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federal register

Tuesday
October 19, 1982

Selected Subjects

Air Pollution Control
Environmental Protection Agency

Aliens
Immigration and Naturalization Service

Animal Drugs
Food and Drug Administration

Banks, Banking
Depository Institutions Deregulation Committee

Drugs
Food and Drug Administration

Food Additives
Food and Drug Administration

Food Grades and Standards
Agricultural Marketing Service

Food Ingredients
Food and Drug Administration

Food Stamps
Food and Nutrition Service

Freedom of Information
Personnel Management Office

Government Procurement
National Aeronautics and Space Administration

Law Enforcement
Postal Service

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Rural Electrification Administration

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Selected Subjects

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Questions and requests for specific information may be directed to the telephone numbers listed under INFORMATION AND ASSISTANCE in the READER AIDS section of this issue.

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Presidential Documents

Title 3—

The President

Presidential Determination No. 83-2 of October 11, 1982

FY 1983 Refugee Ceilings

Memorandum for the Honorable H. Eugene Douglas, United States Coordinator for Refugee Affairs

Pursuant to Sections 207(a) and 207.1(a)(3) and in accordance with Section 209(b) of the Immigration and Nationality Act (INA), after appropriate consultations with the Congress, I hereby determine that:

• the admission of up to 90,000 refugees to the United States during FY 1983 is justified by humanitarian concerns or is otherwise in the national interest;

• the 90,000 refugee admission ceiling shall be allocated as 64,000 for East Asia; 15,000 for the Soviet Union/Eastern Europe; 6,000 for the Near East/South Asia; 3,000 for Africa; and 2,000 for Latin America/Caribbean; and

• an additional 5,000 refugee admission numbers to be available for the adjustment to permanent residence status of aliens who have been granted asylum in the United States is justified by humanitarian concerns or is otherwise in the national interest.

Pursuant to Section 101(a)(42)(B) of the INA and after appropriate consultations with the Congress, I hereby specify that special circumstances exist such that, for the purposes of admission under the limits established herein, the following persons, if they otherwise qualify for admission, may be considered refugees of special humanitarian concern to the United States even though they are still within their countries of nationality or habitual residence:

• persons in Vietnam with past or present ties to the United States; and

• present and former political prisoners, and persons in imminent danger or loss of life, and their family members, in countries of Latin America and the Caribbean.

You will inform the appropriate committees of the Congress of these determinations.

This memorandum shall be published in the **Federal Register.**

Ronald Reagan

THE WHITE HOUSE,
Washington, October 11, 1982.

[FR Doc. 82-28846
Filed 10-15-82; 4:21 pm]
Billing code 3195-01-M

Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each month.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 273 and 282

[Amendment No. 206]

Food Stamp Program: Removal of Certain References and Demonstration Project Pre-Operational Procedures From the Code of Federal Regulations

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: On February 12, 1982 (47 FR 6433), the Department issued proposed Food Stamp Program rules to remove all references to the actual dollar amounts of the maximum income eligibility limits, thrifty food plan (TFP) amounts, standard deduction amounts, child care deduction amounts, and excess shelter deduction amounts from the Code of Federal Regulations (CFR). The proposed rules also required the Department to publish periodic general notices in the **Federal Register** to solicit comments on the subjects and issues of planned demonstration projects that might have significant impact and to announce the start of such demonstration projects. Such proposed and final notice procedures would be in lieu of current requirements.

Comments were solicited on this proposed rule through April 13, 1982. This final action addresses the comments received and explains the basis and purpose of the new procedures. This final rule is supported by most commenters and simplifies administrative procedures in order to provide State agencies with more advance time to implement cost-of-living adjustments in financial eligibility criteria and to begin demonstration projects.

EFFECTIVE DATE: This action is effective November 18, 1982.

FOR FURTHER INFORMATION CONTACT: Thomas O'Connor, Supervisor, Regulations and Policy Section, Program Standards Branch, Program Development Division, Family Nutrition Programs, Food and Nutrition Service, United States Department of Agriculture, Room 708, 3101 Park Center Drive, Alexandria, Virginia 22302: 703–756–3429.

SUPPLEMENTARY INFORMATION: This action has been reviewed under Executive Order 12291 and Secretary's Memorandum No. 1512–1. This action deletes the need to use formal rulemaking procedures for announcing annual changes in certain eligibility, benefit and deduction information and for initiating demonstration projects. This information currently required by the provisions being deregulated can be released to the public by other, more timely, means available to the agency, in lieu of formal rulemaking procedures. Under current procedures annual cost of living or other adjustments required by statute are published as formal regulations, and are codified in the Code of Federal Regulations (CFR). Changes to those levels must be issued through other regulations, also codified in the CFR. These rules will permit routine adjustments through **Federal Register** notices, thus eliminating the lengthier process of rulemaking, and unnecessary amendments to the CFR while still providing timely **Federal Register** notice to the public.

There is no cost involved in this action, thus, the rule would not result in an annual effect on the economy of $100 million or more or a major increase in costs or prices for consumers, industries, Federal, State or local governments, or geographical regions. Additionally, this action would 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. Therefore, the rule has been classified as "not major."

This final action has also been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 (Pub. L. 96–354). Mr. Samuel J. Cornelius, Administrator of the Food and Nutrition Service, has certified that this action has no economic impact on small entities. The action simply results in the deregulation of certain information that can be released to the public through other than formal regulatory procedures and allows more timely release of the information without jeopardizing public interest. In addition, this regulation does not contain reporting and recordkeeping requirements subject to approval by OMB under the Paperwork Reduction Act.

The Department received 20 comment letters on the February 12, 1982 proposed regulations. The majority of commenters supported the provisions as written. Commenters were hopeful that deregulation of the dollar amounts would provide more lead time to implement adjustments in the eligibility and benefit levels.

Commenters generally agreed with the proposed procedures to solicit public input on significant demonstration projects and to announce the start of such a project through publication of General Notices in the **Federal Register**, in lieu of publishing regulations. This procedure will allow more flexibility in designing projects, will expedite project initiation and will avoid needless codifications of project rules in the Code of Federal Regulation. Three commenters opposed the provisions, stating that the Notice procedure eliminates or cuts off the public's opportunity for meaningful comments before a demonstration project begins.

The Department does not share the commenters' conclusion that the public interest would be jeopardized. The current regulations require the agency to publish proposed rules in the **Federal Register** if the proposed demonstration project is likely to have significant impact on the public. Comments are considered and final rules issued prior to project operation.

Under the General Notice procedures, as in the procedures discussed above, advance public comment would be solicited. The subjects and issues involved in potential demonstration projects would be published for publi comments. Moreover, a project likely to have significant impact would be announced in the **Federal Register** along with an analysis of the basis and purpose of the project. A specific and

detailed final Notice will set forth operational procedures and any provisions of law or regulations to be waived.

Comments received in response to a specific final Notice, already based on public input, will still receive serious consideration by the Department. Based on these comments the Department will take such action as may be appropriate before the project is implemented. Notice of significant changes in the operational procedures will be made available to affected participants. The final procedures as amended, will be published in the **Federal Register** if any significant changes have been made in the prior Notice. The relatively limited scope and size of most demonstration projects shall facilitate changes in project operations and in restructuring the evaluation components in response to comments.

The Department has always been committed to improving the efficiency of the Program and the delivery of services. Demonstration projects are one means of carrying out that commitment by testing new procedures. The longer it takes to begin and test alternative procedures through a demonstration project, the longer it takes to put into effect a nationwide procedure that could make a significant improvement in Program administration, or in delivery of services. Delays of 4–6 months have occurred in the implementation of demonstration projects solely because of the use of a formal rulemaking procedure.

These notice procedures which invite public comment are less complicated and less time-consuming than the former procedures but achive the same goals. Both procedures provide opportunity of public participation and the careful consideration of projects likely to have significant impact before their implementation. Additionally, these *General Notice* procedures will avoid needless codification of project requirements in the Code of Federal Regulations. The double cycle of notice and comment analysis should allow for precise fine tuning of these projects.

In light of the majority support from commenters and the reasons set forth herein, the provisions of the proposed rules are by this final action. However, the proposed language to amend demonstration procedures is slightly modified to more clearly express these rules. Also the proposed language to amend 7 CFR 273.9(d)(5) is slightly rearranged for clarity and modified to reflect language added or changed by subsequent final rules issued September 4, 1981 (46 FR 447612) and April 30, 1982 (47 FR 63460).

List of Subjects

7 CFR Part 273

Administrative practice and procedure, Aliens, Claims, Food stamps, Fraud, Grant programs/social programs, Penalties, Recordkeeping and reporting requirements, Social security, Students.

7 CFR Part 282

Food stamps, Government contracts, Grant programs/Social programs, Research.

Accordingly, Parts 273 and 282 are being amended as follows:

PART 273—CERTIFICATION OF ELIGIBLE HOUSEHOLDS

1. In § 273.9:

a. Paragraph (a)(4) is revised;

b. Paragraphs (d)1), (d)(4), and (d)(5) are revised; and

c. Appendicies A, B, C, and D are removed.

The revisions read as follows:

§ 273.9 Income and deductions.

(a) *Income eligibility standards.* * * *

(4) The monthly gross and net income eligibility standards for all areas will be prescribed in General Notices published in the **Federal Register.** * * *

* * * * *

(d) *Income deductions.* * * *

(1) *Standard deduction.* The per household per month standard deduction amounts applicable for use in the 48 contiguous States and the District of Columbia, and the amounts applicable for Alaska, Hawaii, Guam, and the Virgin Islands are adjusted annually and will be prescribed in General Notices published in the **Federal Register.** * * *

(4) *Departure care.* Payments for the actual costs for the care of a child or other dependents when necessary for a household member to accept or continue employment, seek employment in compliance with the job search criteria (or an equivalent effort by those not subject to job search), or attend training or pursue education which is preparatory to employment. The deduction amounts applicable for use in the 48 contiguous States and the District of Columbia, and the amounts applicable for Alaska, Hawaii, Guam, and the Virgin Islands are adjusted annually and will be prescribed in general Notices published in the **Federal Register.**

(5) *Shelter costs.* Monthly shelter costs in excess of 50 percent of the household's income after all other deductions in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this section have been allowed. The shelter deduction alone, or in combination with the dependent care deduction explained in paragraph (d)(4) of this section shall not exceed the maximum limit established for the dependent care deduction. This is applicable unless the household contains a member who is age 60 or over, or who receives Supplemental Security Income benefits (including emergency benefits based on presumptive eligibility) under title XVI, or disability and blindness payments under titles I, II, X, XIV, and XVI of the Social Security Act. Such households shall receive an excess shelter deduction for the montly cost that exceeds 50 percent of their monthly income after all other applicable deductions. The shelter deduction amount applicable for use in the 48 contiguous States and the District of Columbia, and the amounts applicable for use in Alaska, Hawaii, Guam, and the Virgin Islands are adjusted annually and will be prescribed in General notices published in the **Federal Register.**

* * * * *

2. In § 273.10, the parenthetical phrase "(see appendix to § 273.9)", appearing in the first sentence of paragraph (e)(1)(i)(E) is removed; the last sentence of paragraph (e)(4)(i) is revised; and appendix A is removed. The revision reads as follows:

§ 273.10 Determining household eligibility and benefit level.

