of the 1990 amendments.

TABLE 4.—EFFECTIVE DATES FOR THE 1990 AMENDMENTS

Proposed rule	Optional effective dates		
	[1] 1	[1] 2	[1] 3
Declaration of ingredient/color labeling	[2] 11/91		
Percent juice labeling	5/93	11/93	5/94
Raw fruit, vegetables, and fish	11/91		
Cholesterol free and percent fat labeling	5/93	11/93	5/94
Mandatory status of nutrition labeling and nutrient content revision	5/93	11/93	5/94
Nutrient content claims	5/93	11/93	5/94
Cholesterol, fat, and fatty acid labeling	5/93	11/93	5/94
Lite butter	5/93	11/93	5/94
Nutrient content claim and a standardized term	5/93	11/93	5/94
Serving sizes	5/93	11/93	5/94
Petitions requesting exemption from Federal preemption	[2] 11/91		
Health claims general requirements	5/93	11/93	5/94
State enforcement provisions of 1990 Amendments	11/92		

[1] The 1990 amendments allow the Commissioner of Food and Drugs to delay the effective date beyond Option 1 if there is a "substantial economic burden" on industry to comply with any of these regulations. The effective date in Option 1 is prescribed by the 1990 Amendments and the two alternates are 6 month extensions of that date.

[2] The date when manufacturers affected by these regulations and who reprint their labels must be in compliance with the regulation.

FDA notes, however, that in section 10(a)(3)(B) of the 1990 amendments, Congress provides that if the Secretary of Health and Human Services (the Secretary), and by delegation FDA, finds that requiring compliance with section 403(q) of the act, on mandatory nutrition labeling, or with section 403(r)(2) of the act, on nutrient content claims, 6 months after publication of the final rules in the **Federal Register** would cause undue economic hardship, the Secretary may delay the application of these sections for no more than 1 year. In light of the agency's tentative findings in its regulatory impact analysis that compliance with the 1990 amendments by May 8, 1993, will cost $1.5 billion, and that 6 month and 1 year extensions of that compliance date will result in savings that arguably outweigh the lost benefits, FDA believes that the question of whether it can and should provide for an extension of the effective date of sections 403(q) and (r)(2) of the act is squarely raised.

FDA has carefully studied the language of section 10(a)(3)(B) of the 1990 amendments and sees a number of questions that need to be addressed. The first question is the meaning of "undue economic hardship." FDA recognizes that the costs of compliance with the new law are high, but those costs derive in large measure from the great number of labels and firms involved. The agency questions whether the costs reflected in the aggregate number represent "undue economic hardship." Therefore, FDA requests comments on how it should assess "undue economic hardship." Should it assess this question on a firm-by-firm basis, as was provided in the bill that passed the House Committee on Energy and Commerce (H. Rept. 101–538, 101st Cong., 2d sess., 24 (1990)), an industry-by-industry basis, or should it assess this question on an aggregate basis? If the agency should take the latter approach, comments should provide evidence that would permit the agency to make a determination that there is "undue economic hardship" for most companies. FDA also points out that assessing hardship on a firm-by-firm basis would likely be extremely burdensome because of the likely number of requests.

FDA will consider the question of the meaning and appropriate application of section 10(a)(3)(B) of the 1990 amendments as soon as possible after the comment period closes. The agency intends to publish a notice in advance of any final rule announcing how it will implement this section to assist firms in planning how they will comply with the act. The early publication of this notice is to assist firms in avoiding any unnecessary expenses that could be incurred by trying to comply with a compliance date that may cause "undue economic hardship."

c. *Administrative costs.* The administrative costs associated with a labeling regulation are the dollar value of the incremental administrative effort expended in order to comply with a regulation. The administrative activities which are anticipated to be undertaken in response to a change in a regulation include: Identifying the underlying policy of the regulation, interpreting that policy relative to the firm's products, determining the scope and coverage related to product labels, establishing a corporate position, formulating a method for compliance, and managing the compliance method.

The magnitude of administrative costs to a representative firm is a function of several variables including the scope and intricacy of the regulation (positive relationship), the number of distinct products, and the length of the compliance period associated with the regulation (inverse relationship). Minor regulations are those which have little if any effect on product composition or

marketability. The compliance method for these regulations is usually straightforward and no testing or reformulation is involved. Conversely, intricate regulations are those that lead to analytical testing and, possibly, product reformulations or discontinuations. Intricate regulations require more administrative effort than minor ones.

In addition, longer compliance periods decrease administrative costs because firm executives might delegate downward decisions that are less immediate. According to RTI, many firms estimate that administrative effort would be twice as high for a 6-month compliance period as for a 12-month period. Similarly, a 24-month compliance period would reduce administrative effort due to a simplified coordination of the compliance process.

Administrative costs also vary with firm size in that larger firms often have a more comprehensive approval process for label changes than smaller firms. In addition, administrative costs have a largely variable component for labeling decisions such that these costs are part variable and part fixed. Larger firms also tend to have more products and more labels or stockkeeping units (SKU's), so that there are more label changes (per dollar of sales) that the larger firms must coordinate. For this RIA, administrative costs associated with intricate regulations are estimated at $9,000 for small/medium firms (less than 100 employees) and $68,450 for large firms. For less intricate regulations, the costs are estimated at $850 for small/medium firms and $6,300 for large firms. These costs have been estimated for domestic firms only as FDA has no information on administrative costs for foreign firms. Total administrative costs also only reflect costs to domestic firms.

Administrative costs for the one-time relabeling changes for listing ingredients on labels for standardized foods and artificial colors on labels for all foods containing them will affect 12,800 firms (of which 1,145 are large (based on Dunn and Bradstreet study)) who will incur administrative costs of $16 million. These will be administrative costs of overseeing redesign only as these costs will only occur to firms who are reprinting labels in the interim period.

Administrative costs for all of the 1990 amendments (mandatory nutrition labeling, format changes, etc.) are assumed to be those associated with intricate regulations for the 8,900 medium and large firms (based on Dunn and Bradstreet study). These administrative activities are valued at $152 million.

FDA estimates that manufacturers of dietary supplements will incur administrative costs of $850 per firm. Costs for these firms will be $138,000.

These costs are additive because firms affected by the ingredient provisions (who reprint labels in the interim period) must also relabel to comply with mandatory nutrition labeling. In sum, these provisions are estimated to impose one-time costs of $168 million.

d. *Analytical testing.* Analytical tests are typically performed by technical personnel employed by firms or at independent laboratories. These costs consist of tests to determine nutrient and food component quantities required by various labeling provisions.

FDA assumes all firms affected by the percent juice labeling requirements will perform analytical testing to determine the °Brix level, which is the level of soluble solids in fruit juice, in their products. This assumption is conservative in that some firms may already perform °Brix analyses and no testing would be needed for 100 percent juice products. In addition, firms that produce more than one-juice mixed juice beverage would only need to test each individual juice once. FDA has no information as to the extent of either of these conditions.

The current total cost of analytical tests to determine the °Brix level in juices and juice products is $17 per product. This figure is based on the pricing schedules of five independent testing laboratories. It is assumed that three analyses are required for the initial data base. Therefore, the cost of analytical testing for percent juice labeling is $51 for each of approximately 3,800 products (A. C. Nielson study) for a total cost of $196,000. The recurring analytical costs are $65,000 every 5 years. Assuming recurring analytical costs continue 20 years into the future, total discounted analytical costs are $343,000 (5 percent discount rate). If discounted at 10 percent, these costs would be $287,000. These costs are also discounted at 10 percent for comparison purposes as, later in the document, the benefits estimate is discounted at 10 percent.

In determining the extent to which firms will incur analytical testing costs as a result of mandatory nutritional labeling, it is important to estimate the number of products/labels which currently contain nutrition information on their labels. The costs of compliance for those firms who have never voluntarily obtained nutrition information will be higher than for those firms who are currently performing some or all of the newly required tests.

Based on the most recent information from the 1988 FLAPS, nutrition-labeled products account for an estimated 61 percent of the annual sales of processed, packaged foods. However, this estimate refers not to the percentage of products labeled, but rather to the percentage of the dollar value of packaged foods.

Unfortunately, there is no good estimate of the number of products or labels which currently contain nutrition information on the label although it is certainly less than 61 percent. This is because the FLAPS sample is made up of an equal number of market leader (defined as the top three brands in the survey) and nonleader brands. Although market leader brands may account for 75 percent of sales, they are also approximately 1.5 times as likely to provide nutrition labeling than nonleaders. In addition, there are many more nonleaders in the market than market leaders. Consequently, the percentage of brands currently containing nutrition information on the label is estimated to be 40 percent (Ref. 15).

Some firms that do not currently provide nutrition labeling are nonetheless aware of the nutritional characteristics of their food products with the help of prior nutritional testing. Consequently, less than 60 percent of the products may incur the full cost associated with the analysis. FDA has no direct information to estimate the percentage of firms which may be conducting nutrition testing without labeling this information. However, FDA estimates that 20 percent of all firms are already conducting the newly required nutrient analyses, perhaps in anticipation of the 1990 amendments. For this 20 percent of all firms, no additional testing will be required. Although tests already performed are a sunk or historical cost, their inclusion provides an historical account of the costs of these proposed regulations. A cost that has already been incurred is said to be a sunk or historical cost and is not an economic cost because no choice is associated with it. In addition, 32 percent of the firms (40 percent currently labeling × 80 percent not performing all tests) are performing the currently required tests and will, therefore, incur only the incremental analytical testing costs. The remaining 48 percent are assumed not to be currently testing their products and will, therefore, incur the total cost of a nutritional analysis. All tests include both domestic and foreign firms who sell products in U.S. supermarkets.

The total cost of nutrient testing to ensure compliance with current

regulations is approximately $354 per sample. The cost of that portion of the current tests which will no longer be required (testing for thiamin, riboflavin, and niacin) is $135 per sample. In addition to current requirements, firms will be required to test for cholesterol, fiber, fatty acids, and sugars. These tests currently cost $376 per sample. These figures are based on the pricing schedules of five independent testing laboratories. It is assumed that three analyses are required for the initial data base. The formula for determining initial testing costs for the firms who do not currently test their products is [(354–135+376)×3] or $1785 per product. Incremental initial costs for the firms who perform the currently prescribed testing but do not test for the newly prescribed nutrients will be $723 [(376–135)×3] per product. Total initial analytical costs for mandatory nutrition labeling are $112 million (including historical costs). Firms are assumed to retest once every 5 years on average. These costs are reduced to one-third of the original costs, or $37 million. As stated previously, it is assumed that three analyses are required for the initial data base. Only one analysis is required for subsequent testing. Assuming recurring costs continue 20 years into the future, discounted total analytical costs, again including historical costs, are $195 million (5 percent discount rate). At a 10 percent discount rate, these costs would be $163 million. These costs were calculated by adding costs of three tests in the first year and an additional test in the 5th, 10th, 15th, and 20th years, respectively.

TABLE 5.—ANALYTICAL COSTS OF MANDATORY NUTRITION LABELING

	Percent of all products	Incremental cost per product
Currently testing for all nutrients	20	[1] 0
Currently testing for only required nutrients (currently labeled)	[2] 32	$723 [(376 – 135)×3]
Not currently testing (not currently labeled)	[3] 48	$1785 [(354 – 135+376)×3]

[1] Historical cost included in total as $723.
[2] (80 percent×40 percent).
[3] (80 percent×60 percent).

FDA believes the incremental analytical testing costs for manufacturers of dietary supplements would be very small. Due to the nature of the product, FDA believes that full analytical testing is already performed on most dietary supplements. FDA requests information on this assumption.

e. *Printing.* Incremental printing costs depend on the type of printing process(es) used, the complexity of the label change, and the length of the compliance period. Because printing activities are specific to individual labels, computing incremental printing effort on a per-SKU basis is necessary.

There are three printing processes used in the food processing industry. These include lithography, flexography, and gravure. The particular process used will indicate the type of plate or cylinder which will be modified or replaced.

Often referred to as "offset," lithography is the most popular process for glue-applied label printing because of its relative advantages in quality, simplicity, and cost. Approximately 43 percent of all food labels are printed using lithography.

Flexography is acceptable for many products and applications in the food industry. However, because the screen elements on the plates are flexible, vignettes are sometimes printed with ragged, irregular patterns. It is used on approximately 43 percent of food labels.

Gravure is capable of high quality pictorial reproductions, high-color densities, and bright intensive solids because it can deposit thick ink films. However, it does not print type as sharply as lithography or flexography. Gravure is used on 14 percent of food labels.

Flexography and lithography have similar incremental printing costs although lithography is slightly more expensive on average. Gravure is a relatively costly printing process. It is not unusual for the incremental printing cost of a label printed with gravure to be three or four times the cost for the identical change when printed with lithography or flexography.

The complexity of the label change determines the level of effort for artwork (the illustrative and decorative elements of printed materials), stripping or image assembly (the assembly or positioning of negatives (or positives) on a flat prior to platemaking), and engraving (the carving, cutting, or etching into a block or surface used for printing). It also determines the number of plates or cylinders that must be modified or replaced. The most common labeling regulations require lettering changes to an area inside the information panel.

Line copy changes usually affect only one label color (printing plate), and it is unlikely that the services of a label artist will be needed. In most cases, a film assembler and an engraver modify an existing plate or produce a new one.

Despite the similarity and relative simplicity of line copy changes, firms differ in incremental printing effort. If flexography or lithography printing is used, many firms engrave new lettering onto an existing printing plate to save time and resources. Other firms order new printing plates regardless of how minor the line copy change may be. For gravure printing, every label change will result in a new cylinder since modifying gravure cylinders is not possible.

The requirements proposed for listing of ingredients on standardized foods and the listing of colors on labels will result in a relatively simple two-color label change. However, by the second effective date, the entire food label will be redesigned to incorporate all changes. Virtually all food products will be expected to carry revised ingredient labeling, nutrition information, and possibly a new nutrition label format. For those products which do not currently have this information, the current label contents will have to be rearranged in order to make room for the new panels. For those products which currently carry nutrition information, the changes required are so comprehensive that it is assumed that the entire label will be redesigned. In fact, those products affected by the regulations defining various nutrient content claim definitions will incur changes to the principal display panel (PDP) as well as to the information panel. In addition, the format chosen may also cause the PDP to be redesigned, depending on the new size of the nutrition panel.

Complex label changes are influenced by the same variables, but the level of effort required for each printing activity is higher. Any label change affecting the PDP will affect the visual appeal of a label. In such a case, an artist may be used to partially redesign the label. This would frequently affect all colors on the label, resulting in substantial artwork, photography, and engraving to complete the label change.

The length of the compliance period determines the firm's ability to combine planned label changes with mandated changes. The amount of printing costs assigned to a mandated printing change depends primarily on the length of time available to make the change. Label redesigning schedules vary from approximately 4 weeks to longer than 10 years. Most firms redesign food labels at least once every 5 years, with many redesigning branded labels at intervals of less than 1 year. Depending upon the complexity and similarity of planned

and mandated changes, a firm could significantly reduce incremental printing activities by combining both changes.

It is estimated that there are approximately 257,000 food labels currently on the market (based on A. C. Nielsen study). These labels represent both domestic and foreign products. Although products are labeled according to the country of origin, products may be imported and then labeled or exported, labeled in other countries and then reimported or other variations. Such variations make it impossible to distinguish between foreign and domestic firms in terms of bearing the cost of label printing.

Because firms will be able to combine planned and mandated changes for some labels, incremental costs will be incurred for fewer than 257,000 food labels. Using the methodology provided in the contractor's cost study, the cost of printing new labels for the mandated changes which will be effective by at least May 1993 will be $643 million. Printing costs are a function of the number of labels that must be printed, the type of process used for printing the labels, and the complexity of the mandated printing change, i.e., number of colors involved and whether or not the label must be redesigned. The printing activities in response to ingredient labeling (redesign costs only are counted) will cost $112 million.

Printing costs for dietary supplements are expected to be $250 per product. FDA estimates there are approximately 3,400 unique dietary supplement products on the market. This leads to a total printing cost for dietary supplements of $858,000. Thus, total printing costs will be $756 million.

f. *Label inventory disposal costs.* An additional cost category is the label inventory loss associated with the transition from old to new labels. The cost of label inventory loss depends on average label inventory and the length of the compliance period. The key variable in this relationship is average label supply. Label supply differs significantly across industries and firms, but a great deal of variation is sometimes present across product lines within the same firm.

There are many different types of labels, usually classified according to their construction and method of application: preprinted and direct. Preprinted labels are printed on special label paper, cut to size, and applied by machines to the container or package using special adhesives. Direct labels are printed directly on the container or package. Therefore, for certain products, such as canned soft drinks, the label which must be disposed of is actually the container.

As discussed above, the average label supply and length of the compliance period are the most important factors in determining inventory disposal costs. If allowed 2 years, for example, most label inventory will be depleted. Because firms will be able to dispose of inventory prior to making label changes, there will be no incremental inventory disposal costs as a result of the declaration of certified colors and ingredient declaration. However, additional costs of $306 million are estimated to be incurred as a result of the second phase of regulations if a 6-month compliance date must be met. Thus, total costs for inventory disposal of food labels amounts to $421 million. These costs include both domestic and foreign firms.

FDA has no information to determine inventory disposal costs for dietary supplements. We assume firms will be able to use up existing supplies within the 6-month compliance period.

g. *Reformulation.* FDA believes that firms may react to labeling regulations by reformulating existing products or introducing new products. Product reformulation occurs when a firm which must now reveal nutritional characteristics competes to provide more nutritious products for the marginal consumers who drive the market for quality. Many firms conduct market tests before distributing a reformulated or new product. These tests range from small internal taste panels to comprehensive public-use tests.