* * * * *

(e) *Calculating net income and benefit levels.* * * *

(4) *Thrifty Food Plan.*

(i) * * * The Thrifty Food Plan amounts in each area are adjusted annually and will be prescribed in General Notices published in the **Federal Register.**

* * * * *

PART 282—DEMONSTRATION, RESEARCH, AND EVALUATION PROJECTS

3. Section 282.2 is revised in its entirety to read as follows:

§ 282.2 Project initiation.

The Secretary shall, from time to time, publish a list of priority areas being considered for demonstration, research, and evaluation efforts, and invite and consider public comment on such lists. In determining such priority areas, the Secretary shall consider suggestions submitted by State and local agencies and other interested parties. The Secretary shall, as appropriate, seek grant proposals, through publication of a notice of intent in the **Federal Register,**

or contract proposals, in accordance with the procedures prescribed in the Federal procurement regulations. (41 CFR, Ch. L.)

4. Section 282.5 is revised in its entirety to read as follows:

§ 282.5 Public Notice procedures for demonstration projects.

(a) *General Notices:* At least 30 days prior to the initiation of a demonstration project, FNS shall publish a General Notice in the **Federal Register** if the demonstration project will likely have a significant impact on the public. The notice shall set forth the specific operational procedures, shall consider the public comment received under section 282.2, and shall explain the basis and purpose of the demonstration project. If significant comments are received in response to this General Notice, the Department will take such action as may be appropriate prior to implementing the project.

(b) *Amended General Notices:* If the procedures or explanation referred to in paragraph (a) of this section are significantly changed because of comments, an amended General Notice will be published in the **Federal Register** at least 30 days prior to the initiation of the demonstration project, except where good cause exists supporting a shorter effective date. The explanation for the determination of good cause will be published with the amended General Notice. The amended General Notice shall also explain the basis and purpose of the changes.

(c) *Reporting and Recordkeeping Requirements:* In addition, for demonstration projects with reporting and recordkeeping requirements which exceed the requirements set forth in OMB Circular A-102, the Department will obtain the necessary approval from OMB prior to project implementation.

(91 Stat. 958 (7 U.S.C. 2011-2029))

(Catalog of Federal Domestic Assistance, Program No. 10.551, Food Stamps)

Dated: October 13, 1982.

Robert E. Leard,

Associate Administrator Food and Nutrition Service.

[FR Doc. 82-28484 Filed 10-18-82; 8:45 am]

BILLING CODE 3410-30-M

Agricultural Marketing Service

7 CFR Part 906

Oranges and Grapefruit Grown in Texas; Amendment to Container Regulation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: This interim rule amends container regulations issued under the marketing order by deleting the 1⅝ bushel carton currently authorized, while providing handlers an opportunity to deplete their current inventories of this container by permitting such inventories to be used through July 31, 1983. Such action is necessary to eliminate a container, which is no longer needed or considered desirable for the shipment of fresh oranges and grapefruit.

DATES: Interim rule effective October 19, 1982, through December 31, 1982. Comments which are received by November 18, 1982, will be considered prior to issuance of a final rule to become effective January 1, 1983.

ADDRESS: Send two copies of comments to Hearing Clerk, U.S. Department of Agriculture, Room 1077, South Building, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: William J. Doyle, Acting Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202-447-5975.

SUPPLEMENTARY INFORMATION: This interim rule has been reviewed under Secretary's Memorandum 1512-1 and Executive Order 12291, and has been designated a "non-major" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has determined that this action will not have a significant economic impact on a substantial number of small entities. This action is designed to promote orderly marketing of the Texas orange and grapefruit crops for the benefit of producers, and will not substantially affect costs for the directly regulated handlers.

This interim rule is issued under the marketing agreement, as amended, and Order No. 906, as amended (7 CFR Part 906), regulating the handling of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). The action is based upon the recommendations and information submitted by the Texas Valley Citrus Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the Act.

This amendment revokes authorization which currently permits shipment of oranges and grapefruit in the 1⅝ bushel carton (inside dimensions of 19¾ x 13½ x 13 inches), while providing handlers an opportunity to deplete their current inventories of this container. The committee recommended that the container be eliminated because it is reportedly difficult to pack and load due to its shape and relatively large size, and as it does not adequately protect the fruit from bruising when stacked several layers high in trailers for shipment to market. In addition, elimination of the container will reduce the number of types of containers which handlers need maintain in inventory, and should simplify their packing operations.

The committee also recommended that handlers be provided an opportunity to use any supplies of this container which they currently have in their inventories, and it estimates that such inventories will be exhausted by the end of the 1982-83 season. The committee unanimously recommended this action at its meeting of August 31, 1982.

The interim rule also revises CFR numerical designations relating to the United States grade standards for oranges and grapefruit consistent with redesignations appearing in **Federal Register** (46 FR 63203), while not changing the grade standards themselves; and makes minor nonsubstantive changes relating to definitions, and to the removal of obsolete language pertaining to a container for which authorization has expired.

It is found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date of this interim rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) in that the time intervening between the date when information upon which this interim rule is based became available and the time when this interim rule must become effective in order to effectuate the declared policy of the act is insufficient. It is necessary to effectuate the declared purposes of the act to make this interim rule effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 906

Marketing agreements and orders, Oranges, Grapefruit, Texas.

PART 906—[AMENDED]

Therefore, § 906.340, under *Subpart—Containers and Pack Requirements,* is amended by revising the introductory text in paragraph (a); by revising paragraphs (a)(1)(iii), (a)(2)(i)(*a*), (a)(2)(ii), and (c); and by deleting paragraph (a)(1)(ix), to read as follows

(this interim rule expires December 31, 1982, and will not be published in the annual Code of Federal Regulations):

§ 906.340 Container, pack, and container marking regulations.

(a) On and after October 19, 1982 through December 31, 1982, no handler shall handle any variety of oranges or grapefruit grown in the production area unless such fruit is in one of the following containers, and the fruit is packed and the containers are marked as specified in this section.

* * * * *

(iii) Closed fully telescopic fiberboard carton with inside dimensions of 19¾ x 13½ x 13 inches: *Provided,* That the cover section and bottom section each has a Mullen or Cady test of at least 250 pounds: *Provided further,* That such containers are from inventories on hand, and used prior to July 31, 1983;

* * * * *

(2) Pack regulation (i) *Oranges.* (*a*) Oranges, except Navel oranges and Valencia and similar late-type oranges, when packed in any box, bag, or carton shall, except as otherwise provided by regulations issued pursuant to this part, be within the diameter limits specified for the various pack sizes in § 51.691(c) of the United States Standards for Grades of Oranges (Texas and States other than Florida, California, and Arizona);

* * * * *

(ii) *Grapefruit.* Grapefruit, when packed in any box, bag or carton, shall be within the diameter limits specified for the various pack sizes in § 51.630(c) of the United States Standards for Grades of Grapefruit (Texas and States other than Florida, California, and Arizona): *Provided,* That the minimum diameter limit for pack size 96 grapefruit shall be 3 9/16 inches and for pack size 112 grapefruit shall be 3 5/16 inches, and *Provided further,* That any grapefruit in boxes or cartons shall be packed in accordance with the requirements of standard pack.

* * * * *

(c) As used herein, terms relating to grade, pack, standard pack, and diameter mean the same as defined in the United States Standards for Grades of Oranges (Texas and States other than Florida, California, and Arizona), (7 CFR 51.680–51.714), or in the United States Standards for Grades of Grapefruit (Texas and States other than Florida, California, and Arizona), (7 CFR 51.620–51.652); and "closed" means closed in accordance with good commercial practices.

(Secs. 1–19, 48 Stat. 31, as amended: 7 U.S.C. 601–674)

Dated: October 14, 1982.

D. S. Kuryloski,

Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 82-28621 Filed 10-18-82; 8:45 am]

BILLING CODE 3410-02-M

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7 CFR Part 966

Tomatoes Grown in Florida; Tomato Handling Regulation 966.322; Tomato Import Regulation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim rule.

SUMMARY: This interim regulation requires fresh market shipments of tomatoes grown in certain counties in Florida to be inspected and meet minimum grade, size, pack, container and marking requirements. This will promote orderly marketing of such tomatoes and keep less desirable sizes and qualities from being shipped to consumers.

DATE: Interim rule effective October 13, 1982.

FOR FURTHER INFORMATION CONTACT: Charles W. Porter, Chief, Vegetable Branch, F&V, AMS, USDA, Washington, D.C. 20250 (202) 447–2615. The final impact analysis relating to this rule is available on request from Mr. Porter.

SUPPLEMENTARY INFORMATION: Paperwork Reduction Act.

Information collection requirements contained in this regulation (7 CFR Part 966) have been approved by the Office of Management and Budget under the provisions of 44 U.S.C. Chapter 35 and have been assigned OMB # 0581–0073.

This action has been reviewed under Secretary's Memorandum 1512–1 and Executive Order 12291 and has been designated a "nonmajor" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has determined that this action will not have a significant economic impact on a substantial number of small entities. This action is designed to promote orderly marketing of the Florida tomato crop for the benefit of producers and consumers, and will not substantially affect costs for the directly regulated handlers.

Marketing Agreement No. 125 and Order No. 966, both as amended (7 CFR Part 966) regulate the handling of tomatoes grown in designated counties of Florida. The program is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The Florida Tomato Committee, established under the order, is responsible for its local administration.

This action is based upon unanimous recommendations made by the committee at its public meeting at Marco Island, Florida, on September 17, 1982. The recommendations of the committee reflect its appraisal of the composition of the 1982–83 crop of Florida tomatoes and the marketing prospects for this season and are consistent with the marketing policy it adopted. It is hereby found that this action will tend to effectuate the declared policy of the act.

The grade and size requirements specified herein are necessary to prevent tomatoes of lower quality and undesirable size from being distributed in fresh market channels. Such tomatoes are usually of negligible economic value to producers. This will provide consumers with tomatoes of good quality and size throughout the season consistent with the overall quality of the crop. The requirements, including those for containers, container net weights, and size classifications, are intended to standardize shipments in the interest of orderly marketing and to improve returns to growers.

The requirements specified in this rule are the same as those in past seasons with the exception of those pertaining to size, pack, and containers. Tomatoes must meet a minimum size requirement of 2 5/32 inches in diameter, compared with 2 3/32 inches in past seasons. The committee has determined that the lower requirement permits tomatoes of too small a size to enter fresh market channels. Demand is weak for these smaller sizes, and prices for all tomatoes are adversely affected. The increase in the minimum size standard will not have a substantial effect on the volume of tomatoes shipped to fresh market.

The pack specifications have been changed to reflect the increase in the minimum size requirement. The adjustment also will result in a more even distribution of tomato shipments among the established size categories.

The trend over the years has been a shift to the use of smaller containers, as evidenced by last year's replacement of the 30-pound container with one of 25 pounds. This year, the committee has recommended the elimination of the 40-pound container. This change will have no effect on tomato handlers, however, since the 40-pound container is no longer in use.

Exceptions are provided to certain of these requirements to recognize special situations in which such requirements would be inappropriate or unreasonable. Shipments may be allowed to certain

special purpose outlets without regard to minimum grade, size, container or inspection requirements provided that safeguards are used to prevent such tomatoes from reaching unauthorized outlets. Tomatoes for canning are exempt under the legislative authority for this part. Since no purpose would be served by regulating tomatoes used for relief, experimental or charity purposes such shipments are also exempt. Because export requirements differ materially, on occasion, from domestic market requirements such shipments are exempt.

The following types of tomatoes are exempt from these regulations: elongated types commonly referred to as pear shaped or paste tomatoes, cerasiform type tomatoes commonly referred to as cherry tomatoes, hydroponic tomatoes and greenhouse tomatoes. Such types are generally of good quality, readily identifiable either by their distinctive shapes or container markings and usually comprise a very small part of the total crop. Only tomatoes shipped outside the regulated area are being regulated because of an increase in the U-pick type of harvest in Florida production areas close to urban areas and resulting difficulty in obtaining compliance with regulations. The minimum quantity exemption permits persons to handle up to 60 pounds of tomatoes per day without regard to the requirements of this part. This reduces the problem of enforcement on small shipments of essentially noncommercial nature. The requirements concerning special pack shipments are intended to help handlers in the production area compete on an equal basis with those outside the area by not requiring reinspection of previously inspected and certified tomatoes when repacked in consumer size packages.

Occasionally individual fruit of several varieties of tomatoes grown in Florida may be elongated in shape. This characteristic may be exaggerated by adverse growing conditions. It is anticipated that handlers packing these varieties usually will be able to comply with all provisions of the regulation. However, if situations arise in which the incidence of tomatoes not of the normal globular shape makes sizing in accordance with the present pack specifications infeasible, the affected varieties may be exempted from the size requirements of the regulation.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking procedure, and postpone the effective date of this regulation until 30 days after publication thereof in the **Federal Register** (5 U.S.C. 553), and good cause exists for making these regulatory provisions effective as specified in that (1) shipments of the 1982–83 crop tomatoes grown in the production area are expected to begin on or about the effective date herein and this regulation should be applicable to all shipments during the season; (2) the regulation was recommended by the committee following discussion at an open meeting; (3) information regarding these requirements and the effective date has been disseminated among growers and handlers of tomatoes in the production area; (4) the requirements are similar to those in effect during past seasons; and (5) compliance with this section will not require any special preparation on the part of handlers subject thereto which cannot be completed by the effective date.

This interim regulation is effective during the period October 13 through December 31, 1982.

List of Subjects in 7 CFR Part 966

Marketing agreements and orders, Tomatoes, Florida.

PART 966—[AMENDED]

Section 966.321 (46 FR 60175, December 9, 1981) is removed and a new § 966.322 is added as follows:

§ 966.322 Handling regulation.

During the period October 13, 1982, through December 31, 1982, no person shall handle any lot of tomatoes for shipment outside the regulated area unless they meet the requirements of paragraph (a) or are exempted by paragraph (b) or (d).

(a) *Grade, size, container and inspection requirements.* (1) *Grade.* Tomatoes shall be graded and meet the requirements specified for U.S. No. 1, U.S. Combination, U.S. No. 2, or U.S. No. 3, of the U.S. Standards for Fresh Tomatoes. When not more than 15 percent of tomatoes in any lot fail to meet the requirements of U.S. No. 1 grade and not more than one-third of this 15 percent (or 5 percent) are comprised of defects causing very serious damage including not more than one percent of tomatoes which are soft or affected by decay, such tomatoes may be shipped and designated as at least 85 percent U.S. No. 1 grade.

(2) *Size.* (i) Tomatoes shall be at least 2 5/32 inches in diameter and be sized in one or more of the following ranges of diameters. Measurement of diameters shall be in accordance with the methods prescribed in Section 51.1859 of the U.S. Standards for Fresh Tomatoes.

Size classification	Inches	
	Minimum diameter	Maximum diameter
7x7	2 5/32	2 19/32
6x7	2 5/32	2 19/32
6x6	2 19/32	2 29/32
5x6 and larger	2 29/32	

(ii) Tomatoes of designated sizes may not be commingled unless they are over 2 19/32 inches in diameter and each container shall be marked to indicate the designated size.

(iii) Only numerical terms may be used to indicate the above listed size designations on containers of tomatoes, except when tomatoes are commingled the containers can be marked 6x6 & Lgr. or 5x6 & Lgr.

(iv) To allow for variations incident to proper sizing, not more than a total of ten (10) percent, by count, of the tomatoes in any lot may be smaller than the specified minimum diameter or larger than the maximum diameter.

(3) *Containers.* (i) Tomatoes shall be packed in containers of 20 or 25 pounds designated net weights and comply with the requirements of § 51.1863 of the U.S. tomato standards.

(ii) Each container shall be marked to indicate the designated net weight and must show the name and address of the shipper in letters at least one-fourth (¼) inch high.

(iii) If the container in which the tomatoes are packed is not clean and bright in appearance without marks, stains, or other evidence of previous use, the lid of such container shall be marked in a principal display area at least 2½ inches high and 4½ inches long with the words "USED BOX" in letters not less than 1¼ inches high and the name of the shipper and point of origin in letters not less than ⅜ inch high.

(4) *Inspection.* Tomatoes shall be inspected and certified pursuant to the provisions of § 966.60. Each handler who applies for inspection shall register with the committee pursuant to § 966.113. Handlers shall pay assessments as provided in § 966.42. Evidence of inspection must accompany truck shipments.

(b) *Special purpose shipments.* The requirements of paragraph (a) of this section shall not be applicable to shipments of tomatoes for canning, experimental purposes, relief, charity or export if the handler thereof complies with the safeguard requirements of paragraph (c) of this section. Shipments for canning are also exempt from the assessment requirements of this part.

(c) *Safeguards.* Each handler making shipments of tomatoes for canning, experimental purposes, relief, charity or

export in accordance with paragraph (b) of this section shall:

(1) Apply to the committee and obtain a Certificate of Privilege to make such shipments.

(2) Prepare on forms furnished by the committee a report in quadruplicate on such shipments authorized in paragraph (b) of this section.

(3) Bill or consign each shipment directly to the designated applicable receiver.

(4) Forward one copy of such report to the committee office and two copies to the receiver for signing and returning one copy to the committee office. Failure of the handler or receiver to report such shipments by signing and returning the applicable report to the committee office within ten days after shipment may be cause for cancellation of such handler's certificate and/or receiver's eligibility to receive further shipments pursuant to such certificate. Upon cancellation of any such certificate, the handler may appeal to the committee for reconsideration.

(d) *Exemption.* (1) *For types.* The following types of tomatoes are exempt from these regulations: Elongated types commonly referred to as pear shaped or paste tomatoes and including but not limited to San Marzano, Red Top and Roma varieties; cerasiform type tomatoes commonly referred to as cherry tomatoes; hydroponic tomatoes; and greenhouse tomatoes.

(2) *For minimum quantity.* For purposes of this regulation each person subject thereto may handle up to but not to exceed 60 pounds of tomatoes per day without regard to the requirements of this regulation but this exemption shall not apply to any shipment or any portion thereof of over 60 pounds of tomatoes.

(3) *For special packed tomatoes.* Tomatoes which met the inspection requirements of paragraph (a)(4) which are resorted, regraded and repacked by a handler who has been designated as a "Certified Tomato Repacker" by the committee are exempt from (i) the tomato grade classifications of paragraph (a)(1), (ii) the size classifications of paragraph (a)(2) except that the tomatoes shall be at least 2 5/32 inches in diameter and (iii) the container weight requirements of paragraph (a)(3).

(4) *For varieties.* Upon recommendation of the committee, varieties of tomatoes that are elongated or otherwise misshapen due to adverse growing conditions may be exempted by the Secretary from the provisions of paragraph (a)(2).

(e) *Definitions.* "Hydroponic tomatoes" means tomatoes grown in solution without soil; "greenhouse tomatoes" means tomatoes grown indoors. A "Certified Tomato Repacker" is a repacker of tomatoes in the regulated area who has the facilities for handling, regrading, resorting and repacking tomatoes into consumer size packages and has been certified as such by the committee. "U.S. tomato standards" means the revised United States Standards for Fresh Tomatoes (7 CFR 51.1855–51.1877), effective December 1, 1973, as amended, or variations thereof specified in this section. Other terms in this section shall have the same meaning as when used in Marketing Agreement No. 125, as amended, and this part, and the U.S. tomato standards.

(f) *Applicability to imports.* Under Section 8e of the act and § 980.212 "Import regulations" (7 CFR 980.212) tomatoes imported during the period October 31, 1982, through December 31, 1982, shall be at least U.S. No. 3 grade and at least 2 5/32 inches in diameter. Not more than 10 percent, by count, in any lot may be smaller than the minimum specified diameter.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated October 13, 1982 to become effective October 13, 1982.

D. S. Kuryloski,

Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 82-28719 Filed 10-18-82; 8:45 am]

BILLING CODE 3410-02-M

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7 CFR Part 966, 981, 982, 984, and 991

Expenses and Rates of Assessment for Specified Marketing Orders

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation authorizes expenses of the Florida Tomato Committee functioning under Marketing Order No. 966, the Almond Board of California functioning under M.O. No. 981, the Filbert/Hazelnut Marketing Board functioning under M.O. 982, the Walnut Marketing Board functioning under M.O. No. 984, and the Hop Administrative Committee functioning under M.O. No. 991. Funds to administer these programs are derived from assessments on Tomato, Almond, Filbert, Walnut, and Hop, handlers regulated under the orders.

EFFECTIVE DATES: Part 966, August 1, 1982 to July 31, 1983 [§ 966,220], Part 981, July 1, 1982 to June 30, 1983 [§ 981.332], Part 982, May 1, 1982 to June 30, 1983 [§ 982.327], Part 984, August 1, 1982 to July 31, 1983 [§ 984.334], and Part 991, August 1, 1982 to July 31, 1983 [§ 991.317].

FOR FURTHER INFORMATION CONTACT: J. S. Miller, Chief, Specialty Crops Branch, Fruit and Vegetable Division, AMS, USDA, Washington, D.C. 20250 (202) 447–5697.

SUPPLEMENTARY INFORMATION: This rule has been reviewed under Secretary's Memorandum 1512–1 and Executive Order 12291 and has been designated a "non-major" rule under criteria contained therein.

William T. Manley, Deputy Administrator, Agricultural Marketing Service, has determined that this action will not have a significant economic impact on a substantial number of small entities because it would not significantly affect costs for the directly regulated handlers.

These marketing orders are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). These actions are based upon the recommendations and information submitted by the Boards and Committees, established under the respective marketing orders, and upon other information. It is found that the expenses and rates of assessment, as hereinafter provided, will tend to effectuate the declared policy of the act.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice and engage in public rulemaking and good cause exists for not postponing the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553). Each order requires that the rate of assessment for a particular fiscal period shall apply to all assessable Tomatoes, Almonds, Filberts, Walnuts, and Hops handled from the beginning of such period. To enable the Boards and Committees to meet current fiscal obligations, approval of the expenses is necessary without delay. It is necessary to effectuate the declared policy of the act to make these provisions effective as specified, and handlers have been apprised of such provisions, and the effective time.

List of Subjects

7 CFR Part 966

Marketing agreements and orders, Tomatoes, Florida.

7 CFR Part 981

Marketing agreements and orders, Almonds, California.

7 CFR Part 982

Marketing agreements and orders, Filberts, Hazelnuts, Oregon, Washington.

7 CFR Part 984

Marketing agreements and orders, Walnuts, California.

7 CFR Part 991

Marketing agreements and orders, Hops.

Sections 986.219 (M.O. 966); 981.331 (M.O. 981); 982.326 (M.O. 982); 984.333 (M.O. 984) and 991.316 (M.O. 991) are removed and new sections are added as follows: (the following sections prescribe annual expenses and assessment rates and will not be published in the Code of Federal Regulations).