FDA does not have adequate information to determine the amount of product reformulation that may take place as a result of this regulation. Thus, while some firms may alter marketing techniques and strategies, these costs have not been quantified. Furthermore, these costs are inherently difficult to predict because they depend on future choices made by firms.

h. *Loss of trademark names.* Both the percent juice labeling document and the nutrient content claim definitions document may cause firms to alter names currently trademarked. Under Executive Order 12630, a "takings" analysis would be necessary if, in fact, this constituted a potential taking. These regulations, however, serve to reemphasize existing regulations as to how products may be named. Thus, any firm which will be forced to change the name of its product is now using terms that misbrand its products, and therefore no legal property right exists. Thus, no "takings" analysis is necessary. In the past, FDA resources have been used sparingly to enforce economic deception. Nevertheless, the (illegal) value associated with the trademark name will be lost to the firm when they change the name. Further, losses incurred by producers and consumers based on illegal names should not be counted as a societal loss (Trumbull cites Stigler, Buchanan, and others who argue that criminal gains ought not to be counted as societal gains (Ref. 16)).

i. *Costs to food service establishments.* Potential costs of the nutrient content and health claims regulations to food service establishments include costs of changing menus and menu boards, analytical testing, creating nutrition posters or handouts, and administrative costs.

i. Printed menus. To determine the costs of reprinting menus not in compliance with the proposed rules, the estimated number of CFEs having menus with health promotions and/or nutrient content claims will be allocated across different average cost of meal categories. Different menu printing costs may then be applied to the resulting figures. Within each size category, the least-cost menu printing options are considered, but it should be emphasized that these are lower-bound figures. FDA assumes that CFEs with an average cost per meal of less than $15 use a tripanel fold-out paper menu, which is estimated to cost $2.65 to print (Ref. 17). An eight-page booklet estimated to cost $4.25 to print is assumed for a CFE whose average cost per meal is between $15 and $30. For the high-scale CFE with an average cost per meal above $30, printing a single-color menu is assumed to cost $85 per 8.5x11 inch page. This analysis assumes only two pages and one color. An approximate breakdown of affected CFEs by average cost of meal category is as follows:

TABLE 6.—NUMBER OF AFFECTED COMMERCIAL FOOD ESTABLISHMENTS BY AVERAGE COST OF MEAL

Cost of meal	Affected establishments
<$15	106,242
$15 to $29.99	5,929
$30+	1,039
Total	113,210

Another factor affecting costs is the number of menus that must be printed per CFE. The number of menus that must be printed is a function of the average number of customers. Columns 1 and 2 of Table 7 present the average

distribution of seating capacity in the restaurant industry. These percentages have then been applied to the total number of restaurants in each average cost of meal category. This procedure ignores any correlation between the number of seats and the average cost of meal. That is, the same proportion of establishments with various seat sizes is ascribed to each of the average cost of meal categories. FDA is unaware of any correlation between the average meal cost and the size of an individual restaurant.

TABLE 7.—ESTIMATED NUMBER OF AFFECTED COMMERCIAL FOOD SERVICE ESTABLISHMENTS (BY CHECK SIZE AND SEATING CAPACITY) AVERAGE CHECK SIZE

Seating capacity	Percent	<$15	$15 to $29.99	$30 or more
0 to 100	0.14	14,874	830	145
101 to 150	0.21	22,311	1,245	218
150 to 199	0.18	19,124	1,067	187
200 to 400	0.33	35,060	1,957	343
>400	0.14	14,874	830	145
Total		106,242	5,929	1,039

The next step in computing menu reprinting costs is to calculate the total number of menus that must be reprinted and the cost of changing these menus for each of the three check size categories. For simplicity, the average number of seats within each range is used as a proxy for the number of menus and is multiplied by the number of restaurants within each corresponding check size. The total number of printed menus affected for CFEs is shown in table 8.

TABLE 8.—TOTAL NUMBER OF MENUS AFFECTED

Average number of seats	Average check size		
	<$15	$15 to $30	>$30
50	743,694	41,503	7,273
125	2,788,853	155,636	27,274
175	3,346,623	186,764	32,729
300	10,517,958	586,971	102,861
400	5,949,552	332,024	58,184
Total	23,346,680	1,302,898	228,320

If the average number of seats represents the number of menus that must be reprinted, the total cost of reprinting menus, less administrative cost, is $107 million, as shown below.

TABLE 9.—COSTS OF REPRINTING MENUS FOR CFEs

	Average Check Size		
	< $15	$15 to $30	> $30
Total number of seats	23,346,680	1,302,898	228,320
Menu costs	× $2.65	× $4.25	× $175
Subtotals	$61,868,701	$5,537,315	$39,956,044
Total	[1] $107		

[1] Million.

ii. Menu boards. In addition to those CFEs having printed menus, a certain number of CFEs using menu boards are likely to undergo compliance costs as a result of the current proposal. As stated previously, the cost of changing menu boards utilizing separate letters that may be easily affixed or removed will be considered negligible. Thus, only those menu boards using preprinted plastic strips that must be professionally manufactured will be considered. However, FDA requests information on any other sort of menu board or printed menu that may be affected but has not been considered.

Unfortunately, no data are currently available on the percentage of CFEs having this type of menu board, or on the number of items on these boards containing nutrient content claims or health claims. However, a rough estimate of the number of items affected may be possible through the use of reasonable assumptions.

FDA believes the CFEs most likely to have menu boards with either health claims or nutrient content claims are frozen specialty shops such as frozen yogurt shops, some of whose business revolves around the ostensible nutrition advantages of their product.

The assumptions to be made on the number of menu strips affected may be broken down into three parts: (1) The number of establishments in various categories likely to have menu boards with preprinted plastic strips and thus potentially affected; (2) the number of establishments having this type of menu board now using health claims, and (3)

the number of menu strips that must be changed per affected menu board.

With respect to the first issue, the agency assumes that 50 percent of frozen food specialty shops (frozen yogurt and ice cream establishments), and 50 percent of all fast food establishments (including those that have previously been identified as having printed menus), use menu boards with preprinted plastic strips. In addition, as an example, the agency assumes that 10 percent of all other CFEs not previously considered to use printed menus, use this type of menu board.

Next, the agency assumes that 50 percent of the potentially affected menu boards used by frozen food specialty shops will contain either health claims or nutrient content claims. In addition, the agency assumes that 5 percent of all other potentially affected menu boards will have health claims or nutrient content claims. Finally, it will be assumed that an average of two strips must be replaced per affected menu board. Using the previous assumptions as an example, the number of affected menu boards would be as shown in table 10.

TABLE 10.—ESTIMATED NUMBER OF MENU BOARDS AFFECTED, BY TYPE OF ESTABLISHMENT

Limited menu (fast food)	3,657
Commercial cafeterias	37
Ice cream vendors, etc.	3,049
Miscellaneous food service	143
Food contractors	79
Retail hosts	451
Recreation and sports	62
Total	7,478

The cost of printing menu board item strips ranges from about $6 to $18 for a small number of strips (about 1 to 10) and from about $1.50 to $4 for a very large number of strips (500) (Ref. 18). Since the cost depends heavily on the number of identical strips printed at one time, an accurate assessment of these costs would entail knowledge of the number of independent and franchise establishments. As a preliminary estimate, the simple average of the range of item strip printing costs noted above, $7.40, may be used. Under the preceding assumptions, the additional cost due to changing item strips on menu boards would be about $111,000.

iii. Analytical testing costs. All firms wishing to use nutrient content claims and health claims must undergo verification testing. Analytical testing represents a cost to all firms using health claims or nutrient content claims on the menu, including those firms who would normally reprint their menus within the allotted compliance period and which were not included above. Although all firms currently using nutrient content and/or health claims will incur printing and administrative costs, not all firms will incur analytical costs. Some firms currently making claims will not continue to use them in the future, as not all menu items will meet the criteria for making claims, nor will all firms wish to bear the additional costs.

iv. Administrative costs. Firms affected by these regulations will also incur administrative costs—the dollar value of the incremental administrative effort expended in order to comply with a regulation. Although FDA has no specific information in regards to the administrative cost per restaurant, FDA estimates the relationship of administrative costs to total costs for those firms' continuing to use nutrient content and/or health claims to be approximately 15 percent of those firms' total printing and analytical costs for labeling regulations (Ref. 9). For those firms choosing to not continue the use of claims, administrative costs are estimated to be 5 percent of total printing and analytical costs applicable to those firms. Therefore, if 20 percent of firms currently making claims continue to use them, total administrative costs will be $9 million. If only 1 percent of firms currently making claims continue to use them, total administrative costs will be $6 million.

v. Total costs to food service establishments. The costs to restaurants of the regulations to define the use of nutrient content claims and health claims include the costs of changing printed menus ($107 million) and menu boards ($111,000), analytical testing costs, and administrative costs ($9 million if 20 percent of firms currently using claims continue to use them, $6 million if only 1 percent). Therefore, this speculative estimate of the total cost to restaurants of these regulations is $116 million if 20 percent of firms currently using claims continue to use them, and $113 million if only 1 percent. These costs must be considered to be preliminary estimates as many of the assumptions are speculative. Within the next year, FDA will prepare a more accurate analysis of the cost of these proposed regulations on restaurants.

j. Total costs of the mandatory regulations. The total costs of the regulations are provided in table 11:

TABLE 11.—TOTAL COSTS OF FOOD LABELING REGULATIONS [1]

[In millions of dollars]

	Phase I	Phase II	Total
Administrative costs [2]	16	161	177
Analytical costs	0	195	195
Printing costs	112	750	862
Inventory disposal costs	0	306	306
Total	128	1,412	1,540

[1] Excludes labeling of raw fruit, vegetables, and fish.

[2] Costs discounted at 5 percent.

3. Raw Fruit, Vegetables, and Fish

The costs of the action to label raw fruit, vegetables, and fish include laboratory testing; data base compilation; administrative costs; and the printing of signs, posters, handouts, etc. Because the regulation is "voluntary," it is impossible to predict the number of firms that will choose to comply although it is suspected that most, if not all, of the supermarkets will comply. If a substantial number (60 percent of all stores evaluated) are not found in compliance within 2 years, the agency will have to issue mandatory regulations. There are 31,000 chain stores and 68,000 independent grocery stores that fall under the compliance guidelines.

Compliance costs will vary depending on the particular medium chosen to convey the nutrition information. The more elaborate the labeling, the higher the cost. Brochures to be handed out, for example, would cost $4,000 to 6,000 per 100,000 brochures (Ref. 19). However, where some stores do choose to offer complicated labeling schemes as a marketing device, that would not necessarily be considered a cost of this regulation. Also, bulk orders by large chain supermarkets are expected to reduce costs substantially.

Comments have indicated to FDA that the average life of a grocery store sign is 6 months with a yearly cost of between $150 and $200 (Ref. 20). Over a 20-year period, if exactly 60 percent of supermarkets included are in compliance, the discounted cost would be between $117 ($150 per year discounted at 5 percent) and $155 million ($200 per year discounted at 5 percent).

Assuming every consumer spends the same for groceries, each store with over $2,000,000 per year in sales would have an average of 6,500 customers who would benefit from the labeling (250,000,000 consumers × 80.5 percent of sales = 203,750,000;203,750,000/31,000

supermarkets=6,574 customers/supermarket). The independent stores, with sales under $2,000,000, would have an average of 150 customers (250,000,000 consumers × 6.6 percent of sales=16,500,000. 16,500,000/110,000 stores=150 consumers per store). If labeling costs $200 per store every year, labeling costs in the smaller stores would be $1.33 per consumer per year.

B. Benefits of the Proposed Option

The proposed labeling changes will benefit consumers by giving them information to refine their food choices for health or other reasons. This section contains a qualitative description of individual benefits to be derived from the implementation of each of the requirements of the 1990 amendments and a quantitative estimate of the requirements as a whole.

1. Qualitative Description of Benefits of Individual Regulations

This section will discuss the qualitative benefits of the individual regulations. The benefits of mandatory nutrition labeling will be discussed quantitatively in the next section.

a. *Labeling ingredients.* i. Sweeteners listed together. A common complaint among consumers is that the ingredient list, in descending order of predominance, may contain multiple sweeteners which appear to represent a small proportion of ingredients. For example, sugar, high fructose corn syrup, and dextrose may be used in a ready-to-eat cereal and appear to make only a marginal contribution to the product based on individual listings in the ingredient list, although, if combined, the list would show the product to have sweeteners as the primary ingredient. People wishing to control their intake of sweeteners for health reasons (e.g., diabetes, obesity) or any other reason will be better able to adjust their food choices to match their preferences as a result of this rule.

ii. Required listing of protein hydrolysates. Because of trade secrets and the complex technical names of flavors, FDA has always exempted flavors from ingredient listings (FDA is also required to exempt flavors by statute). However, that exemption has never been applied to flavor enhancers such as monosodium glutamate (MSG). This rule clarifies the status of protein hydrolysates, such as hydrolyzed vegetable protein and other protein hydrolysates, which contain small amounts of MSG and which act as both flavors and flavor enhancers, by requiring them to be listed. MSG has long been suspected of causing allergic-like reactions such as the "Chinese restaurant syndrome." This regulation will benefit those consumers who wish to avoid "protein hydrolysates."

iii. Required listing of sodium caseinates. Sodium caseinates, which are milk derivatives, are components of "nondairy" creamers. Caseinates are required to be listed by some states. However, for vegetarians, milk protein sensitive individuals, and others such as those attempting to follow religious proscriptions, it is important to know that nondairy creamers may contain a dairy product. Thus, this regulation will require that manufacturers indicate that sodium caseinates are, in fact, derived from milk.

iv. Statement that ingredients are listed in the descending order of predominance. Although FDA's regulation has been in place for a number of years, some consumers still do not understand that products are listed in the descending order of predominance. This required statement will eliminate that confusion.

v. Listing of colors. A listing of colors will provide consumers who are sensitive to them with this information as well as provide information for those who wish to avoid chemical colorants.

vi. Required listing of ingredients in standardized foods. Very little, if any, benefit will be obtained from this provision of the statute because most or all ingredients are currently listed in standardized foods.

vii. Provision of a uniform format for voluntary declaration of percentage ingredient information. Although FDA has declined to require that ingredients be listed by their percentage contribution to a product because of the potential costs of such a requirement (relative to the potential benefits), some manufacturers may choose to make such lists available in response to consumers demand. FDA is proposing a uniform format that manufacturers would use if they did choose to make such a declaration. By providing a uniform format, consumer confusion over multiple presentations would be avoided.

b. *Labeling of percent juice.* Providing consumers with the listing of percentages of fruit juice in various juice beverages will enable them to make choices consistent with their desire to obtain percentages of juice. Consumers have repeatedly asked for this information.

Other benefits include clarifying the regulation that requires consistent naming of products. Some products now marketed are mislabeled under existing regulations by failure to put the names of juices in descending order of weight predominance in the product name. A product containing 80 percent apple juice and 20 percent grape juice, for example, may not be called "grape-apple juice." This regulation restates and reenforces this regulatory principle. This regulation also clarifies the rules by which manufacturers can count a modified juice as "juice." In some cases, manufacturers have modified juice so much that only water and sugars remain.

c. *Labeling of raw fruit, vegetables, and fish.* To the extent that consumers do not now know the nutritional composition of the raw fruit, vegetables, and fish that are proposed to be included among the "top 20," some change in purchase behavior may be expected leading to a healthier diet.

d. *Standardizing serving sizes.* The 1990 amendments direct FDA to standardize serving sizes for individual foods rather than allowing each manufacturer to establish their own serving size.

In the past, manufacturers were free to select their own serving size for purposes of calculating nutrient amounts. Standardization of measurements such as weights and scales dates as far back as 3500 BC (Ref. 21). The benefits of such standardization to buyers are reduced search costs (a transactions cost of using the market) and concomitantly, an increased ability to accurately select product quality consistent with individual desires. In the case of serving sizes, manufacturers may often "game" nutritional labeling by selecting a favorable serving size. An example would be to select a smaller serving size in order to be able to claim that a product was low in fat or sodium. If similar products use different serving sizes, consumers must make the appropriate calculation to compare products. However, many consumers may not notice that different serving sizes are being used, which leads to erroneous impressions of the nutritional quality of the food.

e. *Standardizing adjectives to describe nutrient content.* Because adjectives such as low, high, etc., are a verbal qualitative description of quantitative measurement, these regulations will have similar benefits to standardization of serving sizes.

f. *Revising the nutrition label format.* Several goals will be met by this regulation. The format chosen will be one which consumers desire, find easy to use, and easily understand. Ultimately, if a new format is selected, it will cause some consumers to direct their purchase behavior towards more healthful foods.

g. *Regulating health claims.* The benefit of these proposed regulations is to provide for new information in the market in the form of health claims that are not misleading in the sense that scientific evidence supports them. Although health claims exist on the market now, they have not been legally allowed for food products. FDA has used its enforcement discretion to act against only those claims that were egregiously misleading and, in the case of restaurants, FDA has traditionally left enforcement of health claims to the states. In the past, a food which made a claim relating to preventing, curing, or treating a disease legally became a drug and was subject to drug regulations. Because the regulation of drug products is much more burdensome than that for foods, this acted as a disincentive to making such claims. These regulations will now permit these claims to be made, if precleared by FDA, so that labels for food products as well as menus and menu boards can contain health claims without being subject to drug regulations. The additional benefit to regulating the use of claims by food service establishments is to prevent consumer confusion that may occur if different rules apply to foods from different sources, i.e., packaged foods versus restaurant foods.

Because the costs to food service establishments of analytical testing and nutrition information printing are high per menu item, many food service firms might choose to remove claims from their menus. This would reduce benefits to the extent that claims that are not misleading will be removed. FDA requests information on the number of food service companies that will discontinue the use of nonmisleading health claims because of the burden imposed by the proposed regulations. FDA also requests information on the likely changes in consumer behavior, and health, if this reduction occurs. In particular, how large would the health costs be, estimated on a basis similar to that used for estimating health benefits, of increased labeling? Would any health gains from restaurants which added nutrition information to menus be as large as the losses from restaurants which stopped making only health claims at all? Would the number of truthful health claims on menus grow larger than at present if regulation did not discourage this?

As a component of labeling in general, health claims may be the primary motivating force behind consumer behavior changes (substituting toward more nutritious foods). As such, much of the benefits of the 1990 amendments will depend on how health claims are regulated. If mostly incorrect claims are prohibited, consumers will benefit from only seeing those claims that are correct. On the other hand, if claims that are likely to be true are removed, this will decrease the total benefits of the 1990 amendments as consumers will lose valuable information. However, the opportunity exists for firms to petition the agency to reinstate "true" claims. It is not clear how much consumer changes in purchases for nutrition reasons can be attributed to health claims on the front of the primary display panel versus the nutrition panel on the back of product. Ippolito and Mathios found large changes in both producer and consumer behavior due to changes in health claims (front of label), but were unable to separate out behavior changes due to the presence or absence of nutrition labeling (back of label) (Ref. 22).

2. Labeling Benefits Model

FDA looked at several possible ways of quantifying the health benefits of the 1990 amendments. The preferred method of estimating benefits is to measure actual market prices for the good in question—a willingness-to-pay model. However, the good in this case is information on the food label, which is not directly traded in the market. The market for most consumer information is for consumer durable goods, but studies on these goods do not translate well to food labeling information.

Yet another method of quantifying benefits is to use contingent valuation studies in which consumers are given structured interviews to determine their willingness to purchase a good that is not normally traded in the market. However, the more hypothetical the question, the less incentive respondents have for accurate responses (Ref. 23). FDA believes that questions relating to information which might be supplied on the food label would be too hypothetical.

Because neither willingness-to-pay nor contingent valuation studies would produce estimates of the value of new food label information, FDA decided to use an alternative market approach which projects changes in consumer purchasing patterns. It is expected that most consumers will react to the new labeling by readjusting their prior expectations about the nutritional quality of the food they are purchasing. That is, the information they learn about the amounts of saturated fat, total fat, and other nutrients will alter their food choice to discover which, among other things, ranks nutritional qualities of food. This factor then, in combination with other characteristics of food, will cause some consumers to alter their purchase behavior toward healthier food.

The model eventually chosen was created by RTI for FDA, is entitled "Estimating Health Benefits of Nutrition Label Changes" attempted to estimate health benefits through a three-step process:

(1) Estimate the changes in consumer purchase behavior and resulting changes in nutrient intakes as a result of receiving new nutrient information about foods.