PART 966—TOMATOES GROWN IN FLORIDA

§ 966.220 Expenses and assessment rate.

Expenses of $176,000 by the Florida Tomato Committee are authorized, and an assessment rate of $0.0025 per 25-pound container of tomatoes is established for the fiscal period ending July 31, 1983. Unexpended funds may be carried over as a reserve.

PART 981—ALMONDS GROWN IN CALIFORNIA

§ 981.332 Expenses and assessment rate.

Expenses of $10,017,766 by the Almond Board of California are authorized for the crop year ending June 30, 1983. An assessment rate for that crop year payable by each handler in accordance with § 981.81 is fixed at 2.85 cents per pound of almonds [kernelweight basis] less any amount credited pursuant to § 981.41 but not to exceed 2.5 cents per pound of almonds [kernelweight basis].

PART 982—FILBERTS/HAZELNUTS GROWN IN OREGON AND WASHINGTON

§ 982.327 Expenses and rate of assessment.

Expenses of $55,444 by the Filbert/Hazelnut Marketing Board are authorized and an assessment rate payable by each handler in accordance with § 982.61 is fixed at 0.2 cent per pound of filberts for the marketing year ending June 30, 1983. Unexpended funds are carried over as a reserve, or made available to handlers.

PART 984—WALNUTS GROWN IN CALIFORNIA

§ 984.334 Expenses and assessment rate.

Expenses of $606,100 by the Walnut Marketing Board are authorized and an assessment rate payable by each handler in accordance with § 984.69 is fixed at 0.4 cent per kernelweight pound of merchantable walnuts for the marketing year ending July 31, 1983. Unexpended funds may be used temporarily during the first five months of the subsequent marketing year, but must be made available to the handlers from whom collected within that period.

PART 991—HOPS OF DOMESTIC PRODUCTION

§ 991.317 Expenses and assessment rate.

Expenses of $310,575 by the Hop Administrative Committee are authorized, and an assessment rate payable by each handler in accordance with § 991.56 is fixed at 0.4 cent per pound of salable hops for the marketing year ending July 31, 1983. Unexpended funds are placed in an operating reserve or returned to handlers.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: October 13, 1982.

D. S. Kuryloski,

Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 82-28620 Filed 10-18-82; 8:45 am]

BILLING CODE 3410-02-M

Rural Electrification Administration

7 CFR Part 1701

Public Information; Appendix A—REA Bulletins Specification for Gas Tube Surge Arresters, PE-80

AGENCY: Rural Electrification Administration.

ACTION: Final rule.

SUMMARY: REA hereby amends Appendix A—REA Bulletins by issuing Addendum 1 to Bulletin 345-83, REA Specification for Gas Tube Surge Arresters, PE-80. A minor relaxation of the impulse transverse voltage requirements applied to three-electrode gas tube surge arresters will permit the use of less costly devices without significantly reducing the level of protection provided.

EFFECTIVE DATE: October 7, 1982.

FOR FURTHER INFORMATION CONTACT: Joseph M. Flanigan, Director, Telecommunications Engineering and Standards Division, Rural Electrification Administration, Room 1355, South Building, U.S. Department of Agriculture, Washington, D.C. 20250, telephone (202) 382-8663. The Final Impact Statement describing the options considered in developing this final rule and the impact of implementing each option is available on request from the above-named individual.

SUPPLEMENTARY INFORMATION: REA regulations are issued pursuant to the Rural Electrification Act as amended (7 U.S.C. 901 et seq.). This final action has been reviewed in accordance with Executive Order 12291, Federal Regulation. This action will not (1) have an annual effect on the economy of $100 million or more; (2) result in a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) result in significant adverse effects on competition, employment, investment or productivity and therefore has been determined to be "not major." This action does not fall within the scope of the Regulatory Flexibility Act and is not subject to OMB Circular A-95 review. This program is listed in the Catalog of Federal Domestic Assistance as 10.853—Community Antenna Television Loans and Loan Guarantees, and 10.851—Rural Telephone Loans and Loan Guarantees.

Background.—While tubes are available which meet the existing requirement, they are significantly more costly than several newer designs with slightly inferior performance with respect to impulse transverse voltage. As experience in the field has not substantiated the need for the higher level of performance, the specification will be relaxed to permit use of the lower cost devices.

If the existing specification was withdrawn rather than revised there would be no REA specification which manufacturers would be required to meet. Unacceptable equipment could be sold to REA borrowers which would result in the loss of telephone system effectiveness, a hazard to human safety, and a threat to REA loan security. As a result, revision of the document along the proposed lines was considered to be in the best interest of the program.

A Notice of Proposed Rulemaking was published in the **Federal Register** on May 14, 1982, Volume 47, Number 94, page 20782. However, no public comments were received in response to the notice.

7 CFR Part 1701, Appendix A—REA Bulletins, is hereby amended by the issuance of Addendum 1 to Bulletin 345-83.

List of Subjects in 7 CFR Part 1701

Loan programs—communications, Telecommunications, Telephone.

Dated: October 7, 1982.

Jack Van Mark,

Acting Administrator.

[FR Doc. 82-28566 Filed 10-18-82; 8:45 am]

BILLING CODE 3410-15-M

Rural Electrification Administration

7 CFR Part 1701

Public Information; Appendix A-REA Bulletins; Specification for Voice Frequency Repeater Equipment, PE-29

AGENCY: Rural Electrification Administration, USDA.

ACTION: Final rule.

SUMMARY: REA hereby amends Appendix A-REA Bulletins by issuing Addendum 1 to Bulletin 345-69, REA Specification for Two-Wire Voice Frequency Repeater Equipment, PE-29. This bulletin sets forth the minimum performance requirements for two-wire voice frequency repeaters which are to be accepted by REA and which may be purchased by REA borrowers with loan funds. The amendment is necessary to provide relief from unduly severe stability and return loss requirements. This action will permit the REA borrower to choose from a wider range of voice frequency repeaters, and encourage a more competitive marketplace.

EFFECTIVE DATE: October 7, 1982.

FOR FURTHER INFORMATION CONTACT: Joseph M. Flanigan, Director, Telecommunications Engineering and Standards Division, Rural Electrification Administration, Room 1355, South Building, U.S. Department of Agriculture, Washington, D.C. 20250, telephone (202) 382-8663. The Final Impact Statement describing the options considered in developing this final rule and the impact of implementing each option is available on request from the above-named individual.

SUPPLEMENTARY INFORMATION: REA regulations are issued pursuant to the Rural Electrification Act as amended (7 U.S.C. 901 et seq.). This final action has been reviewed in accordance with Executive Order 12291, Federal Regulation. This action will not (1) have an annual effect on the economy of $100 million or more; (2) result in a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) result in significant adverse effects on competition, employment, investment or productivity and therefore has been determined to be "not major." This action does not fall within the scope of the Regulator Flexibility Act and is not subject to OMB Circular A-95 review. This program is listed in the Catalog of Federal Domestic Assistance as 10.853—Community Antenna television Loans and Loan Guarantees, and 10.851—Rural Telephone Loans and Loan Guarantees.

Background—The amendment is necessary to provide relief from unduly severe stability and return loss requirements. The use of filled cable has produced more stable cable facilities which in turn has eliminated the need for the extremely severe operation environment imposed on voice frequency repeaters by PE-29. Manufacturers of hybrid repeaters are only able to show marginal compliance with the existing requirements. This action will permit the REA borrower to choose from a wider range of voice frequency repeaters, and encourage a more competitive marketplace.

A Notice of Proposed Rulemaking was published in the **Federal Register** on May 14, 1982, Volume 47, Number 94, page 20782. However, no public comments were received in response to the notice.

7 CFR Part 1701, Appendix A-REA Bulletins, is hereby amended by the issuance of Addendum 1 to Bulletin 345-69, REA Specification for Two-Wire Voice Frequency Repeater Equipment, PE-29.

List of Subjects in 7 CFR Part 1701

Loan programs—communications, Telecommunications, Telephone.

Dated: October 7, 1982.

Jack Van Mark,

Acting Administrator.

[FR Doc. 82-28629 Filed 10-18-82; 8:45 am]

BILLING CODE 3410-15-M

7 CFR Part 1701

Public Information; Appendix A—REA Bulletins, REA Specification for Filled Buried Service Wire, PE-86

AGENCY: Rural Electrification Administration, USDA.

ACTION: Final rule.

SUMMARY: REA hereby amends Appendix A—REA Bulletins by issuing a new REA Bulletin 345-86, REA Specification for Filled Buried Service Wire, PE-86. This new specification will cover a two-pair 22 AWG filled core armored single jacket wire for use as a service drop in lengths not to exceed 500 feet (150 m). This action will allow REA borrowers to take advantage of current wire technology while conserving petroleum raw materials. The improved wire will provide equivalent service at reduced costs.

EFFECTIVE DATE: October 7, 1982.

FOR FURTHER INFORMATION CONTACT: Joseph M. Flanigan, Director, Telecommunications Engineering and Standards Division, Rural Electrification Administration, Room 1355, South Building, U.S. Department of Agriculture, Washington, D.C. 20250, telephone (202) 382-8663. The Final Impact Statement describing the options considered in developing this final rule and the impact of implementing each option is available on request from the above-named individual.

SUPPLEMENTARY INFORMATION: REA regulations are issued pursuant to the Rural Electrification Act as amended (7 U.S.C. 901 et seq.). This final action has been reviewed in accordance with Executive Order 12291, Federal Regulation. This action will not (1) have an annual effect on the economy of $100 million or more; (2) result in a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) result in significant adverse effects on competition, employment, investment or productivity and therefore has been determined to be "not major." This action does not fall within the scope of the Regulatory Flexibility Act and is not subject to OMB Circular A-95 review. This program is listed in the Catalog of Federal Domestic Assistance as 10.851—Rural Telephone Loans and Loan Guarantees.

Background

REA, in its constant effort to provide the best, most cost-effective telecommunications for rural America has developed a specification for improved drop wire. This action will allow REA borrowers to take advantage of current wire technology while conserving petroleum raw materials. The improved wire will provide equivalent service at reduced costs. A Notice of Proposed Rulemaking was published in the **Federal Register** on July 16, 1982, Volume 47, Number 137, page 31004. However, no public comments were received in response to the notice.

PART 1701—[AMENDED]

Appendix A [Amended]

7 CFR Part 1701, Appendix A—REA Bulletins, is hereby amended by the issuance of a new REA Bulletin 345-86, REA Specification for Filled Buried Service Wire, PE-86.

List of Subjects in 7 CFR Part 1701

Loan programs—communications, Telecommunications, Telephone.

Dated: October 7, 1982.

Jack Van Mark,

Acting Administrator.

[FR Doc. 82-28630 Filed 10-18-82; 8:45 am]

BILLING CODE 3410-15-M

7 CFR Part 1701

Public Information; Appendix A—REA Bulletins, Specification for Telephone Sets, PE-41

AGENCY: Rural Electrification Administration, USDA.

ACTION: Final rule.

SUMMARY: REA hereby amends Appendix A—REA Bulletins by issuing a revised REA Bulletin 345-74, REA Specification for Improved 500 Type Telephone Sets, PE-41, and retitling the bulletin "Specification for Telephone Sets". This revision relaxes the transmission requirements, includes electronic telephone set requirements, and where applicable, adopts requirements from the Electronic Industries Association (EIA) Standard RS-470, "Telephone Instruments for Voiceband Applications with Loop Signaling", published in 1981. Appendix A—REA Bulletins is further amended by withdrawing REA Bulletin 345-64, REA Specification for Ringers, PE-47. The ringer requirements contained in PE-47 have been included in PE-41 thereby eliminating the need for a separate ringer specification. The resultant specification reduces the number of different tests required of telephone set manufacturers to show compliance with the same or similar requirements of different specifications or standards with similar objectives.

EFFECTIVE DATE: October 7, 1982.

FOR FURTHER INFORMATION CONTACT: Joseph M. Flanigan, Director, Telecommunications Engineering and Standards Division, Rural Electrification Administration, Room 1355, South Building, U.S. Department of Agriculture, Washington, D.C. 20250, telephone (202) 382-8663. The Final Impact Statement describing the options considered in developing this final rule and the impact of implementing each option is available on request from the above-named individual.

SUPPLEMENTARY INFORMATION: REA regulations are issued pursuant to the Rural Electrification Act as amended (7 U.S.C. 901 et seq.). This final action has been reviewed in accordance with Executive Order 12291, Federal Regulation, This action will not (1) have an annual effect on the economy of $100 million or more; (2) result in a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) result in significant adverse effects on competition, employment, investment or productivity and therefore has been determined to be "not major." This action does not fall within the scope of the regulatory Flexibility Act and is not subject to OMB Circular A-95 review. This program is listed in the Catalog of Federal Domestic Assistance as 10.851—Rural Telephone Loans and Loan Guarantees.

Background

In July 1978, REA revised REA Specification PE-41 to upgrade the requirements covering the physical characteristics and to include changes in transmission requirements of telephone sets. None of the manufacturers of standard telephone sets were able to comply with the transmission requirements of the July 1978 revision, therefore, a "File With" to the specification was issued in July 1979 which permitted marginal noncompliance with the transmission requirements to be considered as being acceptable by REA. Further test results have shown that manufacturers will not be able to meet the original transmission requirements of the July 1978 specification. In addition there exists a need in the telephone industry to consolidate the testing requirements of standards which have the same transmission objectives. The EIA standard (RS-470) has the same basic objectives as PE-41 and is accepted by the telephone industry and the Defense Department.

This revision produces an achievable specification which consolidates PE-41 requirements with applicable EIA Standard RS-470 requirements. The resultant specification reduces the number of different tests required of telephone set manufacturers to show compliance with the same or similar requirements of different specifications or standards with similar objectives.

A Notice of Proposed Rulemaking was published in the **Federal Register** on June 25, 1982, Volume 47, Number 123, page 27565. However, no public comments were received in response to the notice.

PART 1701—[AMENDED]

Appendix A [Amended]

7 CFR Part 1701, Appendix A—Bulletins, is hereby amended by the issuance of a revised REA Bulletin 345-74, REA Specification for Improved 500 Type Telephone Sets (PE-41), which has been retitled "Specification for Telephone Sets," and by withdrawing REA Bulletin 345-64, REA Specification for Ringers, PE-47.

List of Subjects in 7 CFR Part 1701

Loan programs—communications, Telecommunications, Telephone.

Dated: October 7, 1982.

Jack Van Mark,

Acting Administrator.

[FR Doc. 82-28633 Filed 10-18-82; 8:45 am]

BILLING CODE 3410-15-M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Parts 212 and 235

Detention and Parole of Inadmissible Aliens

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This final rule amends the Service's interim rule relating to detention and parole of inadmissible aliens which was published in the **Federal Register** on July 9, 1982, as an interim rule with request for comments. After considering public comments and the Service's experience with the implementation of the detention and parole procedures during the interim period, the Service is amending the interim rule to make revisions where appropriate. The balance of the interim rule, as previously promulgated, remains in effect.

EFFECTIVE DATE: November 18, 1982.

FOR FURTHER INFORMATION CONTACT:

For General Information: Stanley J. Kieszkiel, Acting Instructions Officer, Immigration and Naturalization Service, 425 Eye Street, N.W., Washington, DC 20536 Telephone: (202) 633-3048

For Specific Information: Maurice C. Inman, Jr., General Counsel Immigration and Naturalization Service, 425 Eye Street, N.W., Washington, DC 20536 Telephone: (202) 633-2895

SUPPLEMENTARY INFORMATION: An interim rule was published in the **Federal Register** on July 9, 1982, at 47 FR 30044, in compliance with an order of the District Court for the Southern District of Florida. The Service strongly disagreed with the order. Accordingly, the rule was published "under protest,"

and the Service sought judicial review of the order. The interim rule sought to codify existing Service practices.

Fifteen comments were received from the public including the office of the United Nations High Commissioner, members of the public, legal services groups, and the private bar. The views expressed ranged from criticism for permitting the parole of inadmissible aliens for any reason, to criticism for any detention of aliens seeking to enter the United States. The majority of the commenters took exception to publication of the interim rule for effect and for purported violations of the Administrative Procedure Act (APA) and the United Nations Protocol Relating to the Status of Refugees, (the "Protocol"), 19 U.S.T. 6223, T.I.A.S. No. 2322.

It is the position of the Service that ample justifications were adduced at the time the interim rule was published to warrant publication for effect, and is therefore in compliance with the APA. In addition, there is no conflict with the United Nation's Protocol because the Protocol is a non self-executing treaty which requires implementing legislation before becoming the law of the land. The Refugee Act of 1980 (Pub. L. 96-212; 8 U.S.C. 1157, *et seq.*) implements the Protocol. Nothing in that Act, which limits the number of refugees who may be admitted to the United States and requires the Attorney General to establish procedures under which aliens may apply for asylum, prohibits detention pending adjudication of status. Moreover, the Protocol itself does not prohibit detention of putative refugees pending a determination that an application is bona fide.

Two commenters offered identical criticisms, suggesting that § 235.3(b), as drafted, is too broad and that § 212.5(a) unintentionally creates a uniform parole policy both for aliens without documents or with false documents, and aliens with documents. Upon reviewing these comments, the Service has concluded that these sections as drafted may be read so as to cause the detention of some documented aliens now routinely paroled. Moreover, it appears that the commenters are correct in their assessment that § 212.5(a) unintentionally creates a uniform rule where it was intended that two different standards be applied.

After considering the comments received, the Service is amending paragraph (a) of § 212.5 to make it clear that the criteria set out thereunder apply to those aliens who have been or are in detention and who are now being considered for parole out of detention.

In paragraph (b) of § 235.3, the overly broad phrase "otherwise invalid" is removed from the rule. The rule now provides that an alien who arrives with documentation which appears *on its face* to be false, altered, or *to relate to another person* shall be detained under section 235(b) of the Act.

Paragraph (c) of § 235.3 also is amended to clarify the criteria for detention or parole of those aliens who arrive at a designated port of entry with apparently proper documentation but who, nevertheless, are inadmissible and are likely to abscond, or who pose a security risk.

The rule, as published on July 9, 1982 at 47 FR 30044 and the amendments made by this rule, formally promulgate the Service's detention and parole policy. Except for the amendments made by this rule, the balance of the interim rule, as previously promulgated, remains in effect.

In accordance with 5 U.S.C. 605(b), the Commissioner of Immigration and Naturalization certifies that this rule will not have significant economic impact on a substantial number of small entities.

This is not a major rule within the meaning of section 1(b) of E.O. 12291.

List of Subjects

8 CFR Part 212

Administrative practice and procedure, Aliens, Detention, Parole.

8 CFR Part 235

Aliens, Detention, Inspections, Port of entry, Parole.

In view of the foregoing, Title 8 of the Code of Federal Regulations is amended as follows:

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

1. In § 212.5 The introductory text of paragraph (a) is revised to read as follows:

§ 212.5 Parole of aliens into the United States.

(a) In determining whether or not aliens who have been or are detained in accordance with § 235.3 (b) or (c) will be paroled out of detention, the district director should consider the following:

* * * * *

(Sec. 103, 212 of the Immigration and Nationality Act, as amended; 8 U.S.C. 1103, 1182)

PART 235—INSPECTION OF PERSONS APPLYING FOR ADMISSION

2. In § 235.3, paragraphs (b) and (c) are revised to read as follows:

§ 235.3 Detention and deferred inspection.

(a) * * *

(b) *Aliens with no documentation or false documentation.* Any alien who appears to the inspecting officer to be inadmissible, and who arrives without documents (except an alien for whom documentary requirements are waived under §211.1(b)(3) or § 212.1 of this chapter) or who arrives with documentation which appears on its face to be false, altered, or to relate to another person, or who arrives at a place other than a designated port of entry, shall be detained in accordance with section 235(b) of the Act. Parole of such aliens shall only be considered in accordance with § 212.5(a) of this chapter.

(c) *Aliens with documents.* Any alien who appears to the inspecting officer to be inadmissible, but who does not fall within paragraph (b), may be detained, paroled, or paroled for deferred inspection by the inspecting officer. In determining whether or not an alien shall be detained, paroled or paroled for deferred inspection, the inspecting officer shall consider the likelihood that the alien will abscond or pose a security risk.

* * * * *

(Secs. 103, 233, 235 of the Immigration and Nationality Act, as amended; 8 U.S.C. 1103, 1223, 1225)

§§ 212.5 and 235.3 [Amended]

3. Section 212.5 paragraphs (a)(1) through (3) and (b) through (e) and § 235.3 paragraphs (a) and (d) published as interim rules on July 9, 1982 (47 FR 30044) are hereby confirmed as final rules.

Dated: October 1, 1982.

Alan C. Nelson,

Commissioner of Immigration and Naturalization.

[FR Doc. 82-28563 Filed 10-18-82; 8:45 am]

BILLING CODE 4410-01-M

CIVIL AERONAUTICS BOARD

14 CFR Part 213

[Erratum to Regulation ER-1107]

Terms, Conditions, and Limitations of Foreign Air Carrier Permits; Correction

AGENCY: Civil Aeronautics Board.

ACTION: Erratum to final rule.

SUMMARY: This erratum corrects a word in the Board's regulation concerning the period for effectiveness of orders requiring foreign air carriers to discontinue operation of existing schedules.

FOR FURTHER INFORMATION CONTACT: Joseph Di Bella, Civil Aeronautics Board, Bureau of International Aviation, Legal Division, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428. (202) 673-5035.

Erratum

In our final Rule ER-1107, 44 FR 11205, we inadvertently used the word "issuance" in the last sentence of our rule. To avoid ambiguity, we should have used "adoption." The Rule should read as follows:

§ 213.3 Filing and approval of schedules.

* * * * *

(d) The carrier may continue to operate existing schedules, and may inaugurate operations under proposed schedules 30 days after the filing of such schedules with the Board, unless the Board with or without hearing issues an order, subject to stay or disapproval by the President of the United States within 10 days after adoption, notifying the carrier that such operations, or any part of them, may be contrary to applicable law or may adversely affect the public interest. If the notification pertains to a proposed schedule, service under such schedule shall not be inaugurated; if the notification pertains to existing scheduels, service under such schedules shall be discontinued on the date specified in the Board's order. Such date shall be not less than ten days after adoption of the Board's order unless affirmative Presidential approval is obtained at an earlier date.