(2) Estimate the changes in health states that would result from consumers' changes in nutrient intakes, particularly for reduced incidence of cancer and CHD.

(3) Estimate the value of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits.

a. *Estimation of changes in consumer purchase behavior and nutrient intakes.* The magnitude of changes in nutrient intakes will depend on how consumers use the new information to alter their choice of foods. That will, in turn, depend on whether the information is important to consumers, whether it is in a format easy to understand, and how nutrition is valued relative to other food characteristics (taste, appearance, convenience, and price). The change in purchasing behavior that will ultimately lead to a change in nutrient intake is difficult to estimate. What is being projected is the change in purchasing behavior that would come as a result of new, specific, product information about which consumers already have a prior estimation.

There is no situation which exactly corresponds to this particular set of regulations which could serve as a model to estimate this change. However, FDA does have a market study of purchasing behavior change from a similar kind of situation. This study was conducted as a result of a special program done by FDA in conjunction with Giant Food, Inc. This study, entitled the SDA, used special shelf labels to call consumers' attention to various nutrient content claims of food. For example, a flag may have called attention to a product that qualified under FDA guidelines as being "low cholesterol." In addition, a guidebook was offered either free or at nominal charge.

To compute the changes in nutrient intakes for consumers that resulted during this study a four-step method was used:

(1) Identify products with a significant market share change.

(2) Estimate the number of shelf labeled and unlabeled products in each significant product category and the market share changes in each product category from unlabeled to labeled.

(3) Compute estimated changes in consumption of food from SDA categories by using the "Continuing Survey of Food Intakes by Individuals (CSFII)," and SDA results.

(4) Estimate changes in nutrient intakes from product share changes and extrapolate changes to the U.S. population (Ref. 24).

Table 12 shows the estimated nutrient changes (Ref. 24):

TABLE 12.—ESTIMATED CHANGES IN NUTRIENT INTAKES FROM THE "MARKET STUDY"

	Men	Women
Change in fat intake:		
Grams	−1.49	−0.67
Percent	−1.4	−1.1
Change in saturated fat intake:		
Grams	−0.48	−0.16
Percent	−1.3	−0.7
Change in cholesterol intake:		
Milligrams	−0.42	−0.26
Percent	−0.1	−0.1

This estimate may be construed to be a reasonable underestimate of the changes consumers are expected to make for the following reasons: (1) The SDA experiment did not cover as much of the nutritional profile as will be covered by the 1990 amendments; (2) Not all food products were covered by the SDA study; (3) Consumer awareness and concern for total and saturated fat has increased since that study was done (1988) and will likely continue to increase over the next 20 years for which benefits are estimated; (4) No reformulation was likely to take place for this small market; and (5) No estimate was made for substitutions between products (e.g., potatoes to rice).

However, there are some reasons that drive this estimate to overstate change, particularly. First, because this information was in the form of shelf "flags" as opposed to nutrition panel information on the back of packages, consumers are more likely to be drawn to this type of labeling instead of new information on the backs of labels. However, the effect may be mitigated if firms choose to voluntarily use such nutritional "highlight" flags as an extension of nutrition labeling. Also, the allowance of health claims on the front of the package may tend to simulate the effect of shelf flags.

Secondly, no net effects of dietary changes were estimated. For example, if consumers decreased their intake of milk to lower fat intake and replaced it with apple juice, this might cause a calcium deficiency and increased risk of osteoporosis. These net effects are complicated because of the extraordinarily large number of risk items associated with any food.

Thirdly, this study, when applied to the entire population over 20 years, assumes that the purchase behavior shifts observed in the SDA study will be permanent. In fact, many studies have noted transitory shifts in behavior in response to new information. Nonetheless, as diet/health links are strengthened in the next 20 years and awareness of these links increases, FDA expects that these behavioral shifts will be lasting. Finally the nutritional benefits are extrapolated to the U.S. population using a baseline for nutritional consumption that is derived from 1988 data. If in fact, there is a trend toward better diets, and to the extent that the trend continues independently of labeling changes, then this extrapolation will tend to overstate benefits.

The fact that this model neither allowed for substitutions between products nor calculated the net effect of all dietary components has been discussed as leading to either an overestimate or an underestimate of benefits. One problem that occurs now with substitutions between products is that some products as a category are almost entirely unlabeled. Putler and Frazao (1991) find that women trying to decrease their level of fat simply traded one source of fat for another between food groups (Ref. 25). The product groups that were added included the largely unlabeled dairy products and food fats and oils. Thus, labeling of all food products will mitigate this problem.

In terms of the net effects of product substitutions, FDA believes that fat, saturated fat, and cholesterol consumption changes are likely to have the largest nutritional impact on health. Furthermore, health messages will be regulated such that no claim may be made unless the food is within the boundaries for a healthy food in several aspects, i.e., saturated fat, total fat, cholesterol, and sodium. Content claims require disclosure of "negative nutrients in high amounts in close proximity to the claim and claims are prohibited if the food contains 'negative nutrients' in high amounts." It is unlikely that consumers switching to avoid consuming too much of the primary negative nutrients will encounter gross health effects from consuming different nutrients in an alternate food that would offset the benefit of reducing consumption of the primary negative nutrients. Thus, while there may be some net effects that decrease benefits as estimated, this effect is likely to be minimal. Furthermore, as consumers become more knowledgeable over time about the diet/health link, they are likely to make even more judicious diet substitutions.

b. *Estimation of changes in health states.* The next step in estimating benefits is to establish the link between changes in nutrient intakes and reductions in the probabilities of disease. Because this estimate focused solely on changes in total fat, saturated fat, and dietary cholesterol, health changes are only estimated for CHD and cancer. A computer model, developed by Dr. Warren Browner for DHHS, has been used to estimate the relationship of changes between intake of fat and dietary cholesterol and changes in cancer and CHD (Ref. 26).

This model estimates the number of cases and deaths of CHD and breast cancer, prostate cancer, and colon/rectal cancer for a 10-year period. The model is divided by age group, race, and sex and computes the expected difference in rates of death from all causes and death from CHD and the three cancers. Cancer is affected by intake of total fat and is assumed to have a 10-year latency.

For CHD, relative risks are based on logistic regression coefficients obtained from the Multiple Risk Factor Intervention Trial (MRFIT) and Framingham studies, which specify the change in CHD resulting from a change in the level of serum cholesterol (Ref. 27 and 41). Serum cholesterol changes occur as a result of changes in the intake of dietary cholesterol and saturated fat with a 2-year lag. These changes are predicted by the Hegsted equation (Ref. 28). Finally, changes in health states for both diseases were predicted for the next 20 years.

There are factors in the estimation of health effects that lead to both underestimates and overestimates.

i. Underestimates. Consumers' increased knowledge of the ingredient and nutrient composition of foods is expected to lead manufacturers, particularly those who are not now providing nutrition information and who can make low cost reformulations, to reformulate their products to make "healthier" products. An indirect benefit may thus arise as some consumers, who do not search for nutrition, inadvertently obtain healthier (reformulated) food.

Many health conditions besides CHD and cancer may be improved as a result of nutrition labeling. Examples include osteoporosis, hypertension, obesity, and diabetes.

ii. Overestimates. Use of the Hegsted equation may overestimate the possible reduction of CHD. Recent results indicate that Hegsted may have overestimated the effect of dietary cholesterol on serum cholesterol by a factor of between three or four (Ref. 29).

Many of the provisions of the ingredient labeling regulations are directed at food ingredient sensitivities such as the provision regarding caseinate in "nondairy" products.

Table 13 presents the numbers of cases and deaths from cancer and CHD that are predicted to be avoided as a result of the 1990 amendments over a 20 year period:

TABLE 13.—ESTIMATED HEALTH EFFECTS [1]

[Over 20 Years]

Cases avoided	Total annual cases	
Cancer	35,179	500,000
CHD	4,028	514,000
Deaths avoided	12,902	.....
Life-years gained	80,930	.....

[1] Uses lagtimes of 2 and 10 years for the occurrence of CHD and cancer, respectively following a diet change.

c. *Valuation of health state changes.* In order to facilitate comparison of the costs of implementing the 1990 amendments, the changes in health states (benefits) will be valued in dollars. These estimates are valued using several separate techniques which reflect different assumptions about how to estimate reductions in the probability of early deaths. Together they provide a range for the benefits of the 1990 amendments.

i. Medical care costs. Medical care costs are cash outlays for the costs of medical care (cases). The figures presented here overstate the true reduction in such costs as the costs of competing illnesses are not subtracted. That is, even though cancer or CHD may be avoided, another disease may occur such that only net savings should be reported. Because costs of average cases of all other kinds of disease are not very meaningful, gross average medical care cost savings are reported in Table 14 below (Ref 24):

TABLE 14.—AVERAGE MEDICAL CARE COSTS

[Dollars]

	Men	Women
CHD	39,838	34,241
Prostate cancer	26,880	31,782
Colon/rectum cancer	24,055	25,963

Applying these figures to the discounted (5 percent) total number of cases to be avoided over the 20-year period yields a total of $0.6 billion saved.

ii. Willingness-to-pay estimates. Avoided medical care costs undervalue the true benefits of a health care regulation because they do not include productivity losses or pain and suffering losses. A more inclusive method of valuing these losses is to estimate the amount people are willing-to-pay to reduce risk. The willingness-to-pay estimates in this section are values that consumers and workers place on risk reduction. This is different from values people place on label information, which, as discussed earlier, we were unable to directly estimate.

Willingness-to-pay studies have been done for a variety of risk situations including wage differentials between high and low risk jobs, use of seat belts to reduce risk and contingent valuation surveys. These studies reflect the fact that people routinely make decisions to accept or avoid some incremental amount of risk such as choosing between buying an automobile or a motorcycle, climbing mountains or playing softball or being a policeman versus being a secretary. These decisions may either increase or decrease risk.

The results of these studies have often been mislabeled as "value of life" estimates. These estimates represent not the value of a life, but only the value of a reduction in the statistical risk of death. Thus, it is incorrect to say that if a person values a 1 in 100 risk reduction at $10,000, then that person's life is valued at $1,000,000 ($10,000/.01). It will matter, for example, whether the marginal risk is a reduction from 100/100 to 99/100, or from 2/100 to 1/100.

Consequently, statistical willingness-to-pay figures must be understood to reflect only estimated values of marginal changes in the risk of death. It should also be pointed out that the willingness-to-pay figures used here will be applied to changes in risk (from estimated consumer behavior changes) which places additional uncertainty on these numbers.

Analysts have not reached a consensus on the best method of applying a willingness-to-pay estimate to value changes in health states. The studies mentioned above examine consumers' and workers' willingness-to-pay to reduce risk in various situations, from dying immediately of injury to dying of cancer at old age. Some analysts apply a mean figure to value the prevention of early death, others believe it is important to consider only the likely remaining number of life-years. Thus, this analysis will present both figures.

(a) *Remaining life-years approach.* The remaining life-years approach calculates a discounted value per life-year saved from mean values of willingness-to-pay to reduce the risk of death. According to analysts who favor this view, "* * * statistics about life expectancy tell us a great deal more than do stupefying tallies of death." That is, it is the length of life that is considered important, since dying of a heart attack at age 80 is posited to be of less societal concern than dying in a car accident at age 35. Use of these values, life-years saved, implies that it is worth more to society to save 60 years of life than 5 years of life.

In their study, RTI used the relatively conservative value of $1.5 million for the willingness-to-pay figure. Using the expected discounted life-years remaining from age 40, and a discount value of 5 percent, a value of $89,074 per life-year saved is derived. Combining this figure with the discounted number of life-years saved produces a benefits estimate of $3.6 billion ($7.2 billion if $3.0 million is used for the willingness-to-pay figure as is done in the next section). If benefits are discounted at 10 percent (for comparison purposes, analytical costs, which extend into the future, were also discounted at 10 percent), benefits become $3.1 billion. Benefits do not decline rapidly with discount rates as the original value of life estimate is unchanged and fewer discounted remaining years of life is offset with a higher value per year.

Benefit estimates in each year are discounted back to the time of this decision because changes in risk for CHD and cancer appear at different, distant points in time. The Office of Technology Assessment has noted that health benefits should be discounted, other things equal, because people prefer health benefits today rather than at a future time (Ref. 31). By discounting these health effects to the present time, the value that consumers place today on future benefits may be estimated. Furthermore, it is necessary to discount

benefits in order to be able to compare them to costs. The higher the discount rate used, the lower the discounted health benefits.

(b) *Mean value approach.* The mean value approach is an alternative approach which applies a mean value to all early deaths, without regard to the average remaining years of life. As this approach is based on revealed market data, it avoids a problem of the former approach in that little empirical evidence is available to estimate how consumers value changes in risk for remaining life-years.

Furthermore, some studies have estimated willingness-to-pay values for reductions in risk of death as high as $8.5 million (Ref. 32). For this approach, FDA has conservatively doubled RTIs estimate and used $3.0 million. Combining the discounted number of early deaths (7,027) with a value of $3.0 million per early death avoided produces a benefit estimate of $21 billion ($10.5 billion if $1.5 million is used for the willingness-to-pay figure as is done in the previous section).

FDA realizes the range of values presented for estimating the benefits of reducing risks to health derive from different methodologies appearing in economic literature. It is not clear whether either methodology is inherently preferable either in general or for this particular set of regulations. FDA requests comments as to either the appropriate measure to use to value reductions in health risks or whether it is appropriate to use both in a range, as has been done here.

As has been noted throughout, FDA believes that the estimate of the health gains derived from the SDA study is probably an underestimate. The two primary reasons for this belief are the fact that no reformulation took place during the SDA study and the quantification of early death benefits leave out quality of life gains from fewer cases of CHD and cancer. Each case of cancer and CHD that does not result in early death still tremendously reduces the quality of life for both the afflicted and those around them.

d. *Perfect diet study.* In addition to estimating the benefits that derived from consumers behavior change, RTI estimated the improvement in risk that would obtain if all consumers were to eat a "perfect" diet. A perfect diet is defined as the average consumer consuming over time the DRV for fat, saturated fat, and cholesterol. This estimate represents a baseline of benefits which could be derived from a diet change made by U.S. consumers, particularly affecting their rates of cancer and CHD. Although not an estimate of benefits of nutrition labeling, the estimates provided in this section help to give perspective to the benefits obtained from food labeling. Other health improvements which might take place from a diet change include diabetes, hypertension, osteoporosis, and obesity. These changes are expected to produce small health benefits relative to CHD and cancer reductions. These risk improvements will be partially obtained by FDA's current effort on the 1990 amendments and may be further obtained by FDA's or any other organization's efforts to influence the nutritional intake of the U.S. diet.

To estimate current nutrient intakes, information on U.S. consumption data was obtained from the 1987 Nationwide Food Consumption Survey (NFCS), a self-reported food intake survey conducted by USDA. Next, average DRVs were compared with actual average intakes to estimate the maximum potential change in nutrient intake. Using the same methodology to extrapolate changes in cancer and CHD that was used in the benefits estimation, it is estimated that 725,000 cases of cancer and CHD are potentially avoidable by U.S. consumers over the next 20 years.

All of the health effects avoided from consumers eating the DRVs for fat, saturated fat, and cholesterol are shown in Table 15 below:

TABLE 15.—MAXIMUM HEALTH BENEFITS FROM DIET IMPROVEMENT [1] OVER 20 YEARS

Cases of CHD and cancer avoided	725,155
Deaths avoided	308,366
Life-years gained	2,280,549

[1] Uses lagtimes of 2 and 10 years for the occurrence of CHD and cancer respectively following a diet change.

Table 15 showed the maximum possible benefits from dietary changes of all foods U.S. consumers eat. However, because the 1990 amendments point only to FDA regulated products, this maximum change is adjusted downward to exclude changes in the consumption of meat and poultry, since labels for those products are not affected. Meat and poultry represent 33 percent of total fat intake for men and 30 percent for women, and this consumption is assumed to remain unchanged.

TABLE 16.—MAXIMUM HEALTH BENEFITS FROM DIET CHANGES [1] FDA REGULATED FOODS ONLY (20 YEARS)

Cases of cancer and CHD avoided	503,448
Deaths avoided	212,596
Life-years gained	1,565,350

[1] Uses lagtimes of 2 and 10 years for the occurrence of CHD and cancer respectively following a diet change.

The numbers presented in Table 16 may seem small relative to the overall rates of cancer and CHD in this country. CHD, for example, claims over 500,000 lives per year and cancer approximately 514,000 per year (Ref. 33). However, there are many reasons that food labeling will only make a relatively small impact on these numbers. First, only small percentages of consumers change their behavior in response to new information. Secondly, deaths avoided are net after subtracting increased deaths from other causes. That is, if someone is saved from dying from CHD, he/she may die early from something else. Thirdly, there are competing causes for these diseases.

For cancer, Doll and Peto estimate that approximately 35 percent of all cancers are related to diet (Ref. 34). Yet there are many other dietary factors besides fat which cause cancer, such as natural carcinogens and carcinogens produced by storage or cooking. Similarly, CHD has multiple causes outside of fat intake, including genetic factors, smoking, and diabetes.

i. Consumer behavior. The numbers of life-years that might be gained from a better diet are large, but nutrition competes with other food attributes in determining consumer purchases. Taste, convenience, appearance, brand name, and price are all important in the decision. It is estimated that approximately 45 percent of all consumers are actually aware of labels, read them, and understand them. This estimate is calculated from various consumer studies of label awareness as shown in table 17 below.

TABLE 17.—CALCULATION OF DECISION PROBABILITIES [1] PROBABILITY

Being aware	0.76
Looking for label conditional on being aware	0.85
Reading label conditional on looking	0.92
Understanding the label conditional on having read the label	0.76
Probability of being aware, reading and understanding labels	[2] 0.45

[1] Ref. 24.
[2] Obtained by multiplying the above probabilities.

However, FDA does not assume that 45 percent of all consumers will

presently change their purchase behavior as a result of revised labels. As nutritional awareness expands, the very small percentages of nutrient changes estimated in the SDA study (around 1 percent) should increase as the number of interested consumers increases.

VI. Options Considered

Because much of the 1990 amendments is very prescriptive, FDA has very little flexibility to develop options other than with respect to the compliance period and other options as noted below. Most of the options summarized below and many others of less benefit-cost import are also discussed in the preambles to the various rules.

A. Compliance Period Options

The primary cost option alters the amount of time firms have to comply with mandatory nutrition labeling and other labeling requirements that become effective at the same time. The 1990 amendments allow the Secretary to delay the effective date for nutrition labeling, nutrient content claims, serving sizes, and health claims for up to 1 year if he finds that compliance with these provisions would cause undue economic hardship. The following discussion will provide information on the options of extending the proposed 6-month compliance period an additional 6 months (1-year compliance period) and 1 year (a compliance period of 18 months).

The first option reviewed by FDA is to extend the compliance period for mandatory nutrition labeling, etc. to 1 year (a 6-month extension). Because the length of the compliance period affects all cost categories, except analytical costs, extending the compliance period would result in significant savings. The discounted costs of this option would be $896 million (5 percent discount rate). This amounts to a savings of approximately $644 million. If discounted at 10 percent, the costs would be $872 with a savings of $668 million.