Dated: October 4, 1982.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 82-27808 Filed 10-18-82; 8:45 am]

BILLING CODE 6320-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 81F-0209]

Indirect Food Additives; Paper and Paperboard Components

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a polymer derived from *N*-vinyl pyrrolidone and copolymers derived from the mixed alkyl (C_{12}-C_{15}, C_{16}, C_{18}, C_{20}, and C_{22}) methacrylate esters, butyl methacrylate, isobutyl methacrylate, and methyl methacrylate as a component of defoaming agents used in the manufacture of paper and paperboard intended for contact with food. This action is based on a petition filed by Rohm and Haas Co.

DATES: Effective October 19, 1982, objections by November 18, 1982.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 18, 1981 (46 FR 41863), FDA announced that a food additive petition (FAP OB3527) had been filed by Rohm and Haas Co., Independence Mall West, Philadelphia, PA 19105, proposing to amend Part 176 (21 CFR Part 176) to provide for the safe use of a polymer derived from *N*-vinyl pyrrolidone combined during its polymerization with copolymers derived from the mixed alkyl (C_{12}-C_{15}, C_{16}, C_{18}, C_{20}, and C_{22}) methacrylate esters, butyl methacrylate, isobutyl methacrylate, and methyl methacrylate. Also, the petition proposed that the combined polymer contain no more than 5 weight percent of polymer units derived from *N*-vinyl pyrrolidone and be used as a component of defoaming agents in the manufacture of paper and paperboard intended for food-contact use.

FDA has evaluated data in the petition and other relevant material, and concludes that the proposed food additive use is safe and that § 176.210 (21 CFR 176.210) should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h)(2), the agency will remove from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging, Paper and paperboard.

Therefore under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drug (21 CFR 5.10), Part 176 is amended in § 176.210(d)(3) by revising the entry for "Polymer derived from *N*-vinyl pyrrolidone * * *" to read as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

§ 176.210 Defoaming agents used in the manufacture of paper and paperboard.

* * * * *

(d) * * *

(3) * * *

Polymer derived from *N*-vinyl pyrrolidone and copolymers derived from the mixed alkyl (C_{12}-C_{15}, C_{16}, C_{18}, C_{20}, and C_{22}) methacrylate esters butyl methacrylate (CAS Reg. No. 97-88-1), isobutyl methacrylate (CAS Reg. No. 97-86-9) and methyl methacrylate (CAS Reg. No. 80-62-6); the combined polymer contains no more than 5 weight percent of polymer units derived from *N*-vinyl pyrrolidone and is present at a level not to exceed 7 parts per million by weight of the finished dry paper and paperboard fibers.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before November 18, 1982 submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall

include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective October 19, 1982.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: October 13, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-28712 Filed 10-18-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid Sodium, Roxarsone, and Bacitracin Zinc

AGENCY: Food an Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Hoffman-La Roche, Inc., providing for safe and effective use of lasalocid sodium combined with roxarsone and bacitracin zinc in broiler chicken feeds for prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* as an aid in reduction of lesions due to *E. tenella;* and for increased rate of weight gain or improved feed efficiency.

EFFECTIVE DATE: October 19, 1982.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Bureau of Veterinary Medicine (HFV-128), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, NJ 07110, filed NADA 126-052 providing for safe and effective use of lasalocid sodium combined with roxarsone and bacitracin zinc in broiler chicken feeds for prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* as an aid in reduction of lesions due to *E. tenella;* and for increased rate of weight gain or improved feed efficiency. The NADA is approved and the regulations are amended to reflect this approval.

This approval is based in part on Hoffman-La Roche's approved NADA 96-298 which demonstrates the safety and effectiveness of lasalocid sodium when used in finished chicken feed for prevention of coccidiosis. Another approved NADA (102-485) further demonstrates that addition of roxarsone at a concentration of 45.4 grams per ton to feeds containing lasalocid sodium (68 to 113 grams per ton) aids in reducing lesions due to *E. tenella.* NADA 126-052 demonstrates that addition of bacitracin zinc at either 10 or 30 grams per ton to the combination of lasalocid sodium and roxarsone, at the combinations mentioned, does not interfere with the safety or effectiveness of the latter two drugs. In addition, NADA 126-052 demonstrates animal safety and effectiveness of bacitracin zinc, in the three-way combination, at 10 grams per ton for increased rate of weight gain and at 30 grams per ton for improved feed efficiency. Drug residue depletion studies demonstrate that simultaneous presence of the three drugs in tissue samples does not interfere with their individual assays. The residue depletion studies also reveal that after the 5-day withdrawal period: (1) Roxarsone residues are well below tolerance levels specified in 21 CFR 556.60 (i.e., 0.5 part per million in uncooked muscle tissue and 2 parts per million in uncooked, edible byproducts), (2) lasalocid residues are below the tolerance specified in 21 CFR 556.37 (0.05 part per million for total residues in edible tissues), and (3) no microbiologically active residues of bacitracin zinc are detected at zero withdrawal using a method of assay with a detection limit to 0.5 part per million.

Approval of this NADA poses no increased human risk from exposure to residues of the animal drugs, nor does it change the conditions of the drugs' safe use in the target animal species. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), this NADA has been treated as a Category II supplemental NADA and does not require reevaluation of the human safety data for lasalocid, roxarsone, or bacitracin zinc.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(ii) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

List of Subjects in 21 CFR Part 558

Animal drugs; Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. In § 558.78 by adding new paragraph (e)(3)(viii), to read as follows:

§ 558.78 Bacitracin zinc.

* * * * *

(e) * * *

(3) * * *

(viii) Lasalocid sodium and roxarsone as in § 558.311.

2. In § 558.311 by adding a fourth 3-way combination consisting of lasalocid sodium, roxarsone, and bacitracin zinc to the table in paragraph (e)(2), to read as follows:

§ 558.311 Lasalocid sodium.

* * * * *

(e) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* * *	*	*	*	*
(2) * * *	Roxarsone 45.4 plus bacitracin 10 or 30.	For prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati* and *E. maxima;* as an aid in the reduction of lesions due to *E. tenella;* and for increased rate of weight gain (10 grams per ton) or improved feed efficiency (30 grams per ton).	For broiler chickens only; feed continuously as sole ration; withdraw 5 days before slaughter; roxarsone provided by Nos. 017210 and 011801 in § 510.600(c) of this chapter, bacitracin zinc provided by No. 012769.	000004
* * *	*	*	*	*

* * * * *

3. In § 558.530 by adding new paragraph (f)(4)(iv), to read as follows:

§ 558.530 Roxarsone.

* * * * *

(f) * * *

(4) * * *

(iv) Lasalocid and bacitracin zinc as in § 558.311.

Effective date. October 19, 1982.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: October 6, 1982.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 82-28500 Filed 10-18-82; 8:45 am]

BILLING CODE 4160-04-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 7836]

Income Tax; Taxable Years Beginning After December 31, 1953; State and Local Government Deferred Compensation Plans

Correction

In FR Doc. 82-26521 beginning on page 42335 in the issue of Monday, September 27, 1982, make the following correction:

On page 42341, in § 1.457-3(b)(2), the line that appears second from the top of the middle column now reading, "described in section 402," should have read "described in section 403,".

BILLING CODE: 1505-01-M

VETERANS ADMINISTRATION

38 CFR Part 36

Decrease in Maximum Permissible Interest Rates on Guaranteed Mobile Home Loans, Home and Condominium Loans, and Home Improvement Loans

AGENCY: Veterans Administration.

ACTION: Final regulations.

SUMMARY: The VA (Veterans Administration) is decreasing the maximum interest rates on guaranteed mobile home unit loans, lot loans, and combination mobile home unit and lot loans. In addition, the maximum interest rates applicable to home and condominium loans, and to home improvement and energy conservation loans are also decreased. These decreases in interest rates are possible because of recent improvements in the availability of funds in various credit markets. The decrease in the interest rates will allow eligible veterans to obtain loans at a lower monthly cost.

EFFECTIVE DATE: October 13, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. George D. Moerman, Loan Guaranty Service (264), Department of Veterans Benefits, Veterans Administration, 810 Vermont Avenue, N.W., Washington, D.C. 20420 (202-389-3042).

SUPPLEMENTARY INFORMATION: The Administrator is required by section 1819(f), title 38, United States Code, to establish maximum interest rates for mobile home loans guaranteed by the VA as he finds the mobile home loan capital markets demand. Recent market indicators—including the prime rate, the general decrease in interest rates charged on conventional mobile home loans, and the decrease of other short-term and long-term interest rates—have shown that the mobile home capital markets have improved. It is now possible to decrease the interest rates on mobile home unit loans, lot loans, and combination mobile home unit and lot loans while still assuring an adequate supply of funds from lenders and investors to make these types of VA loans.

The Administrator is also required by section 1803(c), title 38, United States Code, to establish maximum interest rates for home and condominium loans and for loans for home improvement purposes. Market indicators similarly favor reductions in the maximum interest rates for these types of loans. These lower interest rates should assist more veterans in the purchase of homes and condominiums or to obtain improvement loans because of the decrease in the monthly loan payments for principal and interest.

The Administrator's statutory authority to establish interest rates has been delegated by 38 CFR 2.6(b)(3) to the Chief Benefits Director, Deputy Chief Benefits Director, or person authorized to act for them.

Regulatory Flexibility Act/Executive Order 12291

For the reasons discussed in the May 7, 1981 **Federal Register**, (46 FR 25443), it has previously been determined that final regulations of this type which change the maximum interest rates for loans guaranteed, insured, or made pursuant to chapter 37 of title 38, United States Code, are not subject to the provisions of the Regulatory Flexibility Act, 5 U.S.C. 601-612.

These regulatory amendments have also been reviewed under the provisions of Executive Order 12291. The VA finds that they are not "major rules" as defined in that Order. The existing process of informal consultation among representatives within the Executive Office of the President, OMB, the VA and the Department of Housing and Urban Development has been determined to be adequate to satisfy the intent of this Executive Order for this category of regulations. This alternative consultation process permits timely rate adjustments with minimal risk of premature disclosure. In summary, this consultation process will fulfill the intent of the Executive Order while still permitting compliance with statutory responsibilities for timely rate adjustments and a stable flow of mortgage credit at rates consistent with the market.

These final regulations come within exceptions to the general VA policy of prior publication of proposed rules as contained in 38 CFR 1.12. The publication of notice of a regulatory change in the VA maximum interest rates for VA guaranteed, insured or direct loans would deny veterans the benefit of lower interest rates pending the final rule publication date which would necessarily be more than 30 days after publication in proposed form. Accordingly, it has been determined that publication of proposed regulations prior to publication of final regulations is impracticable, unnecessary, and contrary to the public interest.

(Catalog of Federal Domestic Assistance Program numbers, 64.113, 64.114, and 64.119)

These regulations are adopted under authority granted to the Administrator by sections 210(c), 1803(c)(1), 1811(d)(1) and 1819 (f) and (g) of title 38, United States Code and delegated to the undersigned by 38 CFR 2.6(b)(3). The regulations are clearly within that statutory authority and are consistent with Congressional intent.

These decreases are accomplished by amending sections 36.4212(a) (1), (2), and (3), and 36.4311(a), (b) and 36.4503(a), title 38, Code of Federal Regulations.

List of Subjects in 38 CFR Part 36

Condominiums, Handicapped, Housing, Loan programs—housing and community development, Mobile Homes, Veterans.

Approved: October 12, 1982.

By Direction of the Administrator:

John W. Hagan, Jr.,

Deputy Chief Benefits Director.

PART 36—LOAN GUARANTY

The Veterans Administration is amending 38 CFR Part 36 as follows:

1. In § 36.4212, paragraph (a) is revised as follows:

§ 36.4212 Interest rates and late charges.