The second option available to FDA, extending the compliance period for mandatory nutrition labeling, etc. to 18 months (a 1-year extension), would result in a savings of $835 million. Total discounted costs of this option are estimated to be $705 million (5 percent discount rate).

The 1990 amendments do not allow the Secretary the option of allowing all label changes to be effective at once (i.e., delay the implementation of ingredient labeling changes until nutrition labeling regulations are final). Nor is it possible to extend the compliance period beyond 18 months.

Extending the compliance period would also reduce costs to food service establishments by allowing firms to incorporate mandated menu changes with normally scheduled changes. However, FDA has no information to quantify the reduction caused by extending the compliance period. Therefore, any comments suggesting an extension of the compliance period for these provisions should include information as to the value to restaurants and other food service establishments of extending the compliance period for these actions.

Table 18 shows the costs and benefits of each of the above options. Benefits will decline by a maximum 2.4 percent with each additional 6 months extension of time to comply, depending on how much relabeling were to take place during that period. Benefits decline only because of discounting (2.4 percent). All benefits will be obtained despite the compliance deadlines. However, because benefits today are preferred to benefits tomorrow, giving firms more time to comply with labeling will delay benefits and reduce them by the discount rate. In fact, this is only true because of the finite 20-year horizon. Benefits will decline slightly if labeling is delayed as more cases should be prevented over an infinite timespan.

TABLE 18.—ESTIMATED COSTS OF THE COMPLIANCE OPTIONS [1] (IN MILLIONS OF DOLLARS OVER 20 YEARS)

Cost type	Option 1	Option 2	Option 3
	6 months	12 months	18 months
Mandatory labeling:			
Administrative	177	93	70
Analytical	195	195	195
Printing	862	600	436
Inventory	306	8	4
Total	1,540	896	705
Benefits [2]	3,600	3,513	3,429

[1] Excludes voluntary labeling of raw fruit, vegetables, and fish.
[2] Estimate based on life-years saved. Excludes regulation of restaurant menus.

B. Options for Ingredients Labeling Provisions

FDA considered options for each of the provisions listed in the ingredients document that were not required by the 1990 amendments. Many of the options considered required more extensive labeling (e.g., source labeling for sweeteners). FDA rejected these options where there appeared to be no market failure. The most important option rejected is the elimination of "and/or" labeling for fats and oils. Because mandatory nutrition labeling allows consumers to discover the nutrients in the products they consume, the need to eliminate "and/or" labeling for fats and oils became irrelevant. Furthermore, because all mandatory ingredients in standardized foods must now be listed, FDA will consider altering current food standards policy.

C. Options for Percentage Juice Labeling Provisions

In the proposed regulation for percentage juice labeling, different options were considered to define the amount of modification that could be made to the juice counted in the percentage juice statement. If the juice has been modified in any way other than concentrating it, it may not be counted in the "contains x percent juice" statement. For example, if the color is removed from grape juice and the resulting modified juice is added to a blend of other juices, it would not be counted as adding to the total percentage juice. The more tightly "modification" is defined, the less incentive to modify the juice. It is not clear how juice products will be affected by this proposal, but other options for the definition of "modification" might allow more modification and still be counted as juice in the percentage statement.

D. Options for Voluntary Labeling of Raw Produce and Seafood

In the voluntary labeling of raw fruit, vegetables, and fish, FDA has chosen the option of allowing virtually any format to comply with this labeling. For sampling to determine compliance, one option considered was to include only large supermarkets with sales of $2 million or more (approximately 31,000 stores). This would have allowed the labeling to reach at least 80 percent of the population. By including firms under $2 million, an additional 6.6 percent of the population is reached by including an additional 68,000 stores. This increases discounted costs over a 20-year period from $54 to 99 million to $117 to 155 million. FDA has also proposed to allow less than 100 percent compliance per store and still be counted as "in substantial compliance." Because costs are relatively fixed, aggregate net benefits decrease with smaller store size and fewer consumers utilizing individual signs.

E. Options for Health Claims

For health claim regulations, FDA is required to process requests for new claims rapidly. The agency has considerable latitude concerning how well specified the supporting data for

either a new general health claim or the use of a claim in a brand name must be. The more completely specified, the lower the likelihood the potential claim will be denied because of small omissions and the higher the cost of preparing the initial request. However, total costs are likely to be higher with repeated submissions. The agency will look closely at this issue.

FDA will also have considerable latitude in choosing levels of disqualifying nutrients with the effect that, any food outside of the boundaries set for the four nutrients of concern (fat, saturated fat, sodium, and cholesterol) will be disqualified from any health claim unless firms petition the agency for an exception. The agency can also choose whether or not it will establish separate procedures and standards for claims for supplements.

The proposed regulation of health claims is different from other regulations proposed under of the 1990 amendments (except the proposed regulation of nutrient content claim definitions) in that the health claims proposal would allow firms to provide additional information where such firms believe that the additional information will benefit the marketing of their products. In determining which claims are to be allowed, the agency has some latitude. That is, the agency must establish what constitutes "significant scientific agreement among experts qualified by scientific training and experience * * *" that the claim is "valid" when determining whether or not a particular health claim will be allowed. The level of stringency that is set for what constitutes significant agreement will affect both "Type I" and "Type II" errors (A Type I error is finding something true when it is false and a Type II error is finding something false when it is true). A Type I error would occur if insufficient stringency were set and a false claim were approved. This would cause consumers to make choices toward foods that might be unwarranted substitutions. On the other hand, if the degree of stringency is set too high, a Type II error may occur in which claims that are true are not allowed. In this case, consumers may not be given valuable information to help them choose foods that contribute to better health.

These decision rules have been considered by two health claims researchers who find that a fixed consensus rule requiring a high level of consensus "assumes the costs of a Type I error (allowing a claim that proves to be false) are far greater than the costs of a Type II error (prohibiting a claim that proves to be true)" (Ref. 35). The authors point out that a consensus rule, if flexible, can be equivalent to an expected value rule.

Other authors have pointed out that a consensus is difficult to determine. An article in the *Journal of the American Medical Association* (Ref. 36) makes the point that consensus may have as much to do with "fashion" in medical theory as with objective measures of the effectiveness of the treatment. The ability to reach a consistent measure of consensus is further hampered by the uneven state of knowledge about diet and health in different areas (Ref. 37). Nevertheless, the 1990 amendments direct the agency to permit claims only if there is significant scientific agreement.

In addition, the agency has discretion with respect to how claims can be worded. If a claim may be applied to a specific brand of food, for example, manufacturers will have a stronger incentive to make such claims. If the claim must apply to a generic food group, a "free ride" problem arises. That is, firms not advertising "free ride" on the advertising of those who do. This leads to suboptimal provision of information as firms are less inclined to provide information when competitors also benefit from that information. Depending on how health claims are structured, "Sellers may also attempt to internalize the benefits of generic information by stating simply that their product possesses the desired attribute (or lacks the undesired ones) without mentioning that all competing brands do too (Ref. 38). However, such a claim may be perceived as either deceptive advertising or spurious product differentiation (Ref. 38). Whether or not a claim may be applied to a specific brand may ultimately depend on whether or not the brand has been manufactured to be different from other foods in the class or whether all foods in the class simply meet the definition for the claim. An example would be a food that has reduced fat because its ingredients are different from other foods in the class, versus a frozen vegetable where all the vegetables meet the definition for the claim. An example would be a food that has reduced fat because its ingredients are different from other foods in the class, versus a frozen vegetable where all the vegetables met the definition for the claim.

F. Options for Serving Sizes

Section 2(A)(i) of the 1990 amendments provides for packaged foods to be labeled with the serving size expressed as either a common household measure (e.g., oz.) or the common household unit of measure that expresses the serving size of the food (e.g., slice of bread). FDA has full flexibility under the law to define what these measures are and all nutrient declarations will follow from these definitions. An alternative divisor that could have been chosen (by Congress) for this purpose would be to express all foods in a single measure, e.g., 100 grams. This type of measure would be useful for making comparisons between food whereas different measures, such as common household serving sizes, must be manipulated in order to make these comparisons. The single measure approach has the additional benefit of not overloading the consumer with too much information. Nevertheless, as different foods are customarily consumed in different amounts, the single measure approach is not consistent with the 1990 amendments.

However, the option of providing information in addition to what is required remains open to manufacturers. Thus, a manufacturer who wishes to provide nutrient content information on a per ounce or per 100 gram basis in addition to the information on a standard serving size basis may do so. This type of information would help improve consumer choices across products and thus improve the total diet. Although this additional information may prove confusing to consumers, normal market forces should dictate when and where it will be useful.

G. Options for Nutrition Labeling in Food Service Establishments

FDA is not compelled by the 1990 amendments to require nutrition labeling for restaurants, even those using nutrient content claims and/or health claims. Thus, one option is to require no nutrition labeling to accompany these terms. Under this option, eating establishments might be able to use computerized data bases to determine if they are within required levels set for disqualifying nutrients. FDA has no information on whether or not such data bases would, in fact, be adequate, nor on the cost of these data bases.

An additional option is to require full nutrition labeling for all restaurants using health claims or nutrient content claims on the menu or elsewhere. Analytical tests for these nutrients, if such testing is required, would cost $1785 per menu item (three samples of the initial analysis is assumed). Firms would also bear the cost of providing nutrition information to the customer. This information could be on the menu.

a poster or sign, in a notebook, or any other possible form. FDA does not have the information to calculate these costs.

Further, FDA could opt to require an abbreviated form of nutrition information for all restaurants using health claims or nutrient content claims on the menu. Restaurants would be required, for example, to provide information on the amount of calories, total fat, saturated fat, total carbohydrates, protein, sodium, cholesterol, and the nutrient for which the claim is made (if different from the above mentioned nutrients). The cost for nutritional analyses for these nutrients is $661 per menu item (three samples for the initial analysis is assumed).

FDA also has several options regarding which firms should or should not be exempted from any requirement to provide nutrition labeling. The options available are: (1) to require nutrition information in all food service establishments with no exemptions, (2) to exempt small restaurants as defined by sales volume, or (3) to require nutrition labeling only in restaurants that are "chains." FDA has no information to calculate the costs of each of these options and requests comments with such information. Also, any proponents of these options should submit a comment including information concerning the utility of data bases and potential costs.

H. Federalism

Executive Order 12612 requires that a federalism analysis be performed whenever there is a question as to whether or not a Federal solution is mandatory for a particular problem. This analysis should include whether or not to refrain from a Federal standard and encourage States to develop their own policies to achieve program objectives, whether or not to consult State and local authorities for Federal decisionmaking, and whether or not to allow maximum flexibility for enforcement of Federal policies by States and Local governments.

The 1990 amendments direct FDA to provide regulations governing the use of health claims and nutrient content claims for all food for human consumption, including restaurants. However, in addition to regulation directly required by the amendments, FDA is proposing to require some nutrition labeling whenever a health claim or nutrient content claim is used. One option of this regulation is to remand to States or localities the decision as to whether or not nutrition labeling should be required. However, because use of health claims and nutrient content claims in restaurants is required to be regulated by the Federal Government, and because nutrition labeling is only required when triggered by the use of these terms, this action is tied to Federal law. Further, that option would have two drawbacks, however. First, travelers would have difficulty comparing menu items between different localities. Second, the costs of this regulation would be increased as chain restaurants operating in different localities would be forced to print different menus for each locality in which they operate. States and localities have the option of requiring full nutrition and/or ingredient labeling in addition to that required by FDA. If FDA regulates restaurant menus, this may raise a Federalism issue under Executive Order 12612, and the agency welcomes comment on this question.

I. Options for Other Provisions

For other actions such as definitions of nutrient content claim definitions and RDI's and DRV's, FDA will review comments on the proposals relative to definitions of Codex Alimentarius and those adopted by U.S. trading partners to attempt, where possible, to facilitate international trade.

FDA has a number of nutrition panel formats available with potentially different costs for each format. At the time this document was written, no format was chosen. However, one concern may be that the nutrition panel size of one potential format is a 240 percent increase in size over the existing format. For some products, this may cause a more extensive label redesign of the PDP than currently estimated.

VII. International Impacts

In accordance with Executive Order 12291 and other guidance received from the Office of Management and Budget (OMB), FDA has also evaluated the effects on international trade of these regulations. Guidance received from OMB requires agencies to make no explicit distinction between domestic and foreign resources when calculating costs and benefits of regulations.

FDA has evaluated the costs of this regulation to both foreign and domestic manufacturers jointly for all costs except administrative costs. It is likely that administrative costs for foreign firms will equal or exceed those of domestic firms but FDA has no information on either the number of firms or the magnitude of the costs per firm. FDA requests information on these costs.

The United States is a signatory to three agreements that provide for efforts to harmonize, inter alia, food labels bilaterally or internationally (Ref. 39). The Canada-U.S. Free Trade Agreement provides for bilateral harmonization efforts. The two international agreements are the Codex Alimentarius Commission (Codex) and the General Agreement on Tariffs and Trade (GATT). Codex, a subsidiary of the United Nations' Food and Agriculture Organization and the World Health Organization, creates advisory information on food labeling and standards for its 130 member countries with the objective of facilitating international trade while protecting consumers' health. The GATT, an agreement signed by 90 nations, provides a framework for settling trade disagreements and for conducting multilateral trade negotiations, including negotiations on nontariff trade barriers such as inconsistent labeling requirements.

The Treaty of Rome of the European Community (EC) is another international agreement with U.S. trade implications. In working toward harmonization of food labeling requirements for its 12-member countries, the EC Council has adopted a directive on nutrition labeling and is developing another directive on labeling claims.

Despite increased efforts by the United States to consider the food labeling requirements of other countries, complete harmonization of food labeling requirements is often not possible because of differing language requirements or other unique national concerns.

The primary differences between the U.S. proposed regulations and the provisions of Codex, Mexico, Canada, the EC, and other trading partners are that many of the mandatory provisions are voluntary in other countries and some of the voluntary provisions are not permitted in other countries. These regulations will cause foreign firms to have to change their English label to market their food products in the United States. Also, because definitions of some nutrients differ, additional analytical testing and compliance activities may be required; other requirements may simply provide manufacturers incentive for product reformulation. The costs for these foreign firms should be identical to those incurred by domestic firms to meet the requirements of these regulations.

Some of the key differences in FDA labeling rules compared to those of Canada, the EC, or other trading partners, which could contribute to the need for foreign firms to change English food labels or conduct additional product testing are:

(1) *The mandatory status of nutrition labeling.* Most food products FDA regulates must have nutrition labeling, whereas in Canada and the EC nutrition labeling is largely voluntary.

(2) *The expanded required content for nutrition labeling.* Nutrition labeling may be limited in Canada or the EC to the declaration of energy value, protein, carbohydrate, and fat content unless claims are made and additionally, in the case of Canada, when vitamins or minerals are added. In contrast, FDA would require the mandatory listing of a number of additional food components, including saturated fat, cholesterol, complex carbohydrate, sugars, dietary fiber, sodium, two vitamins, and two minerals.

(3) *The expanded optional content for nutrition labeling and RDI's.* Because of the proposed rule's expanded list of RDI's, FDA would permit several vitamins and minerals to be listed that would not be permitted by Canada or the EC and would also permit certain other food components to be declared relative to RDI's. The same food product marketed in the United States, Canada, and the EC might also require different percentages to be listed for some vitamin and mineral content because of differing daily intake reference values.

(4) *The definitions of food components.* FDA would define saturated fat, unsaturated fat, and sugars differently from both Canada and the EC, with implications for the formulation, analytical testing, and labeling of food products. FDA would also define carbohydrate differently from Canada but not the EC by excluding dietary fiber.

(5) *Nutrition label format and terms.* Examples of differences between the United States compared to Canada and the EC would include the permitted use of the aggregate category of unsaturated fat, the less prominent order of listing of protein, and the terms used to describe RDI's.

(6) *The mandatory declaration of nutritional content on a per serving basis expressed in household measures and parenthetically in metric units.* Canada also requires the declaration of nutritional content on a per serving basis in metric units, and permits as well the declaration in household measures (although Canada uses Imperial measures and the United States uses avoirdupois). Unlike Canada, which has established guidelines for ranges for serving sizes to use to declare nutritional content, FDA would require that single regulatory reference serving sizes serve as guidance to declare nutritional content and as the basis for labeling claims. As long as FDA's regulatory serving size falls within the range used by Canada, no trade barriers are anticipated.

Finally, dual declaration of nutritional content on a per serving basis and on a 100 gram (milliliter) basis would be permitted by FDA, Canada, and the EC, although in contrast to the United States and Canada, declaration on a 100 gram (milliliter) basis is required by the EC.

(7) *The voluntary declaration of content claims.* FDA would limit the use of terms for content claims to those defined by regulation, some of which would differ in terminology or definition from those in Canadian regulations or guidelines. The EC does not yet have a directive on content claims.

(8) *The voluntary declaration of health claims.* FDA would allow the use of certain health claims if requirements are met; in contrast, Canada is prohibited by law from allowing claims related to diet and disease on food labels. The EC does not yet have a directive on health claims.

(9) *The voluntary nutrition labeling of raw fruit, vegetables, and fish.* FDA would require an appropriate compositional data base for these products.

As before, all firms wishing to import or export into the United States must have two labels. Importing firms are faced with the same relabeling costs as U.S. firms. In addition, many are likely to have to perform two sets of analytical tests (one additional test must be performed as a result of these proposals) because of different definitions. An example is the use of different definitions for saturated fats (length of the carbon chain). It is unclear how much other countries will follow the United States' lead in changing the food label.

VIII. Summary

Total costs of these regulations have been estimated to be $1.5 billion. These costs include administrative, analytical, printing, and inventory costs, the latter three including costs to foreign firms. Reformulation costs were not estimated. These costs do not include the voluntary labeling of raw fruit, vegetables, and fish.

Benefits are reduced risk of illnesses such as CHD, cancer, obesity, osteoporosis, and allergic reactions to food ingredients. The value of these benefits are estimated to be $3.6 billion. Estimated costs, benefits, and estimated health effects are shown in Tables 19 and 20 respectively:

TABLE 19.—ESTIMATED COSTS OF THE COMPLIANCE OPTIONS

(In Millions of Dollars Over 20 Years)

Cost type	Option 1	Option 2	Option 3
Mandatory labeling	6 months	12 months	18 months
Administrative	177	93	70
Analytical	195	195	195
Printing	862	600	436
Inventory	306	8	4
Subtotal	1,540	896	705
Voluntary Labeling	136	136	136
Total costs	1,676	1,032	841
Benefits [2]	3,600	3,513	[1] 3,429

[1] Benefits are reduced by discounting only because a 20-year time horizon was used.
[2] Estimate based on life-years saved. Excludes regulation of restaurant menus.

TABLE 20.—ESTIMATED HEALTH EFFECTS [1] (OVER 20 YEARS)

	Effective date		
	6 months	12 months	18 months
Cases avoided:			
Cancer	35,179	33,356	31,533
CHD	4,028	3,962	3,896
Deaths avoided	12,902	12,438	11,973
Life-years gained	80,930	75,199	69,468

[1] Uses lagtimes of 2 and 10 years for the occurrence of CHD and cancer, respectively following a diet change.

FDA has analyzed the total costs and benefits of these proposals and has determined that the costs exceed the $100 million threshold, requiring the agency to declare that these proposals constitute in a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has determined that these proposals will have a significant adverse impact on a substantial number of small entities, including small businesses.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Levy, A.S., O. Mathews, M. Stephenson, J.E. Tenney, and R.E. Schucker, "The Impact of a Nutrition Information Program on Food Purchases," *Journal of Public Policy and Marketing*, pp. 1–13, 1988.

2. Leftwich, R., "Market Failure Fallacies and Accounting Information," *Journal of Accounting and Economics 2*, p. 194, 1980.

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X. Comments

Interested persons may, on or before February 25, 1992, submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91–27171 Filed 11–26–91; 8:45 am]

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21 CFR Parts 101, 102, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, and 169

[Docket Nos. 90N–0361 and 80N–0140]

RIN 0905–AD08 and 0095–AC48

Food Labeling; Declaration of Ingredients and Food Labeling; Declaration of Ingredients, Common or Usual Name for Nonstandardized Foods, Diluted Juice Beverages

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; delay of statutory effective date.

SUMMARY: The Food and Drug Administration (FDA) is announcing changes in the statutory effective date of the ingredient labeling provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This action is in response to an amendment of section 10(c) of the 1990 amendments. FDA published proposed rules to implement the ingredient labeling provisions on June 21, 1991 and July 2, 1991.

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF–312), Food and Drug Administration, 200 C Street, SW., Washington, DC 20204, 202–485–0229.

SUPPLEMENTARY INFORMATION: Section 7 of the 1990 amendments modified section 403(i) of the Federal Food, Drug and Cosmetic Act (the act) to require the declaration of all ingredients in standardized foods, the declaration of certified color additives in foods, and the declaration, on the information panel, of the percentage of a fruit or vegetable juice in a food purporting to be a beverage containing fruit or

vegetable juice. FDA published proposed regulations to implement these requirements in the **Federal Register** of June 21, 1991 (56 FR 28592) and July 2, 1991 (56 FR 30452), with opportunity for comment through August 5, 1991. Both proposals are part of the Department of Health and Human Services' (DHHS') major initiative to reform the nation's food labeling system and part of DHHS' response to the 1990 amendments.

Although FDA proposed to make the ingredient labeling regulations and percent juice labeling regulations effective on the same date as the mandatory nutrition labeling final rule (i.e., May 8, 1993), the agency pointed out that the 1990 amendments state in section 10(c) that ingredient listing provisions for standardized foods, certified color additives, and percent juice labeling were to take effect 1 year after enactment. Thus, on November 8, 1991, these statutory provisions would be in effect.

In response to the proposals, many comments from the food industry strongly urged FDA to reconsider the effective date for ingredient labeling regulations and percent juice labeling regulations. The comments argued that a November 8, 1991, effective date would not allow the food industry enough time to develop the required labeling and would significantly increase costs because present inventory would have to be discarded. The comments strongly urged FDA to establish a uniform effective date to comply with the effective date for section 403(q) of the act (mandatory nutrition labeling) and section 403(r) of the act claims, which were added by the 1990 amendments. Even though FDA agreed with these comments, it had no authority to provide the requested extensions.

A technical amendment was enacted on August 17, 1991, in which Congress amended the 1990 amendments to delay or modify the effective date of the new ingredient and percent juice labeling requirements. To reflect these changes, the agency is giving notice that a food for which a standard of identity has been established, or with one or more colors required to be certified, that bears a label that was printed before July 1, 1991, and that was attached to the food before May 8, 1993, will not be subject to changes made in section 7(1), which modifies section 403(i) of the act to require that all mandatory as well as optional ingredients in a standardized food be declared, and in section 7(3) of the 1990 amendments, which modify section 403(i) of the act to require the declaration of certified colors. Labels on these foods printed after July 1, 1991 but before the effective date of a final implementing regulation and attached to the food before May 8, 1993, must conform with requirements of the June 21, 1991 proposal. Labels attached to food after May 8, 1993, will be subject to the amended section 403(i) of the act and to FDA's final regulations. Finally, the new ingredient labeling requirements for fruit and vegetable juice beverages will not apply to labels attached to these products before May 8, 1993.

Dated: November 13, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91-27749 Filed 11-26-91; 8:45 am]

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federal register

Wednesday
November 27, 1991

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101

Food Labeling; Nutrition Labeling; Guidelines for Voluntary Nutrition Labeling; and Identification of the 20 Most Frequently Consumed Raw Fruit, Vegetables, and Fish; Definition of Substantial Compliance; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0122]

RIN 0905-AB68

Food Labeling: Nutrition Labeling of Raw Fruit, Vegetables, and Fish; Guidelines for Voluntary Nutrition Labeling of Raw Fruit, Vegetables, and Fish; Identification of the 20 Most Frequently Consumed Raw Fruit, Vegetables, and Fish; Definition of Substantial Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is: (1) Identifying the 20 most frequently consumed raw fruit, vegetables, and fish in the United States; (2) establishing guidelines for the voluntary nutrition labeling of these foods; and (3) defining "substantial compliance" with respect to the adherence by food retailers to those guidelines. This action is in response to the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: November 8, 1991.

FOR FURTHER INFORMATION CONTACT: Jean A. T. Pennington, Center for Food Safety and Applied Nutrition (HFF-260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1064.

SUPPLEMENTARY INFORMATION:

I. Background

In response to requirements of the 1990 amendments (Pub. L. 101-535), FDA published in the **Federal Register** of July 2, 1991 (56 FR 30468) a proposal to identify the 20 most frequently consumed raw fruit, vegetables, and fish in the United States; to establish guidelines for the voluntary nutrition labeling of these foods; and to define "substantial compliance" with respect to the adherence by food retailers to those guidelines. FDA requested comments on these proposed regulations and on the proposed guidelines. Interested persons were given until August 1, 1991 to comment. FDA received approximately 40 responses, each of which contained one or more comments, from trade and retail associations, government organizations, retailers, consumer groups, State groups, private organizations, professional societies, and one university. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., consumer education programs for nutrition labeling) and will not be discussed here. A number of comments suggested modification and revision in various provisions of the proposal. A summary of the suggested changes and the agency's responses follows.

II. Nutrition Labeling of Raw Fruit, Vegetables, and Fish Under the 1990 Amendments

A. Timeframes for Implementation

1. The agency stated in the July 2, 1991 proposal (56 FR 30468 at 30471) that the guidelines for the voluntary nutrition labeling of the 20 most frequently consumed raw fruit, vegetables, and fish, to be issued by November 8, 1991, would be revised, as necessary, after the first report to Congress on retailers, compliance with the voluntary guidelines to reflect other forthcoming labeling regulations. There were requests in several comments that FDA issue all the needed information in its final form for the labeling of raw fruit, vegetables, and fish. Several comments suggested delaying the issuance of the guidelines until the final regulations on serving size, label content, daily intake standards, and label format have been issued. These comments stated that such a delay would allow the agency to develop guidelines for the nutrition labeling of raw fruit, vegetables, and fish that would be consistent with the labeling requirements for processed foods. As a result, it would not be necessary to modify the guidelines when the final rules on those aspects of nutrition labeling are published or to update or replace in-store labeling at that time.

FDA understands the advantages of having all of its regulations that bear on nutrition labeling in place at the time that it issues the guidelines for the nutrition labeling of raw fruit, vegetables, and fish. However, the agency is required by the 1990 amendments to issue these guidelines by November 8, 1991. The guidelines must include information on serving size, label content, daily intake standards (i.e., U.S. Recommended Daily Allowances (U.S. RDA's)), and label format, even though these aspects of the nutrition label are subject to change with the final rules that bear on these matters.

The agency is also required by the 1990 amendments to issue a report to Congress on compliance with the guidelines by retailers by May 8, 1993. This report must be based on actions taken by retailers during the 18 months between November 8, 1991 and May 8, 1993. Realistically, it will take retailers some time after November 8, 1991 before the nutrition labeling programs are in the marketplace, and it will be necessary for the agency to complete its review of the market several months before the report to Congress is due to ensure that the report is submitted on time. Therefore, the time in the marketplace for nutrition labeling of raw produce and fish before assessment of compliance will be closer to 14 to 15 months than 18 months. If the guidelines for nutrition labeling for raw fruit, vegetables, and fish were to be delayed until after the publication of all relevant final regulations (due November 8, 1992), there would be insufficient time to accomplish these tasks and meet the legislative requirement for a report on voluntary compliance by May 8, 1993. Thus, the agency cannot delay issuing the guidelines for the nutrition labeling of raw fruit, vegetables, and fish until the other nutrition labeling regulations are finalized.

2. One comment was concerned with the timeframe for obtaining the labeling data and for providing it in the marketplace. The comment stated that only if FDA can provide the data by November 8, 1991 will there be time for trade associations to distribute it and for retail stores to develop and print the information programs. The comment stated that if the provisions relating to nutrition labeling of raw produce and raw fish are confusing to retailers (because of changes to be made to them), the retailers will not provide the information properly or completely. The comment also noted that the information must be simple and standardized to be useful to consumers. The comment therefore requested that FDA provide the necessary information in final form, with the appropriate serving sizes and in the format desired, before expecting retailers to comply with the regulations.

The agency appreciates these concerns and is providing interim nutrition labeling data for the 60 foods in this final rule (appendices A and B). These data may be used to develop in-store nutrition labeling programs. FDA is providing the data for these foods in serving portions that are generally consistent with the FDA reproposal on serving sizes that is published elsewhere in this issue of the **Federal Register**. The data in appendices A and B include those that should appear on the label as specified in § 101.45(b) for FDA to find the information to be in compliance. Data are provided for calories, protein, fat, carbohydrate, sodium, and percent

U.S. RDA for vitamin A, vitamin C, calcium, and iron. In addition, data are also provided for the dietary fiber content of fruit and vegetables and for the saturated fat and cholesterol content of fish. The guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish will, however, be subject to change after the first report to Congress by May 8, 1993 to make them consistent with the final rule for Mandatory Nutrition Labeling.

B. Presentation of the Nutrition Information in Retail Stores

There was general support for the flexibility offered by FDA in presenting the nutrition information to the consumer. Several comments noted the importance of presenting the information in a clear, conspicuous, and prominent manner in close proximity to the commodity. One comment stressed that the information must be easily used and understood by consumers.

3. One comment requested that FDA specifically permit the use of more advanced technology, such as electronic signage, for presenting nutrition information.

The language used in § 101.45(a) does not prohibit more advanced technology, and FDA does not think it necessary to specifically provide for its use. Nutrition information should be available to all consumers, and FDA is concerned that information available only on computer screens, TV monitors, or other electronic media might not be available to all when they wish to use it. Mechanical breakdown of equipment, for example, would make the information unavailable. The 1990 amendments suggest that nutrition information presented through video, live demonstration, or other media may be supplementary, but that signs, brochures, notebooks, or leaflets should be the primary means by which nutrition information is presented to consumers.

C. Label Content

4. Comments regarding label content generally supported FDA's proposal. The comments included requests for voluntary declaration of percent U.S. RDA for protein and expressions of support for voluntary declaration of complex carbohydrates and sugars (although one comment argued that the 1990 amendments require that these nutrients be included in the nutrition label); for flexibility in not requiring declaration of nutrients unlikely to be present in a food; for voluntary declaration of dietary fiber for produce; and for voluntary declaration of fatty acids and cholesterol for fish. The comments also included requests to exempt most produce from labeling for calories from fat, saturated fat, cholesterol, complex carbohydrates, and sugars. These requests argued that most raw produce is low in fat, saturated fat, and cholesterol, and that it is costly to analyze these foods for these components. Comments also pointed out that complex carbohydrates are not yet defined, and that raw produce does not contain added sugars. Although several comments agreed that declaration of thiamin, riboflavin, and niacin should be voluntary (56 FR 30468 at 30471), one comment did not agree that information about these nutrients would not add information that is useful to consumers. One comment was against labeling any foods with calories from fat. One comment supported voluntary labeling of omega-3 fatty acids (sum of eicosapentaenoic and docosahexaenoic acids) for fish.

The agency agrees that the inclusion of percent U.S. RDA for protein should be voluntary. While FDA mistakenly failed to state in proposed § 101.45(b)(1) that the inclusion of this information is voluntary (56 FR 30468 at 30482), the examples for nutrition labeling that FDA provided (56 FR 30468 at 30472) did not include the listing of percent U.S. RDA for protein. The codified language in § 101.45(b)(1) now provides that the percent of U.S. RDA for protein, thiamin, riboflavin, and niacin may be voluntarily declared. Declaration of complex carbohydrates, sugars, dietary fiber, saturated fat, and cholesterol are also voluntary under § 101.45(b)(1).

Although not required in the nutrition labeling of raw produce or raw fish, FDA is providing interim data on the dietary fiber content of fruit and vegetables in appendix A and interim data on the saturated fat and cholesterol content of fish in appendix B. These data, which may be used in nutrition labeling of these foods, are provided by FDA because fruit and vegetables are major sources of dietary fiber, fish contain saturated fat and cholesterol, and the levels of these three food components are of interest and importance to consumers.

The mandatory inclusion of calories from fat, saturated fat, cholesterol, complex carbohydrates, sugars, and omega-3 fatty acids on the nutrition label is a label content issue that is outside the scope of this rulemaking. Comments concerning these components should be submitted in response to the agency's supplementary proposal on mandatory nutrition labeling, which is published elsewhere in this issue of the **Federal Register**.

5. One comment requested that FDA modify the lower level for reporting nutrition labeling values for fish for vitamins A and C, calcium, and iron from 2 percent to 10 percent of the U.S. RDA. The comment stated that fish may contain these nutrients, but that they are not considered important sources. Because the levels of these nutrients are low and variable within some species, the 2 percent cutoff requires costly analysis of fish to be within the technical limits of nutrition labeling.

FDA understands the concern but notes that it is outside the scope of this rulemaking. Comments concerning levels of nutrients in foods and daily values should be submitted in response to the supplementary proposal for mandatory nutrition labeling. The final rule in that proceeding will affect the revision of the guidelines for nutrition labeling of raw fruit, vegetables, and fish. FDA also notes that for consistency of nutrition labeling among all foods, which is necessary to minimize consumer confusion, the lower limits for reporting the nutrient content of foods must not vary among food groups (i.e., the lower limits used for fish should be the same as those used for produce and for processed foods). Finally, FDA believes that it is important for consumers to know which foods can be consumed to increase one's intake, and which foods cannot, of nutrients of public health significance (such as vitamin A, vitamin C, calcium, and iron).

6. One comment stated that carotene, not vitamin A, occurs in fruit and vegetables, and that consumers are aware and knowledgeable of carotene and its role in health. The comment argued that it would be more informative to consumers to label the carotene content (not the vitamin A content) of fruit and vegetables.

FDA believes that this issue is also beyond the scope of this rulemaking. The purpose of this rulemaking is to establish a voluntary program for the nutrition labeling of raw produce and raw fish. The agency believes that such labeling should be consistent for all food products. If this comment is of the opinion that the declaration of vitamin A on the nutrition label should be modified, the comment should be submitted in the mandatory nutrition labeling proceeding. In that rulemaking, FDA is considering under section 403(q) of the Federal Food, Drug, and Cosmetic Act (the act) what nutrients should be included in the nutrition label. If the agency concludes that a change is warranted, it will revise the nutrition labeling regulations and the guidelines for the nutrition labeling of raw fruit, vegetables, and fish to reflect that change.

D. Label Format

7. FDA proposed (56 FR 30468 at 30482) that a simplified format may be used for the nutrition labeling of raw fruit, vegetables, and fish. The comments generally supported the use of a simplified label, but those who evaluated it in more detail noted that it only applies to one fruit (apples) and one vegetable (mushrooms). These are the only two of the 60 foods that have more than half of the required nutrients in insignificant amounts. Comments expressed concern about the qualifying statement, "Not a significant source of ____," because FDA uses the term "significant" when referring to 10 percent or more of the U.S. RDA for a comparative claim, and FDA uses the term "insignificant" when referring to values that are less than 2 percent of the U.S. RDA for nutrition labeling. Comments indicated that the qualifying statement could be misinterpreted to mean that the food contained less than 10 percent U.S. RDA rather than less than 2 percent U.S. RDA. One comment requested liberalizing the definition of "significant" for the simplified label to increase its use. Another comment stated that the term "significant source" was not understood by consumers.

Because of the concern expressed about these issues, FDA has decided to remove proposed § 101.45(b)(2) which deals with use of the simplified label and the qualifying statement for the nutrition labeling of raw fruit, vegetables, and fish. FDA notes that there are only nine nutrients that would have to appear in nutrition labeling for raw produce and raw fish for FDA to find the labeling in compliance. Thus, the labels for these foods are already rather simple. After the final rule on mandatory nutrition labeling is in place, and the agency has modified the guidelines to reflect that final rule, FDA will reconsider the use of the simplified format for raw produce and raw fish. The supplementary proposal on mandatory nutrition labeling will address the use of a qualifying statement for nutrition labeling.

E. Serving Sizes

8. Comments expressed support for serving sizes based on portions commonly consumed and agreed that uniformity in serving sizes will be beneficial for shopping comparisons. The comments also agreed with FDA that there was no need for the statement "servings per container" for raw fruit, vegetables, or fish.

As provided in § 101.45(b)(3), information on servings per container need not be included on the nutrition labeling for raw fruit, vegetables, and fish. However, for raw fruit, vegetables, and fish that are sold in packages with multiple serving per package, the retailer may state the number of servings contained in the package.

9. In the proposal in this proceeding, FDA mentioned the serving sizes (56 FR 30468 at 30472) for the nutrition labeling of raw fruit, vegetables, and fish that conformed to the proposed rule for serving sizes (55 FR 29517, July 19, 1990). In Appendices A and B, FDA has provided interim nutrient values for the 20 most frequently consumed raw fruit, vegetables, and fish in serving portions that are generally consistent with the reproposal for the regulation on serving sizes which is published elsewhere in this issue of the **Federal Register**.

The agency's reproposal on serving sizes is based on product category specific reference amounts instead of standard serving sizes. The reproposal lists the following reference amounts for nutrition labeling of raw fruit, vegetables, and fish: 85 grams (g) for fish, 280 g for watermelon, 55 g for fruit used primarily as ingredient (e.g., avocado), 140 g for all other fruit, 30 g for green onion, and 85 g for other vegetables. Because lemons and limes are used primarily for juice and are not eaten whole like other fruit, the serving considered to be appropriate for these fruits are 1 medium lemon (58 g; 2 ounces (oz)) and 1 medium lime (67 g; 2.5 oz), rather that the reference amount of 140 g, which would be closer to 2 lemons or 2 limes.