(a) The interest rate charged the borrower on a loan guaranteed or insured pursuant to 38 U.S.C. 1819 may not exceed the following maxima except on loans guaranteed or insured pursuant to guaranty or insurance commitments issued by the Veterans Administration prior to the respective effective date: (38 U.S.C. 1819(f))

(1) Effective October 13, 1982, 14½ percent simple interest per annum for a loan which finances the purchase of a mobile home unit only.

(2) Effective October 13, 1982, 14 percent simple interest per annum for a loan which finances the purchase of a lot only and the cost of necessary site preparation, if any.

(3) Effective October 13, 1982, 14 percent simple interest per annum for a loan which will finance the simultaneous acquisition of a mobile home and a lot and/or the site preparation necessary to make a lot acceptable as the site for the mobile home.

* * * * *

2. In § 36.4311, paragraphs (a) and (b) are revised as follows:

§ 36.4311 Interest rates.

(a) Excepting loans guaranteed or insured pursuant to guaranty or insurance commitments issued by the Veterans Administration which specify an interest rate in excess of 12½ per centum per annum, effective October 13, 1982, the interest rate on any home or condominium loan guaranteed or insured wholly or in part on or after such date may not exceed 12½ per centum per annum on the unpaid principal balance. (38 U.S.C. 1803(c)(1))

(b) Effective October 13, 1982, the interest rate on any loan solely for energy conservation improvements or other alterations, improvements or repairs which is guaranteed or insured wholly or in part on or after such date may not exceed 13 per centum per annum on the unpaid principal balance. (38 U.S.C. 1803(c)(1))

* * * * *

3. In § 36.4503, paragraph (a) is revised as follows:

§ 36.4503 Amount and amortization.

(a) The original principal amount of any loan made on or after October 1, 1980, shall not exceed an amount which bears the same ratio to $33,000 as the amount of the guaranty to which the veteran is entitled under 38 U.S.C. 1810 at the time the loan is made bears to $27,500. This limitation shall not preclude the making of advances, otherwise proper, subsequent to the making of the loan pursuant to the provisions of § 36.4511. Except as to home improvement loans, loans made by the Veterans Administration shall bear interest at the rate of 12½ percent per annum. Loans solely for the purpose of energy conservation improvements or other alterations, improvements, or repairs shall bear interest at the rate of 13 percent per annum. (38 U.S.C. 1811 (d)(1) and (2)(A))

* * * * *

[FR Doc. 82-28654 Filed 10-18-82; 8:45 am]

BILLING CODE 8320-01-M

POSTAL SERVICE

39 CFR Part 233

Inspection Service Authority; Conforming Changes

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The purpose of this final rule is to conform the text of Postal Inspection Service regulations on wanted circulars and rewards published in the **Federal Register** with the same regulations published in the Postal Service's Administrative Support Manual. When the Manual was published, editorial and various other changes and additions were made in the text of some of the regulations. This rule brings the two texts in this area into agreement.

EFFECTIVE DATE: November 18, 1982.

FOR FURTHER INFORMATION CONTACT: C.P. Nelson, (202) 245-5449.

SUPPLEMENTARY INFORMATION: To carry out the purpose described above, paragraphs (a) and (b) of § 233.2 of title 39 CFR are revised to conform with comparable provisions of the Administrative Support Manual. For example, editorial and clarifying changes are made in paragraph (a). In paragraph (b)(1)(iv) specific reference is made to Postal Service property. Paragraph (b)(1)(v) is renumbered as (b)(1)(vii). New paragraphs (b)(1)(v), dealing with obstructing or retarding the passage of mail, and (b)(1)(vi), dealing with altering, counterfeiting, forging and unlawful uttering or passing of postal money orders, are added to the postal offenses for which rewards for information and services are authorized.

Paragraph (b)(2) is amended in minor, editorial respects. The text of Notice 96, which follows paragraph (b)(2), is not changed.

List of Subjects in 39 CFR Part 233

Law enforcement, Crime, Postal Service.

Accordingly, 39 CFR is amended as follows:

PART 233—INSPECTION SERVICE AUTHORITY

In § 233.2 paragraphs (a) and (b) are revised to read as follows:

§ 233.2 Circulars and rewards.

(a) *Wanted circulars.* The Inspection Service issues wanted circulars to assist in locating and arresting fugitive postal offenders. Post these circulars in the most conspicuous place in the post office lobby and in other prominent places. Post near the Notice of Reward sign. Telephone or telegraph immediately to the postal inspector in charge any information on the possible location of the person wanted. Remove and destroy circulars immediately when notified of their cancellation or when the circular is not listed in the periodic Postal Bulletin notices of current wanted circulars.

(b) *Rewards.* (1) Rewards will be paid in the amounts and under the conditions stated in Notice 96, *Notice of Reward,* for the arrest and conviction of persons for the following postal offenses:

(i) Robbery or attempted robbery.

(ii) Mailing bombs, explosives, poison, or controlled substances.

(iii) Post office burglary.

(iv) Stealing or unlawful possession of mail or money or property of the United States under the costody or control of the Postal Service, including property of the Postal Service.

(v) Obstructing or retarding the passage of mail.

(vi) Altering, counterfeiting, forging, and unlawful uttering or passing of postal money orders.

(vii) Assault on postal employee.

(2) The postmaster or a designated employee should personally present reward notices to representatives of firms transporting mail, security or detective units of firms, police officers, sheriffs and their deputies, if practicable, and encourage their cooperation in protecting mail and Postal Service property. (See 273.14 of the Administrative Support Manual).

* * * * *

(39 U.S.C. 401(2), 404(a)(8), 410(b)(2))

W. Allen Sanders,

Associate General Counsel, Office of General Law and Administration.

[FR Doc. 82-28711 Filed 10-18-82; 8:45 am]

BILLING CODE 7710-12-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

41 CFR Ch. 18, Parts 1 and 3

[NASA Procurement Notice 82-7]

Regulatory Coverage Prescribing Additional Documentation Required to Support Exercise of Options for Extensions to Service Contracts

Dated: June 11, 1982.

AGENCY: National Aeronautics and Space Administration.

ACTION: Rule Related Notice.

SUMMARY: This Notice 82-7 prescribes additional documentation requirements prior to the exercise of an option for extensions to service contracts when the proposed extension period was included in the Source Selection Official's (SSO) selection statement and the applicable approved procurement plan to firm up the contractual arrangements.

EFFECTIVE DATE: October 19, 1982.

FOR FURTHER INFORMATION CONTACT: James H. Wilson, Policy Division (Code HP-1), Office of Procurement, NASA Headquarters, Washington, DC 20546, Telephone: 202-755-2237.

SUPPLEMENTARY INFORMATION: Where the proposed extension requires negotiation to firm up the contractual arrangements, the option provision is considered merely an agreement to agree. The following documentation is required to be included in the contract file in such cases:

a. A new Determinations and Findings (D&F) authorizing negotiation.

b. A new method of contracting D&F.

c. A "Justification for Noncompetitive Procurement" (JNCP) is *not* required to negotiate with the incumbent contractor for the proposed extension period, provided the conditions in the "Summary" of this Notice 82-7 are satisfied. In such circumstance, a "Justification for Source Selection" signed by the procurement officer which clearly and convincingly demonstrates the advantages to the Government in contracting with the incumbent contractor for the proposed extension period must be prepared in lieu of the JNCP.

d. If the proposed extension can be effected without negotiation by the exercise of a firm priced option and the initial D&F authorizing negotiation included such option, no new D&F is required. The requirements of NASA Procurement Regulation 1.1505 must be adhered to by the contracting officer.

e. See NASA Procurement Regulation 1.1500, 3.200, 3.405, 3.802-3 and 3.852.

List of Subjects in 41 CFR Ch. 18, Parts 1 and 3.

Government procurement.

(The provisions of this document are issued under 42 U.S.C. 2473(c)(1).)

L. E. Hopkins,

Deputy Assistant Administrator for Procurement.

[FR Doc. 82-28575 Filed 10-18-82; 8:45 am]

BILLING CODE 7510-01-M

41 CFR Ch. 18, Part 3 and Appendix J

[NASA Procurement Notice 82-5]

Regulatory Coverage for the Increased Threshold for Approval of Research and Development Determinations and Findings (D&F's)

Dated: April 23, 1982.

AGENCY: National Aeronautics and Space Administration.

ACTION: Rule Related Notice.

SUMMARY: On December 1, 1981, the President signed the FY 1982 Department of Defense Authorization Act (Pub. L. 97-86). That law, among other things, raised the threshold under 10 U.S.C. 2311 at which Research and Development Determinations must be approved at the Administrator's level from $100,000 to $5 million. The purpose of this NASA Procurement Notice 82-5 is to implement that change in the law, since NASA is one of the agencies affected thereby.

EFFECTIVE DATE: October 19, 1982.

FOR FURTHER INFORMATION CONTACT: James H. Wilson, Policy Division (Code HP-1), Office of Procurement, NASA Headquarters, Washington, DC 20546, Telephone: 202-755-2237.

SUPPLEMENTARY INFORMATION: Pending a formal change to the NASA Procurement Regulation, paragraphs 3.211, 3.302(i), 3.303(a)(iv), 3.306, J.205-20 (Notes), J.502 (Notes), and J.502-50, the following levels of approval and ranges of dollar amounts are established for executing D&F's pursuant to 10 U.S.C. 2304(a)(11) (NASA PR 3.211).

a. Individual D&F's (3.302(i) and 3.303(a)(iv)):

Over $5,000,000—Administrator or Deputy Administrator;

$5,000,000 or less—Assistant Administrator for Procurement;

$500,000 or less—Procurement Officer;

$100,000 or less—Contracting Officer.

b. Class D&F's (3.303(b)). When it is estimated that a class D&F will consist of two or more contracts, each of which is estimated to exceed $5,000,000 in value, the class D&F shall be submitted to the Assistant Administrator for Procurement (Code HS-1) for the signature of the Administrator or Deputy Administrator and may only be executed by one of those two officials. When it is estimated that a class D&F will consist of two or more contracts, each of which is estimated to exceed $500,000, but not exceeding $5,000,000, in value, the class D&F shall be submitted to the Assistant Administrator for Procurement (Code HS-1) for execution. When it is estimated that a class Determination and Findings will consist of two or more contracts, each of which is estimated to be $500,000 or less in value, the class Determination and Findings will be signed by the Procurement Officer.

List of Subjects in 41 CFR Ch. 18, Part 3

Government procurement.

(The provisions of this document are issued under 42 U.S.C. 2473(c)(1).)

L. E. Hopkins,

Deputy Assistant Administrator for Procurement.

[FR Doc. 82-28573 Filed 10-18-82; 8:45 am]

BILLING CODE 7510-01-M

41 CFR Ch. 18, Parts 1, 3, 5, 7, 8, 15, 16, Appendix E and Supplement 2

[Procurement Regulation Directive 82-2 (dated May 28, 1982)]

Procurement Regulations; Miscellaneous Amendments

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: This document amends the NASA Procurement Regulation (41 CFR Ch. 18). It reflects amendments contained in Procurement Regulation Directive 82-2 concerning the following areas:

1. Interdepartmental Procurement
2. Use of GSA Supply Sources by Prime Contractors
3. Progress Payment Rates
4. Cost Accounting Standards
5. Prohibition of Recovery of Lobbying Costs
6. Procurement Forms
7. File Maintenance, Closeout, and Disposition

EFFECTIVE DATE: October 19, 1982.