The reproposal states that serving sizes for products that come in distinct individual units (e.g., apple, orange, or potato) are to be expressed in the number of units that most closely approximate the reference amount, and serving sizes for products that are usually divided for consumption (e.g., cucumber, honeydew melon) are to be expressed in a fraction of the unit that most closely approximates the reference amount. Products in discrete individual units that weigh 67 percent or more, but less than 200 percent, of the reference amount will constitute one serving. However, a whole unit weighing 200 percent or more of the reference amount may be declared as one serving, if the whole unit can reasonably be consumed at a single-eating occasion. Under the reproposal, serving sizes for multi-serving products are required to be expressed in a common household measure that is most appropriate for the specific product. When oz are used as the serving size, an appropriate visual unit of measure, such as a dimension of a piece, is to be provided.

The reproposal specifies that the label statement regarding serving portion is to be the serving size expressed in common household measures followed by the equivalent metric quantity in parentheses. Serving size may be declared in oz in parentheses, following the metric measure where other common household measures are used as the primary unit for serving size (e.g., 1 ½ cup (138 g) (5 oz)). One oz is defined to weigh 28 g. Ounce measurements are to be expressed in 0.5 oz increments most closely approximating the reference amount.

10. One comment argued that the proposed serving size for fish (i.e., 4 oz) was "unrealistically small." Other comments favored a 1 oz serving for fish so that consumers could multiply the number of oz they eat by the values for 1 oz.

FDA disagrees with the use of a 1 oz serving because it could confuse consumers and is not consistent with "serving size" as defined by the 1990 amendments. The amendments define serving size to be "* * * an amount customarily consumed * * * expressed in a common household measure that is appropriate to the food * * *." In the reproposal for the serving size regulation, the agency is proposing a reference amount for cooked fish (85 g or 3 oz) that is based on the amount of fish customarily consumed as reported in the Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture (USDA). Most comments generally favored a 3 oz portion for fish. They pointed out that a 3 oz serving for fish conforms to the serving used in Seafood Nutri-Facts (Ref. 1), an in-store nutrition labeling program, and that the 1990 amendments directed FDA to take into account the actions taken by food retailers before November 8, 1991, to provide nutrition information on raw agricultural commodities and raw fish to consumers.

11. Several comments requested the use of common household units in addition to, or in place, of g quantities for fruits and vegetables. They stated that consumers would be unfamiliar with the quantity of fruit or vegetable represented by a g weight.

FDA agrees and is allowing for the use of household units (including oz) in addition to the weight of the food in g. The nutrition information provided by FDA for the most frequently consumed raw fruit and vegetables (appendix A) provides the household unit, the weight of a serving in g, and the weight in oz. The nutrition information provided by FDA for the most frequently consumed fish (appendix B) sets forth values that

are for a 3 oz (85 g) portion that has been cooked without fat or seasoning. For several fish (clams, oysters, and scallops), FDA included the number of pieces equivalent to 3 oz.

F. Raw Versus Cooked

12. FDA proposed in § 101.45(b)(5) that nutrition labeling for fruits and vegetables be on a raw basis. Comments generally agreed that nutrient values for fruit and vegetables should be provided on a raw basis, although several comments suggested that values for some vegetables (e.g., potato, sweet corn, sweet potato, green beans, asparagus) should be provided on a cooked basis.

FDA does not agree that nutrition labels for some vegetables should be based on cooked portions because of the need for consistency of labeling within food categories. Therefore, the label values for all fruit and vegetables shall be provided on a raw basis as proposed in § 101.45(b)(5), which is redesignated as § 101.45(b)(4). The values that FDA is presenting in appendix A were derived for fruit and vegetables on a raw basis.

13. FDA proposed in § 101.45(b)(5) that nutritional labeling for fish be on a cooked basis. Several comments argued that all values should be on a raw or as purchased basis to be consistent with the nutrition labeling of the rest of the food supply. However, the majority of the comments on this issue supported using values for fish that are derived on a cooked basis because such values will be most useful to consumers and will prevent the notion that raw fish should be consumed. Several comments argued strongly about the potential for food-borne illness if data were provided for raw fish, and consumers mistook the information as an endorsement for eating raw fish. Several comments noted that the 1990 amendments require that FDA consider programs put in place by retailers, such as the Seafood Nutri-Facts (Ref. 1) which is based on cooked fish. Several comments noted that the label should clearly state that the values are for cooked fish and provide the cooking method or indicate that no fat or seasoning was added. One comment noted that data from analyses of cooked fish are preferred to applying correction factors to data for raw fish.

As provided in proposed § 101.45(b)(5), redesignated as § 101.45(b)(4), FDA continues to believe that nutrient values for fish on a cooked basis (cooked without added fat or seasoning) will be most appropriate under the 1990 amendments because the cooked values are consistent with the nutrient labeling programs that have been developed by retailers for fish, and because cooked values will not encourage the consumption of raw fish. FDA agrees with the comment that the label should state the cooking method used, and, in the nutrition labeling data for fish that FDA has provided in appendix B, the cooking method is stated.

14. One comment noted that the term "cooked without fat or skin" (56 FR 30468 at 30473) was misleading because many fish cannot readily be cooked without their skin (e.g., salmon, trout).

FDA agrees and notes that the nutrient values for fish should be provided on the basis of the cooked, edible portion. The fish need not be cooked without the skin.

G. Nutrient Data

15. There was strong support for the use of single values rather than ranges of values for the nutrition labeling of raw fruit, vegetables, and fish. Comments stated that single values would be more useful and understandable to consumers. One comment suggested that a general statement should be used to indicate to the consumer that nutrient levels vary, and that the values represent averages.

FDA acknowledges that nutrient values for all foods vary. However, the data in appendices A and B on the nutritional labeling of raw fruit, vegetables, and fish reflect nutrient levels for these foods that are available in the United States marketplace, and FDA does not believe that it is necessary to qualify these data. Therefore, FDA is not requiring use of such statements to alert the consumer to nutrient variability. Retailers may optionally use such statements in their brochures, posters, or other methods of displaying the nutrition labeling, if they wish to do so.

16. There was general agreement among the comments that FDA should be responsible for providing the information for the nutrition labeling of raw fruit, vegetables, and fish. The comments also agreed with the use of nutrient values from food composition data bases for the nutrition labeling of these foods. Comments suggested that data from Seafood Nutri-Facts (Ref. 1) and USDA's revised Agriculture Handbook No. 8 might be used for fish and some fruits and vegetables until better data become available. Other comments expressed concern about the lack of reliable data for some fruit, vegetables, and fish and about the cost of generating new data when so many data are already available. One comment suggested that groups or individuals submitting data to FDA for review and evaluation, carefully evaluate and use (if possible) available data and focus new analyses on the foods and nutrients for which information is truly lacking.

Although FDA is not obligated to provide data for the nutrition labeling of the 20 most frequently consumed raw fruit, vegetables, and fish, the agency is providing a chart of interim data (appendices A and B) that retailers may use to initiate their in-store nutrition labeling programs. FDA is providing these data to hasten the development of the in-store programs and the delivery of the information to consumers.

Appendix A lists the 20 most frequently consumed raw fruit and vegetables. The household serving and g and oz edible portion weight of the serving appear below the name of the food. Values are provided for 10 nutrients and food components on a raw basis. Labeling values for 13 fruits (bananas, apples, watermelon, oranges, cantaloupe, grapefruit, strawberries, honeydew melon, avocados, lemons, pineapple, sweet cherries, and kiwifruit) and 17 vegetables (potatoes, iceberg lettuce, tomatoes, onions, carrots, celery, broccoli, green cabbage, cucumbers, bell peppers, cauliflower, leaf lettuce, mushrooms, green beans, radishes, summer squash, and asparagus) were obtained primarily from the Produce Marketing Association (PMA). These values, which were calculated according to the procedures in the FDA manual "Compliance Procedures for Nutrition Labeling" (Ref. 2), were submitted to FDA for review and evaluation. Data for seven fruits (grapes, peaches, pears, nectarines, plums, tangerines, and limes) and three vegetables (sweet corn, sweet potatoes, green onion), which reflect mean values, were derived from USDA Agriculture Handbook No. 8–9 (fruits and fruit juices) (Ref. 3) and No. 8–11 (vegetables and vegetable products) (Ref. 4), and other sources.

Appendix B lists the 20 most frequently consumed raw fish. The serving portion is a 3 oz (85 g) edible portion, cooked. Values are provided for 11 nutrients and food components. The data, which reflect mean values, were derived from Seafood NutriFacts (Ref. 1) (which is based on USDA data), USDA Agriculture Handbook No. 8–15 (finfish and shellfish products) (Ref. 5), and other sources.

FDA stated in the proposal (56 FR 30468 at 30474) that sources of nutrient data for the nutrition labeling of raw fruit, vegetables, and fish could include: (1) Analytical data previously generated by trade associations that were reviewed by FDA and found to be acceptable; (2) data generated from

analyses initiated by retailers, trade associations, or other groups that are submitted to FDA for review and evaluation; and (3) analytical data that have been previously generated by various groups and that are available in the literature, data bases, or elsewhere, which retailers, trade associations, or other groups gather (with appropriate documentation and statistical information) and submit to FDA for review and evaluation.

If FDA does not receive improved data for the seven fruits, the three vegetables, and all 20 fish, the agency will subject the data for these foods that were used in appendices A and B to the FDA compliance calculations and publish the resulting labeling values in the next edition of the charts. As stated in § 101.45(i), which FDA is adding in this final rule to provide for these appendices, FDA intends to revise and publish, with an opportunity for comment, the charts of nutrition labeling data for the 20 most frequently consumed raw fruit, vegetables, and fish at least every 2 years in the **Federal Register** as new data are derived or received and accepted. This activity will be coordinated with the biennial report to Congress on compliance with voluntary guidelines as long as nutrition labeling of raw produce and fish remains a voluntary activity. The agency has decided not to publish the nutrition labeling values in the CFR at this time because the values are interim and subject to change on a frequent basis. Publication in the CFR may lead to confusion about appropriate values. FDA may wish to reconsider publication in the CFR as newer and better data are submitted to the agency.

17. There was general support for the use of adequately supported and derived composite data. The comments stated that composite data provide a consistent standard for nutrition labeling among stores and a decreased burden for retailers. However, comments also noted that composite labeling could be misleading for some species of fish. For example, one comment noted that composite data for salmon are not specific enough to be useful to consumers because of the differences in fat content among the major species of salmon. The comment suggested that FDA should specify the predominant species of salmon and several other fish listed among the 20 most frequently consumed in the United States.

In response, FDA has identified salmon, mackerel, trout, and crab as encompassing several species with differing nutrient content and has specified in § 101.44(c) the major types of salmon (Atlantic/coho salmon), mackerel (Atlantic/Pacific and jack mackerel), trout (rainbow trout), and crab (blue crab) consumed in the United States (Refs. 6 and 7). The nutrition labeling data in appendix B pertain to these specific types, and the nutrition label should use these specific names.

18. One comment raised a question as to whether attempts could be made to block imports of Canadian produce to the United States on the grounds that their nutrient content was at variance with the nutrition profile generated for produce sold in the United States.

It is not FDA's intention that nutrition labeling be used as a trade barrier. The nutrient data bases generated and accepted for nutrition labeling purposes for raw produce and fish should encompass all products normally consumed in the United States, including imported products. If for some reason a new cultivar of a fruit or vegetable is introduced to the United States, or the levels of importation of fruit or vegetables change, the composite nutrition labeling data should be modified to reflect the change. Nutrition labeling values are expected to change over time to reflect what Americans are consuming. FDA will not attempt to block imports of specific raw fruit, vegetables, and fish to the United States if the nutrient content of these foods does not conform to the composite nutrition labeling data accepted by FDA for these foods.

H. Statistical Treatment of Nutrient Data

19. FDA stated in the July 2, 1991 proposal (56 FR 30468 at 30475–30476) that values for nutrition labeling should be determined according to the procedures outlined in the FDA manual "Compliance Procedures for Nutrition Labeling" (Ref. 2). Several comments expressed a preference for use of mean values for the nutrition labeling of raw fruit, vegetables, and fish rather than the compliance calculations suggested by FDA. There were also comments concerning the confidence intervals of label values based on FDA compliance calculations. Several comments were in favor of current prediction intervals (± 20 percent), while several others offered statistical alternatives to the FDA compliance procedures in the manual.

FDA notes that it is revising its "Compliance Procedures for Nutrition labeling" (Ref. 2), and that some of the concerns expressed about statistical prediction intervals and use of mean values may be resolved with the forthcoming revised manual. FDA requests that data developed for purposes of nutritional labeling conform to the instructions provided in the manual (or subsequent revisions of this manual) for the following reasons:

1. Mean and median values for nutrients and food components do not provide information about the variability of the values. It is not possible, because of space considerations, to put information about standard errors or standard deviations on food labels, and even if it were, the consumer would probably be confused by them. The use of compliance calculations allows the variance to be considered when developing the nutrient values used on food labels. The calculations thus aid the consumer by providing conservative label values in which the consumer can have a high degree of confidence.

2. The use of mean and median nutrient values for nutrition labeling may be misleading. For nutrients that are normally distributed (e.g., have a normal distribution of values around the mean), there is a 50 percent chance that a mean or median value on the label would be above, or below, the actual levels of nutrients in the food. For example, for vitamins, minerals, and protein, there is only a 50 percent chance that if the mean or median values are used for nutrition labeling, they would present the minimum amounts of the nutrient present in a serving of the food. It is equally as likely that the food contains a smaller amount of the nutrient than is declared, as it is that the food contains more of the nutrient. Similarly for calories, cholesterol, fat, and sodium, there is only a 50 percent chance that if the mean or median levels are used for nutrition labeling, they would represent the minimum amount of these substances per serving. Moreover, mean values are influenced by extreme values (e.g., a few outlying values may greatly increase a mean value). The probability that a serving of food will actually contain mean levels of nutrients or food components decreases as the variance increases and as the number of outliers increases. Thus, nutrition labeling values based on mean or median values may provide a low level of confidence.

3. The compliance calculations suggested by FDA give the consumer reasonable assurance that the vitamins, minerals, and protein will be present at levels that are at least 80 percent of label claim, and that calories, fat, cholesterol, and sodium will be present at levels that are no greater than 120 percent of label claim. The use of these calculations is therefore of benefit to the consumer and provides consumer protection.

4. It is important that all foods in the marketplace be labeled consistently. The same procedures that are used for packaged, processed foods should be used for raw produce and for raw fish. The consumer may be confused and deceived by inconsistent labeling of different products. The compliance calculations provided by FDA for nutrition labeling have been recommended and used since 1973.

5. Consumers and nutrition professionals benefit from the improved data bases developed by industry and trade associations and other groups. The use of FDA compliance calculations provides retailers, retail trade associations, and other trade associations with an incentive to continue routine analysis of foods, to analyze more samples, and to improve analytical methods. More analyses (properly done) allow researchers to more clearly define the levels of nutrients in foods and to identify outliers. Often, more analyses lead to a better estimate of the variance or allow the variance to be more clearly defined. As better estimates of the variance of nutrient levels are obtained, the values that can be used for nutrition labeling become more informative.

I. Submission of Data to FDA and Acceptance of Data by FDA

20. There was support for FDA review and evaluation of labeling data submitted to the agency, although one comment, which said that FDA's approach was impractical and burdensome, favored certification of privately generated data bases. One comment requested clarification regarding the submission of data to FDA and the review process for the data. There were several comments related to concerns about inconsistency of data among stores because of several sets of accepted data for a commodity. One comment asserted that approved composite data bases should be made available to all retailers, whether or not they are members of the association developing the data. Another comment asked if FDA will have a system for tracking data, and how the data base will be made available. Another comment asked about acceptance of data sets for wild, as opposed to farmed, fish and species of fish that were more specific than those included in the top 20.

To promote uniformity and consistency of values among stores, FDA is providing in Appendices A and B to this final rule the nutrition labeling data for the 20 most frequently consumed raw fruit, vegetables, and fish. FDA will review and evaluate data that are submitted to the agency for the 20 most frequently consumed raw fruit, vegetables, and fish and for other raw fruit, vegetables, and fish. FDA is providing in § 101.45(i) that, at least every two years, it intends to publish in the **Federal Register**, and to provide an opportunity for comment on, updates of these data sets or a notice that the data sets have not changed from the previous publication. FDA may publish revisions of the data sets more frequently than every two years if better data become available. FDA will keep a log and files of all data submitted and accepted for raw fruit, vegetables, and fish.

FDA will not accept multiple data sets for the nutrition labeling of the 60 commodities. If new data are submitted for a commodity, and FDA judges those data to be superior to previous data, the agency will publish the newer data to replace the old with an opportunity for comment. FDA may decide to replace data for one or more or all nutrient values for a fruit, vegetable, or fish.

As stated in § 101.45(f), accepted data (if not replaced) may be reaccepted by FDA at the end of 10 years. FDA has stated in § 101.45(i) that data accepted by the agency for nutrients other than those listed in appendices A and B for the 20 most frequently consumed raw fruit, vegetables, and fish, and data accepted by FDA for other raw fruit, vegetables, and fish, will be available upon request to FDA (Division of Nutrition, 200 C St. SW., Washington, DC 20204).

J. Identification of the 20 Most Frequently Consumed Raw Fruit, Vegetables, and Fish in the United States

Comments supported a national list (rather than regional lists) for the most frequently consumed raw fruit, vegetables, and fish. There was general support for FDA's definition of "most frequently consumed" and the identification of the foods based on sales, production, and consumption data. Several comments noted a minor misstatement in the proposal (56 FR 30468 at 30476, III.C.1., third paragraph). The statement should have been that the agency has interpreted the phrase "most frequently consumed" to mean those varieties purchased raw (not consumed raw) in the largest quantities by the United States population. FDA does not believe that this minor misstatement had any substantive effect.

21. Several comments wanted a longer list of fish (e.g., 30 rather than 20) to include more species, more regional variation, and a distinction between farmed and wild seafood. As noted previously, one comment wanted salmon to be specified by the predominant type (e.g., Atlantic/coho) because composite nutrient values for all salmon would not be useful to consumers. One comment questioned whether raw, shucked oysters would be included for nutritional labeling. One comment noted that rockfish is a local name in Maryland and Virginia for striped bass and asked for clarification of this fish name for consumers.

Fish that are not among the 20 most frequently consumed may be nutrition labeled. Nutrition labeling data for other fish or for specific varieties of fish that are among the top 20 may be submitted to FDA for review and evaluation or may be used subject to § 101.45(h). FDA does not have sufficient data to provide separate information for farmed and wild fish. However, such data, if available, should be submitted to FDA for review and evaluation and possible acceptance for nutrition labeling. Several of the fish (salmon, mackerel, crab, and trout), identified in the proposal (§ 101.44(c)) as being among the 20 most frequently consumed, have been more specifically defined as Atlantic/coho salmon, Atlantic/Pacific & jack mackerel, blue crab, and rainbow trout. The nutrient values that apply specifically to these species are less variable and, therefore, more useful to consumers. Oysters, which are listed among the 20 most frequently consumed fish, include raw, shucked oysters.

According to FDA's Fish List (Ref. 8), rockfish have many common and regional names, and the term "rockfish" is, indeed, used in some areas for striped bass. FDA hopes that over time, at least in part through nutrition education programs, consistency can be achieved in the names of fish used in retail stores. The fish names listed in appendix B should be used for nutrition labeling at the retail level because these names are accepted nationally and are used by FDA (Ref. 8). FDA believes that it would be misleading to place nutrition labeling data for rockfish under the name of "rockfish" in some areas and under "striped bass" in other areas. Consistency in nutrition labeling of raw produce and fish among stores throughout the United States is essential if the program is to be beneficial to consumers. Consumers may shop in different stores in different areas. They should see the same fish names and nutrition labeling values for the same fish no matter where they shop. Retailers may, if they feel it is necessary, provide clarification to customers about local fish names. Such clarification may be presented as a parenthetical name or a footnote on the

labeling information that is presented in the store. For example, the labeling information might state: "Rockfish (locally known as Striped Bass)."

22. One comment argued that when and where fish are packaged should not be the determining factors in deciding whether fish are to be included in the voluntary labeling program. The comment noted that raw fish may be packaged both by manufacturers and by retailers and asked that there not be different treatment of products identical in species, form, packaging material, and presentation to the consumer. The comment also asked that the definition of fish be extended to include molluscan shellfish and other finfish market cuts such as steaks, chunks, and fillets.

In response to the comment, FDA believes that it is appropriate to clarify which fish, under the 1990 amendments, may voluntarily be labeled and which are required to be nutrition labeled. Fish included under the voluntary nutrition labeling program are: raw (i.e., not heat treated), whole or market cuts of finfish and shellfish; raw, whole, peeled, shelled, or shucked shrimp, scallops, oysters, clams, and lobster; and shelled or unshelled lobster, crab, and shrimp that have been thermally processed. These fish are generally sold in fish stores or in the fresh fish section of grocery stores. They may be frozen or iced. They are generally not packaged or packaged by the retailer in paper or with cellophane and plastic or paperboard tray. Raw, frozen fish that are packaged by a manufacturer (usually in a box with a printed label) and sold in the frozen food case of a grocery store are subject to mandatory nutrition labeling.

K. Substantial Compliance Definition and Determination

23. There was general agreement among comments with the 90 percent compliance requirement for individual stores. There were questions about how the sample of 2,000 stores was derived, and about how representative the sample would be of the United States marketplace. One comment stated that rural America had been overlooked. Several comments feared that the margin of error in the estimation of substantial compliance could over estimate compliance (i.e., that an estimate of 60 percent compliance could really be 56 percent). Several comments said that a chain was 11 or more (not four or more) stores under common ownership.

FDA responds by noting that sample size is study specific and is based on two factors, survey design and desired precision. The survey design incorporates different aspects of the study (in this case, annual sales, proportion of chain versus independent stores, regional variability, and county size) to insure representativeness of the overall population of stores. The desired precision is the degree of certainty of estimates to minimize sampling error.

The selection of a sample of 2,000 stores was based upon the survey design and the assurance that a sample of 2,000 stores provides a relatively narrow margin of uncertainty around an observed compliance level (e.g., a maximum of ±4 percent for 50 percent compliance and a maximum of ±3 percent for 60 percent compliance), with an acceptable degree of statistical confidence (95 percent). The percent error decreases as the percent compliance increases. Every estimation of percent compliance has a degree of error; however, the error could be positive or negative. For an identified compliance level of 60 percent and a sample of 2,000, the chances are 95 in 100 that the actual level falls between 56.1 percent and 63.9 percent. Any further increases in sample size are not necessary, because the percentage of further reductions in uncertainty achieved would only be small and diminishing.

Based on the characteristics of the retail grocery distribution system, which were shown in Table 8 of the proposed regulation (56 FR 30468 at 30481) and discussed in the text (56 FR 30468 at 30477), chain versus independent ownership and store volume are key factors in constructing a survey sample that is representative of the total distribution system. Representativeness by rural versus urban areas is further assured by allocating the store sample in proportion to food sales in counties that are highly urbanized, relatively urbanized, rural, and very rural. The specific county size definitions and classifications are based on the 1980 United States census of the population.

Although various definitions of a chain (e.g., 4, 8, or 11 stores under common ownership) are used within the retail food industry, after considering the comments, FDA has decided not to change its definition of a "chain" as four or more stores. This definition is commonly accepted and is used by the major marketing firm that will serve as the contractor for the survey that FDA will undertake to assess compliance with the guidelines.

24. Opinion was divided among the comments about the definition of substantial compliance as "at least 60 percent of all stores that are evaluated in compliance" with the guidelines in § 101.45. Some comments, especially those from retailers and retailer organizations, felt it was appropriate. Others, especially those from consumer groups and professional societies, wanted a higher value of 80 to 90 percent.

FDA understands the concerns of retailers in initiating a new program and the desire of consumer groups to ensure that consumers have access to the information. FDA is concerned that it may take some time to get the programs going and does not want to judge them unfairly, particularly at the onset. As evidenced by the discussion in the preamble to the proposed rule (56 FR 30468 at 30478), FDA carefully considered the statutory criteria for defining "substantial compliance." FDA continues to believe that the criterion that it proposed represents an appropriate balance among the factors that Congress directed it to consider. To meet the 60 percent criterion, well over half of all covered stores will have to provide nutrition labeling. Moreover, if this criterion is met, based on the size and the market share of the stores that FDA will survey, nutrition labeling will be provided for well over half of the sales of raw produce and raw fish in this country. FDA believes that this level of compliance and of providing information to consumers is fairly characterized under the criteria in the law as substantial. Moreover, while the comments that disagreed with FDA's standard asserted that a higher percentage was appropriate, none provided a meaningful basis for a change or demonstrated that FDA's criterion was inconsistent with the act. Therefore, FDA is adopting the standard for "substantial compliance" that it proposed.

25. Several comments requested that substantial compliance be determined separately for raw produce and fish. They stated that the produce section of a store should not be considered to be out of compliance if the fish section did not meet the requirements.

FDA agrees with these comments because of the inherent separateness between the produce industry and the fish industry. The two groups are served, for the most part, by separate retail and trade associations. Also, produce and fish are generally sold in different locations in the grocery stores. FDA believes that the failure to achieve substantial compliance for either produce or fish should not hinder the voluntary nutrition labeling program for the other. FDA has clarified in proposed § 101.43(a) that the raw produce and raw fish in individual stores are to be evaluated separately for compliance and has specified in proposed § 101.43(d)

that substantial compliance is to be evaluated separately for raw produce and for raw fish. FDA will make both evaluations on the basis of samples of 2,000.

L. Exemptions

26. One comment requested that the exemption for small United States operations be matched by a requirement that United States retailers not pass the labeling responsibility to small volume third country suppliers of produce.

The 1990 amendments specify that it is the responsibility of the retailer, not the supplier, to provide the nutrition labeling information to consumers. In addition, FDA is supplying the necessary interim nutrition labeling information for retailers. Because of these facts, FDA believes that no burden regarding nutrition labeling will fall upon small volume third country suppliers of produce, and, hence, there is no need for an exemption for them.

27. One comment stated that the exemptions specified in the law for small businesses, restaurants, delis, self-service food bars, and foods prepared and processed at the store must be included in the final regulation. One comment felt that FDA should clarify that all raw fruit, vegetables, and fish not within the top 20 are exempt from nutrition labeling. One comment requested clarification that mixtures of fruits and vegetables (e.g., melon cups, fruit salad, vegetable trays with dip, salads) are exempt from labeling requirements. Another comment said that nutrition labeling of minimally processed raw produce packaged with a separate packet of sauce or dressing should be voluntary.

FDA has reviewed the exemptions from nutrition labeling specified in the 1990 amendments as they pertain to the nutrition labeling of raw fruit, vegetables, and fish (56 FR 30468 at 30478). Exemptions from mandatory nutrition labeling of foods are fully covered in the supplementary nutrition labeling proposal.

FDA notes that section 403(q)(5)(A)(ii) of the act provides exemptions from nutrition labeling for food "which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in section 403(q)(5)(A)(i) of the act, and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment." FDA considers in-store prepared packages that contain mixtures of fruit and vegetables (e.g., carrot and celery sticks; slices of mushrooms, green pepper, and cucumber; cantaloupe, honeydew, and watermelon balls; slices of apples, pineapple, and kiwifruit) to be prepared for immediate consumption. They therefore fall within the description offered in section 403(q)(5)(A)(ii) of the act and are exempt from nutrition labeling. Because such products are exempt from nutrition labeling, FDA will not consider them when making determinations of compliance.

Raw fruits or vegetables that are sold with separate packets of sauce or dressing are not included in the voluntary nutrition program. Such products intended for immediate consumption are exempt from nutrition labeling. Such products requiring cooking with the addition of a sauce fall under the requirements for mandatory nutrition labeling.

28. One comment recommended that FDA raise the annual gross sales requirement for small business from $50,000 to $300,000 to assure that small business can avail themselves of this exemption.

The 1990 amendments specify that retailers shall be exempt if they have "annual gross sales made or business done in sales to consumers which is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than $50,000 * * *". These legislative values cannot be changed administratively. The values are discussed fully in the supplementary mandatory nutrition labeling proposal.

M. Costs of Program Implementation

29. FDA estimated (56 FR 30468 at 30479) the cost of program implementation to be from $100 to $165 million over 20 years for compliance of at least 60 percent for 99,000 stores. Several comments stated that costs estimated by FDA for the nutrition labeling of raw fruit, vegetables, and fish were conservative because the life of a sign in a grocery store is only 6 months to a year (not 5 years), and because use of an interim program (until the issuance of revised guidelines) will cause the cost of compliance to increase because signs and labels will need to be updated when final regulations and formats are established. Costs were estimated by these comments to be about $150 to $200 per year per store.

FDA has considered the estimates provided by several of the comments and notes that at a yearly cost of $150 for 60 percent compliance, the 20-year cost would be $117 million (at a 5 percent discount rate), and at a yearly cost of $200 for 60 percent compliance, the 20-year cost would be $155 million (at a 5 percent discount rate). FDA is modifying its estimates of the cost of this rule accordingly.

III. Conclusion

In response to comments submitted regarding the proposal for the voluntary nutrition labeling of raw fruit, vegetables, and fish (56 FR 30468), FDA has modified §§ 101.43, 101.44, and 101.45. The agency has adopted the provisions of § 101.42 and other parts of §§ 101.43 through 101.45 as proposed because the agency did not receive any comments concerning them or because, as explained above, the comments received did not provide any basis to justify a change. The following summarizes the changes being made to §§ 101.43 through 101.45 by this final rule:

FDA has modified § 101.42(e) and (f) and § 101.43(a) to clarify that substantial compliance will be assessed separately for raw agricultural commodities (i.e., raw fruit and vegetables) and for raw fish.

In § 101.43(b), FDA has changed the phrase "* * * raw fruit, vegetables, and fish * * *" to "* * * raw fruit and vegetables and of raw fish * * *" to clarify that substantial compliance will be assessed separately for raw agricultural commodities and for raw fish.

As discussed above, section 101.43(d) is being added and states "FDA will evaluate substantial compliance separately for raw agricultural commodities and for raw fish."

In § 101.44(c), the types of salmon, mackerel, crab, and trout that are among the 20 most frequently consumed raw fish are being more precisely identified, so that the nutrient values will be of greater use to consumers. These fish are now being described as Atlantic/coho salmon, Atlantic/Pacific and jack mackerel, blue crab, and rainbow trout.

In § 101.45(b)(1), as explained above, FDA is changing the statement "Thiamin, riboflavin, and niacin may be declared in the nutrition labeling" to "The percent U.S. RDA for protein, thiamin, riboflavin, and niacin may be declared in the nutrition labeling." A statement has been added that declaration of complex carbohydrates, sugars, dietary fiber, saturated fat, and cholesterol is voluntary.

As explained above, proposed § 101.45(b)(2), which concerned the use of a simplified label and a qualifying statement, has been removed. Sections 101.45(b)(3) through (b)(5) have been redesignated as § 101.45(b)(2) through (b)(4).

In redesignated § 101.45(b)(2), in the first sentence of this paragraph, the phrase "for the full or simplified formats" is being removed because the discussion about the simplified format has been removed.

In § 101.45(e), in the first sentence, the word "booklet" is being replaced by "manual" to be consistent with the text of the **Federal Register**. The phrase "(or subsequent revisions of this manual)" is being inserted after the name of the manual. In the second sentence, the word "It" was replaced by "The manual" for clarification.

In § 101.45(f), in the first sentence, the phrase "* * * of the data base * * *" is being replaced by "* * * of a submitted data base * * *" for clarification.

In § 101.45(f), the following is being added to the end of the second sentence, "* * * or until another data base on the same commodity is submitted to FDA and found to be superior." In addition, in § 101.45(f), in the fourth sentence, the following is being inserted after "unless," "* * * the data base is being superseded by another on the same commodity or * * *." These changes reflect the fact that, as discussed above, FDA will not accept multiple data sets but will only maintain the best data available.

In § 101.45(h), the word "raw" is being inserted before "fruit" for clarification.

As discussed above, section 101.45(i) is being added. This new section states: "FDA will publish, and provide an opportunity for comment on, updates of the nutrition labeling data for the 20 most frequently consumed raw fruit, vegetables, and fish (or a notice that the data sets have not changed from the previous publication) at least every 2 years in the **Federal Register**. FDA accepted data for other raw fruit, vegetables, and fish or for other nutrients are available from the Division of Nutrition, Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204."

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**.

The costs of compliance with this final rule alone are discussed in section II.M. above. FDA has estimated the costs that may be incurred as a result of the provisions of the 1990 amendments covered by this final rule to be between $117 million to $155 million. FDA welcomes comments on these cost estimates.

VI. References

1. "Seafood Nutri-Facts," Fresh Seafood Nutrition Information Program, developed by the Food Marketing Institute and the National Fisheries Institute, Washington, DC, 1988.
2. Division of Mathematics, Center for Food Safety and Applied Nutrition, FDA, "Compliance Procedures for Nutrition Labeling," Washington, DC, 1973.
3. "Composition of Foods—Raw, Processed, Prepared, Fruits and Fruit Juices," Agriculture Handbook No. 8–9, USDA, Human Nutrition Information Service, Washington, DC, 1982.
4. "Composition of Foods—Raw, Processed, Prepared, Vegetables and Vegetable Products," Agriculture Handbook No. 8–11, USDA, Human Nutrition Information Service, Washington, DC, 1984.
5. Composition of Foods—Raw, Processed, Prepared, Finfish and Shellfish Products," Agriculture Handbook No. 8–15, USDA, Human Nutrition Information Service, Washington, DC, 1987.
6. National Fisheries Institute, data on fish production, provided to FDA, Washington, DC, letter dated January 4, 1991.
7. Personal communication, L. Weddig, National Fisheries Institute, Inc., August 15, 1991.
8. The Fish List, FDA Guide to Acceptable Market Names for Food Fish Sold in Interstate Commerce, Superintendent of Documents, U.S. Government Printing Office, Washington, DC, 1988.

VII.—Appendix A

[Nutritional labeling accepted by FDA for the 20 most frequently consumed raw fruit and vegetables (August 1991).]

Fruit (Edible portion weight)	Kilocalories	Protein (g)	Carbohydrates (g)	Fat (g)	Dietary Fiber (g)	Sodium (mg)	Percent U.S. RDA			
							Vitamin A	Vitamin C	Calcium	Iron
Banana, raw, 1 medium, (126 g) (4.5 oz)	120	1	28	1	3	0	(1)	15	(1)	2
Apple, raw, 1 medium, (154 g) (5.5 oz)	80	0	18	1	5	0	(1)	6	(1)	(1)
Watermelon, raw, 1/18 medium melon; 2 cups diced pieces (280 g) (10 oz)	80	1	19	0	1	10	8	25	(1)	2
Orange, raw, 1 medium, (154 g) (5.5 oz)	50	1	13	0	6	0	(1)	120	4	(1)
Cantaloupe, raw, 1/4 medium melon, (134 g) (5 oz)	50	1	11	0	0	35	80	90	2	2
Grape, raw, 1 1/2 cups, (138 g) (5 oz)	85	1	24	0	2	3	3	9	2	2
Grapefruit, raw, 1/2 medium, (154 g) (5.5 oz)	50	1	14	0	6	0	6	90	4	(1)
Strawberry, raw, 8 medium, (147 g) (5.5 oz)	50	1	13	0	3	0	(1)	140	2	2
Peach, raw, 2 medium, (174 g) (6 oz)	70	1	19	0	1	0	20	20	(1)	(1)
Pear, raw, 1 medium, (166 g) (6 oz)	100	1	25	1	4	1	(1)	10	2	2
Nectarine, raw, 1 medium, (140 g) (5 oz)	70	1	16	1	3	0	20	10	(1)	(1)
Honeydew melon, raw, 1/10 medium melon, (134 g) (5 oz)	50	1	12	0	1	50	(1)	40	(1)	2
Plum, raw, 2 medium, (132 g) (4.5 oz)	70	1	17	1	1	0	9	20	(1)	(1)
Avocado, raw, 1/3 medium, (55 g) (2 oz)	120	1	3	12	2	5	(1)	5	(1)	(1)
Lemon, raw, 1 medium, (58 g) (2 oz)	18	0	4	0	0	10	(1)	35	2	(1)
Pineapple, raw, 2 slices, 3" diameter, 3/4" thick, (112 g) (4 oz)	90	1	21	1	2	10	(1)	35	(1)	(1)
Tangerine, raw, 2 medium, 2 5/8" diameter (168 g) (6 oz)	70	1	19	0	2	2	30	85	2	(1)
Sweet cherry, raw, 21 cherries; 1 cup, (140 g) (5 oz)	90	1	19	1	3	0	(1)	10	2	(1)
Kiwifruit, raw, 2 medium, (148 g) (5.5 oz)	90	1	18	1	4	0	2	230	4	4
Lime, raw, 1 medium, (67 g) (2.5 oz)	20	0	7	0	3	1	(1)	35	2	2
Potato, raw, 1 medium, (148 g) (5.5 oz)	110	3	23	0	3	10	(1)	50	(1)	8
Iceberg lettuce, raw, 1/6 medium head, (89 g) (3 oz)	20	1	4	0	1	10	2	4	(1)	(1)

VII.—APPENDIX A—Continued

[Nutritional labeling accepted by FDA for the 20 most frequently consumed raw fruit and vegetables (August 1991).]

Fruit (Edible portion weight)	Kilocalories	Protein (g)	Carbohydrates (g)	Fat (g)	Dietary Fiber (g)	Sodium (mg)	Percent U.S. RDA			
							Vitamin A	Vitamin C	Calcium	Iron
Tomato, raw, 1 medium, (148 g) (5.5 oz)	35	1	6	1	1	10	20	40	(1)	2
Onion, raw, 1 medium, (148 g) (5.5 oz)	60	1	14	0	3	10	(1)	20	4	(1)
Carrot, raw, 7" long, 1¼" diameter (78 g) (3 oz)	40	1	8	1	1	40	330	8	2	(1)
Celery, raw, 2 medium stalks (110 g) (4 oz)	20	1	4	0	2	140	(1)	15	4	(1)
Sweet corn, raw, kernels from, 1 medium ear (90 g) (3 oz)	75	3	17	1	1	15	5	10	(1)	3
Broccoli, raw, 1 medium stalk, (148 g) (5.5 oz)	40	5	4	1	5	75	10	240	6	4
Green cabbage, raw, 1/12 medium head (84 g) (3 oz)	18	1	3	0	2	30	(1)	70	4	(1)
Cucumber, raw, ⅓ medium, (99 g) (3.5 oz)	18	1	3	0	0	0	4	6	2	2
Bell pepper, raw, 1 medium, (148 g) (5.5 oz)	25	1	5	1	2	0	2	130	(1)	(1)
Cauliflower, raw, ⅙ medium head (99 g) (3 oz)	18	2	3	0	2	45	(1)	110	2	2
Leaf lettuce, raw, 1.5 cup shredded (85 g) (3 oz)	12	1	1	0	1	40	20	4	4	(1)
Sweet potato, raw, medium, 5" long, 2" diameter (130 g) (4.5 oz)	140	2	32	0	3	15	520	50	3	4
Mushroom, raw, 5 medium, (84 g) (3 oz)	25	3	3	0	0	0	(1)	2	(1)	(1)
Green onion, raw, ¼ cup chopped (25 g) (1 oz)	7	0	1	0	0	0	3	20	(1)	5
Green (snap) bean, raw, ¾ cup cut (83 g) (3 oz)	14	1	2	0	3	0	2	8	4	(1)
Radish, raw, 7 radishes (85 g) (3 oz)	20	0	3	0	0	35	(1)	30	(1)	(1)
Summer squash, raw, ½ medium, (98 g) (3.5 oz)	20	1	3	0	1	0	4	25	2	2
Asparagus, raw, 5 spears (93 g) (3.5 oz)	18	2	2	0	2	0	10	10	(1)	(1)

[1] Less than 2% U.S. RDA.

Notes

Data sources:

Produce Marketing Association (all data except as noted below).

USDA Revised Agriculture Handbook No 8-9 (Fruits and Fruit Juices, 1982) and 8-11 (Vegetables and Vegetable Products, 1984) for grape, peach, pear, nectarine, plum, tangerine, lime, sweet corn, sweet potato, and green onion; dietary fiber for pineapple, tomato, and carrot; dietary fiber for grape and plum based on similar foods.

Dietary fiber for nectarine, tangerine, lime, and green onion from *McCance and Widdowson's The Composition of Foods* by A.A. Paul and D.A.T. Southgate, 4th revised ed., Elsevier/North-Holland Biomedical Press, NY, 1978 or *Nutrient Content of Food Portions* by J. Davies and J. Dickerson, The Royal Society of Chemistry, Cambridge, U.K., 1991.

Serving portion weights in oz from PMA were multiplied by 28 to obtain g weights; 55 g were used for 2 oz, and 85 g were used for 3 oz. Ounces were rounded to the nearest 0.5 oz for the chart. Serving portions weights in g from USDA were divided by 28 to obtain oz; oz were rounded to the nearest 0.5 oz.

Values were rounded in accordance with 21 CFR 101.9. Percent U.S. RDA was based on 5,000 IU for vitamin A, 60 milligrams (mg) for vitamin C, 1,000 mg for calcium, and 18 mg for iron.

Avocado data were derived from two data sets and are based on California varieties.

VIII. APPENDIX B

[Nutrition labeling accepted by FDA for the 20 most frequently consumed fish (August 1991)]

	Kilocalories	Protein (g)	Carbohydrates (g)	Fat (g)	Saturated Fatty Acid (g)	Cholesterol (mg)	Sodium (mg)	Percent U.S. RDA			
								Vitamin A	Vitamin C	Calcium	Iron
Fish, 3 oz edible portion, cooked [2]											
Shrimp, boiled	110	22	0	2	0	160	155	(1)	3	3	15
Cod, broiled, skinless	90	19	0	1	0	50	60	(1)	2	(1)	2
Pollack, broiled, skinless	100	21	0	1	0	80	90	(1)	(1)	(1)	(1)
Catfish, baked, skinless	120	19	0	5	1	60	65	(1)	(1)	3	5
Scallop, broiled, 5.7 large or 14 small	150	26	0	1	0	60	275	(1)	3	2	(1)
Salmon, Atlantic/coho, baked, skinless	150	22	0	7	1	50	50	(1)	2	(1)	4
Flounder, baked, skinless	100	20	0	1	0	50	85	(1)	(1)	2	2
Sole, broiled, skinless	100	21	0	1	0	60	90	(1)	(1)	2	2
Oyster, steamed, 12 medium	120	12	0	4	1	90	190	(1)	(1)	8	65
Orange roughy, broiled, skinless	130	16	0	7	0	20	70	(1)	(1)	(1)	(1)
Mackerel, Atlantic/Pacific & jack, broiled, skinless	190	21	0	12	3	60	95	7	(1)	(1)	9
Ocean perch, baked, skinless	100	20	0	2	0	50	80	(1)	(1)	10	6
Rockfish, baked, skinless	100	20	0	2	0	40	65	4	(1)	(1)	3
Whiting, baked, skinless	100	19	0	1	0	70	75	2	(1)	5	2
Clam, steamed, 12 small	130	22	0	2	0	60	95	10	(1)	8	130
Haddock, baked, skinless	90	20	0	1	0	60	70	(1)	(1)	4	6
Blue crab, steamed	90	19	0	1	0	80	310	(1)	(1)	9	4
Rainbow trout, broiled, skinless	130	22	0	4	1	60	30	(1)	5	7	10
Halibut, broiled, skinless	120	22	0	2	0	30	60	3	(1)	5	5
Lobster, boiled	100	20	0	1	0	100	320	(1)	(1)	5	2

[1] Less than 2% U.S. RDA.
[2] Cooked without fat or seasoning.

Notes

Data sources:

Seafood Nutri-Facts by the Food Marketing Institute and the National Fisheries Institute, 1988 (all values except vitamin A, vitamin C, calcium, iron).

USDA Agriculture Handbook No. 8-15 (Finfish and Shellfish Products, 1987) and NOAA (National Oceanic and Atmospheric Administration) Technical Memo NMFS F/SEC-11 (1981) (vitamin A, vitamin C, calcium, iron).

([1]) = assumed less than 2 U.S. RDA (no data available).

Atlantic/coho salmon was selected for labeling because most pink salmon is canned, and most sockeye salmon is exported to Japan. Atlantic/Pacific and jack mackerel were selected for labeling because consumption of Spanish mackerel is low. Personal communication with L. Weddig of National Fisheries Institute, August 15, 1991.

Nutrient values were averaged for Atlantic and coho salmon and for Atlantic and Pacific and jack mackerel.

Atlantic cod was used for cholesterol and sodium; Pacific cod would be 40 mg cholesterol and 75 mg sodium.

Values were rounded in accordance with 21 CFR 101.9. Percent U.S. RDA was based on 5,000 IU for vitamin A, 60 mg for vitamin C, 1,000 mg for calcium, and 18 mg for iron.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Subpart C is added to read as follows:

Subpart C—Specific Nutrition Labeling Requirements and Guidelines

Sec.

101.42 Nutrition labeling of raw fruit, vegetables, and fish.
101.43 Substantial compliance of food retailers with the guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.
101.44 Identification of the 20 most frequently consumed raw fruit, vegetables, and fish in the United States.
101.45 Guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

Subpart C—Specific Nutrition Labeling Requirements and Guidelines

§ 101.42 Nutrition labeling of raw fruit, vegetables, and fish.

(a) The Food and Drug Administration (FDA) urges food retailers to provide nutrition information, as provided in § 101.9(c), for raw fruit, vegetables, and fish at the point-of-purchase. If retailers choose to provide such information, they should do so in a manner that conforms to the guidelines in § 101.45.

(b) In § 101.44, FDA has listed the 20 varieties of raw fruit, vegetables, and fish that are most frequently consumed during a year and to which the guidelines apply.

(c) FDA has also defined in § 101.43, the circumstances that constitute substantial compliance by food retailers with the guidelines.

(d) By May 8, 1993, FDA will issue a report on actions taken by food retailers to provide consumers with nutrition information for raw fruit, vegetables, and fish under the guidelines established in § 101.45.

(1) The report will include a determination of whether there is substantial compliance, as defined in § 101.43, with the guidelines.

(2) In evaluating substantial compliance, FDA will consider only the 20 varieties of raw fruit, vegetables, and fish most frequently consumed as identified in § 101.44.

(e) If FDA finds that there is substantial compliance with the guidelines for the nutrition labeling of raw fruit and vegetables or of fish, the agency will so state in the report, and the guidelines will remain in effect. FDA will reevaluate the market place for substantial compliance every 2 years.

(f) If FDA determines that there is not substantial compliance with the guidelines for raw fruit and vegetables or for raw fish, the agency will at that time issue proposed regulations requiring that any person who offers raw fruit and vegetables or fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by § 101.9. Final regulations would have to be issued 6 months after issuance of proposed regulations, and they would become effective 6 months after the date of their promulgation.

§ 101.43 Substantial compliance of food retailers with the guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

(a) The Food and Drug Administration (FDA) will judge a food retailer who sells raw agricultural commodities or raw fish to be in compliance with the guidelines in § 101.45 with respect to raw agricultural commodities if the retailer displays or provides nutrition labeling for at least 90 percent of the raw agricultural commodities listed in § 101.44 that it sells, and with respect to raw fish if the retailer displays or provides nutrition labeling for at least 90 percent of the types of raw fish listed in § 101.44 that it sells. To be in compliance, the nutrition labeling shall:

(1) Be presented in the store or other type of establishment in a manner that is consistent with § 101.45(a);

(2) Be presented in content and format that are consistent with § 101.45(b); and

(3) Include data that have been provided by FDA (see § 101.45(i)), that have been accepted by FDA (see § 101.45 (c), (f), and (g)), or that are consistent with § 101.45 (d) and (e) and have not been found to be out of compliance after a review under § 101.9(e) (see § 101.45(h)).

(b) To determine whether there is substantial compliance by food retailers with the guidelines in § 101.45 for the voluntary nutrition labeling of raw fruit and vegetables and of raw fish, FDA will select a representative sample of 2,000 stores, allocated by store type and size, for raw fruit and vegetables and for raw fish.

(c) FDA will find that there is substantial compliance with the guidelines in § 101.45 if it finds based on paragraph (a) of this section that at least 60 percent of all stores that are evaluated are in compliance.

(d) FDA will evaluate substantial compliance separately for raw agricultural commodities and for raw fish.

§ 101.44 Identification of the 20 most frequently consumed raw fruit, vegetables, and fish in the United States.

(a) The 20 most frequently consumed raw fruit are: Banana, apple, watermelon, orange, cantaloupe, grape, grapefruit, strawberry, peach, pear, nectarine, honeydew melon, plum, avocado, lemon, pineapple, tangerine, sweet cherry, kiwifruit, and lime.

(b) The 20 most frequently consumed raw vegetables are: Potato, iceberg lettuce, tomato, onion, carrot, celery, sweet corn, broccoli, green cabbage, cucumber, bell pepper, cauliflower, leaf lettuce, sweet potato, mushroom, green onion, green (snap) bean, radish, summer squash, and asparagus.

(c) The 20 most frequently consumed raw fish are: Shrimp, cod, pollack, catfish, scallop, Atlantic/coho salmon, flounder, sole, oyster, orange roughy, Atlantic/Pacific and jack mackerel, ocean perch, rockfish, whiting, clam,

haddock, blue crab, rainbow trout, halibut, and lobster.

§ 101.45 Guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

Nutrition labeling for raw fruit, vegetables, and fish listed in § 101.44 should be presented to the public in the following manner:

(a) Nutrition labeling information should be displayed at the point of purchase by an appropriate means, including by affixing it to the food, by posting a sign, or by making the information readily available in brochure, notebook, or leaflet form in close proximity to the foods. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(b) Nutrition information should be provided on the label or in labeling in accordance with § 101.9, as modified by the following guidelines:

(1) The percent U.S. RDA for protein, thiamin, riboflavin, and niacin may be declared in the nutrition labeling. Declaration of complex carbohydrates, sugars, dietary fiber, saturated fat, and cholesterol is also voluntary.

(2) Nutrition labeling information may be presented on individual labels or in charts in vertical columns or in lines. When lines are used, any subcomponents declared should be listed parenthetically after principal components (e.g., saturated fat should be parenthetically listed after fat).

(3) Declaration of the number of servings per container need not be included in nutrition labeling of raw fruit, vegetables, and fish.

(4) The nutrition label data should be based on raw edible portion for fruit and vegetables and on a cooked edible portion for fish. The methods used to cook fish should be those that do not add fat, breading, or seasoning (e.g., salt or spices).

(c) Nutrient data and proposed nutrient values for nutrition labeling for raw fruit, vegetables, and fish may be submitted to the Division of Nutrition (HFF-260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, for review and evaluation. The data and nutrient values for nutrition labeling are appropriate for use if they are accepted by the Food and Drug Administration (FDA). The submission to FDA should include information on the source of the data (names of investigators, name of organization, place of analysis, dates of analyses), number of samples, sampling scheme, analytical methods, statistical treatment of the data, and proposed quantitative label declarations. The nutrient values for the nutrition labeling should be determined in accordance with FDA guidance.

(d) Composite data that reflect representative nutrient levels for various varieties, species, cultivars; seasons; and geographic regions may be used to label raw fruit, vegetables, and fish. Alternatively, data that reflect a specific variety, species, cultivar; season; or geographic region may be used to label raw fruit, vegetables, and fish; the nutrition labeling information for such variety, etc., should provide food names and descriptions for the fruit, vegetables, and fish that appropriately reflect the samples analyzed for nutrient values.

(e) The FDA manual "Compliance Procedures for Nutrition Labeling" (or subsequent revisions of this manual) should be used to develop nutrition label values from data base values. The manual is available from the Division of Nutrition.

(f) If the agency's Center for Food Safety and Applied Nutrition agrees to all aspects of a submitted data base, FDA will notify a submitter in writing of its acceptance of the nutrient data and nutrient values for nutrition labeling. FDA's acceptance will be for a period of 10 years or until other data for the same food are submitted to FDA and found to be superior. Those obtaining data base and nutrient value acceptance from FDA are responsible for continued maintenance of the data base. FDA will renew its acceptance of a data base upon request after 10 years unless the data have been superseded by other data on the same food or there have been demonstrated changes in agricultural or industry practices. When agricultural or industry practices change (e.g., a change occurs in a predominant variety produced), or when FDA monitoring suggests that the data base or nutrient values are no longer representative of the item sold in this country, FDA will take steps to revoke its acceptance of the data base and nutrient values. A revised data base and proposed nutrient values may be submitted to FDA for acceptance.

(g) If the nutrition information is in accordance with an FDA-accepted data base, the nutrient values have been computed following FDA guidelines, and the food has been handled in accordance with current good manufacturing practices to prevent nutrient loss, a nutrition label will not be subject to the agency compliance review under § 101.9(e).

(h) Organizations may use data bases that they believe validly reflect the nutrient content of raw fruit, vegetables, and fish; however, labeling computed from data bases not reviewed, evaluated, and accepted by the agency is subject to the compliance procedures of § 101.9(e).

(i) FDA will publish, and provide an opportunity for comment on, updates of the nutrition labeling data for the 20 most frequently consumed raw fruit, vegetables, and fish (or a notice that the data sets have not changed from the previous publication) at least every 2 years in the **Federal Register**. FDA accepted data for other raw fruit, vegetables, and fish, or for other nutrients, are available from the Division of Nutrition, Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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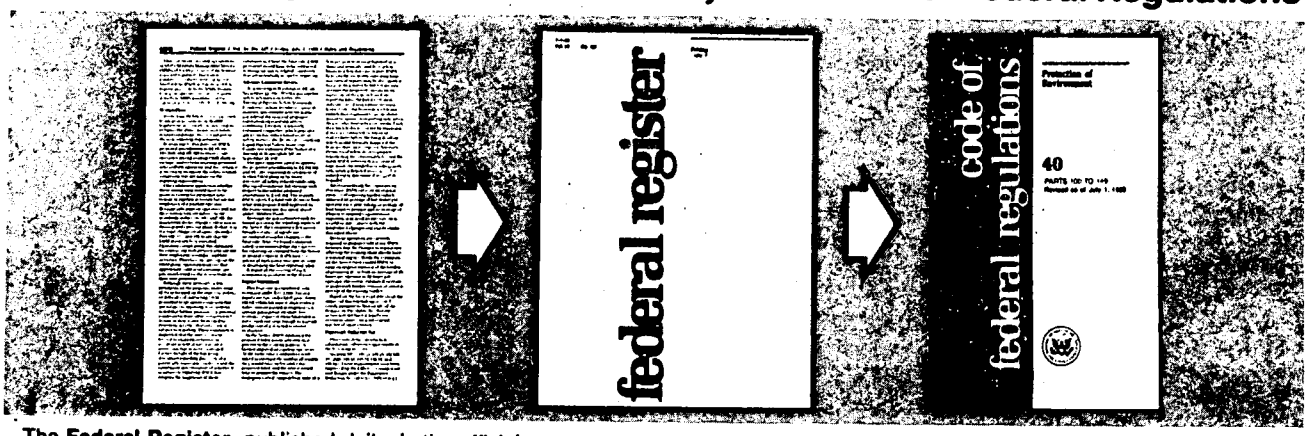

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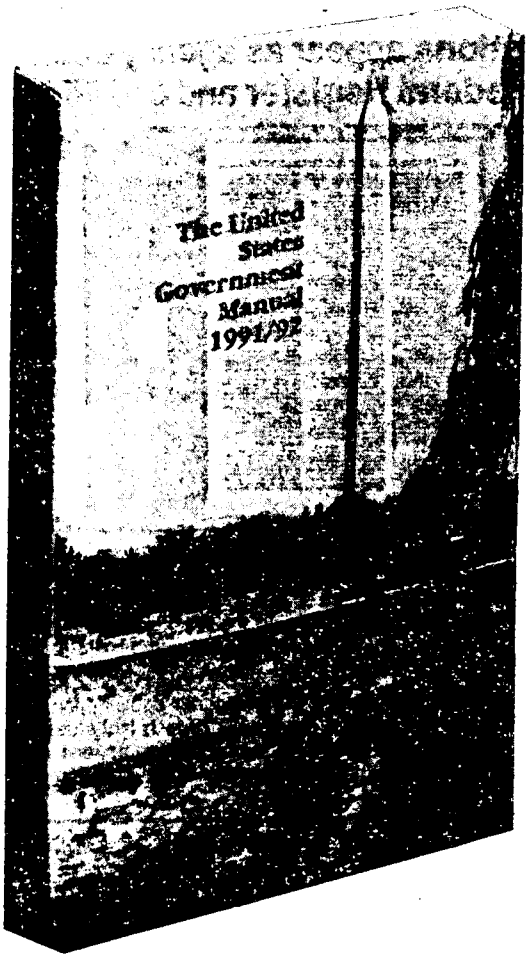

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