FOR FURTHER INFORMATION CONTACT: James H. Wilson, Policy Division (Code HP-1), Office of Procurement, NASA Headquarters, Washington, DC 20546, Telephone: 202-755-2237.

SUPPLEMENTARY INFORMATION: 1. (a) In Part 5, §§ 5.704, 5.704-1 and 5.704-2 are revised to update references to the Department of Energy (DOE) and DOE forms.

(b) In Part 5, §§ 5.752, 5.752-3, 5.752-8, 5.752-9 and 5.752-10 are revised, as necessary, to correct titles of offices and forms, correct NASA Codes and to make editorial changes.

2. In Part 5, Subpart 9 is revised to ensure NASA installation oversight and control of Government furnished material by setting out more specifically, installation and contracting officer responsibilities and procedures.

3. In Part 7 and Appendix E, uniform standard progress payment rates are increased to 90 percent for other than small business concerns; and 95 percent for small business concerns. The frequency of progress payments is changed from biweekly to monthly. The clauses at § 7.104-35 (a) and (b) and Appendix E, Subpart 5 are revised to reflect the new progress payment rate and frequency of payment policies.

4. In order to implement recommendations from the Cost Accounting Standards Board, and for the purpose of maintaining closer alignment with the Defense Acquisition Regulation, the following revisions to the NASA Procurement Regulation are made:

(a) Cost Accounting Standard 416, Accounting for Costs. NASA Procurement Regulation 15.205-16, Insurance and Indemnification, is revised to incorporate the provisions of Cost Accounting Standard 416. In addition, NPR 15.205-16(a)(2)(iii) is revised to substitute the word "Property" for "casualty." This change will clarify the intent to refer to insurance which the contractor has against damage to its own property, and not insurance against liability for damage to property of third parties.

(b) Accounting for Termination Costs. In response to a recommendation from the Cost Accounting Standards Board, NPR 15.205-42 is revised to require the establishment of separate cost accounts to accommodate and identify significant settlement expenses. Reference to the revised cost principle is added to 8.203 and 8.205.

5. In Part 15, a new cost principle, § 15.205-41 *Lobbying Costs,* is issued to prohibit charging lobbying costs to NASA contracts. Further, Part 3, Subpart 7—*Negotiated Overhead Rates,* is amended by adding a new paragraph 3.709, *Lobbying Costs.*

6. In Part 16, § 16.001 is revised to update dates and titles of various NASA, Standard and miscellaneous forms and to delete obsolete forms.

7. In Supplement 2, S2.102-1 (ix) is revised to correct the title of DD Form 254. Paragraph S2.301-2 is revised to update the definition of a "closed" contract.

List of Subjects in 41 CFR Ch. 18, Parts 3, 5, 7, 8, 15, 16, Appendix E and Supplement 2

Government procurement.

(The provisions of this document are issued under 42 U.S.C. 2473(c)(1))

L. E. Hopkins,

Deputy Assistant Administrator for Procurement.

PART 1—GENERAL PROVISIONS

§ 1.356 [Amended]

1. In Part 1, § 1.356(a) is amended by removing the "C" following "5101.12".

§ 1.805-3 [Amended]

2. In Part 1, § 1.805-3(a) is amended by increasing the figure "$5,000" to read "$10,000".

PART 3—PROCUREMENT BY NEGOTIATION

3. In Part 3, Table of Contents is amended by adding "3.709 Lobbying Costs . . . . . 3-7:6" at the end of "Subpart 7—Negotiated Overhead Rates."

4. In Part 3, Subpart 7 is amended by adding § 3.709 to read as follows:

§ 3.709 Lobbying Costs.

The costs of lobbying for the procurement of specific supplies or services by the Federal Government are unallowable under 15.205-51, Lobbying Costs. Legislative liaison costs, as defined in the cost principle, are allowable costs. Where the contractor's accounting systems are not capable of differentiating unallowable lobbying costs from otherwise allowable costs, the contractor may be required to certify in writing that its overhead rate proposal does not include any unallowable lobbying costs. The certification shall be executed by the contractor, if an individual. When the contractor is not an individual, the certification shall be executed by a senior company official in charge at the contractor's plant or location involved, or by an officer or general partner of the contractor having overall responsibility for the conduct of the contractor's affairs.

PART 5—INTERDEPARTMENTAL PROCUREMENT

5. In Part 5, in the Table of Contents, the page numbers for §§ 5.704 through 5.752-9 and §§ 5.903 through 5.910 are revised to read as follows:

* * * * *

5.704	Procurement From Energy Research and Development Administration.	5—7:2
5.704-1	General	5—7:2
5.704-2	Procurement of Radioisotopes	5—7:2
5.705	Procurement of Materials From Surplus Strategic and Critical Materials Stockpile.	5—7:3
5.705-1	General	5—7:3
5.705-2	Procurement of Listed Materials	5—7:3
5.750	Procurement of Liquid Hydrogen	5—7:3
5.751	Procurement of Potentially Hazardous Items.	5—7:3
5.751-1	General	5—7:3
5.751-2	Policy	5—7:3
5.752	Procuring Materials from the Department of the Air Force Missile Procurement Fund.	5—7:4
5.752-1	Requests for Procurement	5—7:4
5.752-2	Delivery Requests	5—7:4
5.752-3	Receiving Procedures	5—7:4A
5.752-4	Billing	5—7:4B
5.752-5	Reporting Responsibility	5—7:4B
5.752-6	Report Content	5—7:4B
5.752-7	Basis for Developing Materials Requirements.	5—7:4C
5.752-8	Solicitation of Data from Contractors	5—7:4C
5.752-9	Availability of Forms	5—7:4C
	* * * * *	
5.903	Orders under Federal Supply Schedule Contracts, GSA Nonmandatory ADTS/ADP Schedule, and GSA ADP Requirements Contracts.	5—9:3
5.904	Orders for GSA Stock	5—9:3
5.905	Furnishing Information to Contractors	5—9:3
5.906	Format for Authorization for Contractors to Use GSA Suply Sources.	5—9:3
5.907	Payment for GSA Shipments	5—9:5

5.908	Title	5—9:5
5.909	Contract Clause	5—9:5
5.910	Acquisition of Filing Cabinets by Contractors.	5—9:5

* * * * *

6. In Part 5, § 5.704 is revised to read as follows:

§ 5.704 Procurement from the Department of Energy.

§ 5.704-1 General.

This paragraph covers the procurement of material and supplies from the Department of Energy (DOE).

§ 5.704-2 Procurement of Radioisotopes.

(a) DOE Form EV 375, *"U.S. Department of Energy Isotope Order Blank,"* and NRC Form 313, *"U.S. Nuclear Regulatory Commission Application for Byproduct Material License,"* shall be used for the procurement of radioisotopes as stated on the back of DOE Form EV 375. No other type of order blank, purchase order, or contract shall be used in lieu of these forms.

(b) In the procurement of radioisotopes, NRC Form 313 shall be filed with the Chief, Radioisotopes Licensing Branch, Division of Fuel Cycle and Material Safety United States Nuclear Regulatory Commission, Washington, D.C. 20555. If the application meets all regulatory requirements and applicable standards, NRC Form 374, *"U.S. Nuclear Regulatory Commission Materials License,"* will be issued to the applicant by the Radioisotopes Licensing Branch, Nuclear Regulatory Commission. After receipt of the NRC Form 374, a complete DOE Form EV 375 (in duplicate, if the procurement office desires to receive an accepted copy of the form back from the supplier), the license (NRC Form 374), and a Standard Form 1103, *"U.S. Government Bill of Lading,"* shall be sent to the appropriate DOE laboratory. If a bill of lading is not furnished, shipment shall be made collect on a commercial bill of lading, to be converted at destination.

(c) The *"Terms and Conditions"* on the reverse side of the DOE Form EV 375 shall control all requisitions for radioisotopes purchased by NASA from the Department of Energy Laboratories.

(d) NRC Form 313, *"U.S. Nuclear Regulatory Commission for Byproduct Material License,"* and DOE Form EV 375, *"U.S. Department of Energy Isotope Order Blank,"* shall be requisitioned directly from: *United States Nuclear Regulatory Commission, Attn: Radioisotopes Licensing Branch, Division of Fuel Cycle and Material Safety, Washington, DC 20555.*

7. In Part 5, § 5.752 the title of the paragraph and the second sentence are revised to read as follows:

§ 5.752 Procuring materials from the Department of the Air Force Fuels Division-AF Stock Fund. * * *

Propellants, *i.e.*, oxidizers, fuels, pressurants, and related materials are financed under a single Air Force appropriation designated the "Missile Procurement Fund" (MPF). * * *

§ 572-5 [Amended]

8. In Part 5, §§ 572-5 and 572-5(a) are amended by changing the "AF Form 558" number, that appears in the last sentence of the introductory text to read "AF Form 858" and in the first sentence of paragraph (a) change the first sentence to read as follows:

(a) The reports shall be forwarded so as to reach the NASA Headquarters Space Shuttle Ground Systems to Flight Test Office (Code MGL-9) no later than June 1 and December 1.

* * * * *

9. In Part 5, §§ 5.752-8, 5.752-9 and 5.752-10 are revised to read as follows:

§ 5.752-8 Solicitation of data from contractors.

Estimated requirements and other pertinent data required from contractors shall be obtained on Air Force Form 858, "Forecast of Propellant Requirements," and Bureau of the Budget Approval Number 21-RO225 shall be cited.

§ 5.752-9 Availability of forms.

Supplies of Air Force Forms 857 and 858 may be obtained from Headquarters, San Antonio Air Logistics Center, Kelly Air Force Base, Texas, Attention: SFS.

§5.752-10 NASA headquarters review.

The NASA Headquarters Space Shuttle Systems Operation Office (Code MGL-9) shall be responsible for consolidating reports from installations and Headquarters Program Offices, and for coordinating the review of all data with the Headquarters Program Offices. The data will then be used as the basis for NASA requirements reports to various Government agencies for planning and supply support.

10. In Part 5, §§ 5.900 through 5.906 are revised to read as follows:

Subpart 9—Use of GSA Supply Sources by Prime Contractors

§ 5.900 Scope.

This Subpart prescribes policies and procedures for contracting officers regarding the use of General Services Administration (GSA) supply sources (*i.e.*, items available through Federal Supply Schedule contracts, GSA nonmandatory ADTS/ADP schedule contracts, GSA/ADP requirements contracts, and from GSA stock) by contractors in performing certain Government contracts. The term "contractor" as used in this Subpart, unless the context otherwise requires, includes subscontractors who qualify in accordance with the provisions of 5.902(b). (The use of GSA sources by grantees is not authorized.) This Subpart is applicable to the procurement of supplies to be delivered in the United States, its possessions, or Puerto Rico.

§ 5.901 Policy.

(a) It is the policy of the General Services Administration to make GSA supply sources available to all eligible users in order to promote greater economy and efficiency in Government procurement programs.

(b) To the extent provided in this Subpart, the policy is applicable to contractors working wholly or substantially on cost-reimbursement contracts.

(c) NASA installations are responsible for establishing internal control over contractor use of GSA and other Federal supply sources.

§5.902 Authorization to contractors.

(a) When the contracting officer determines that it is in the best interest of the Government to do so, the prime contractors shall be authorized in writing, and, where appropriate, their subcontractors to utilize GSA supply sources in performing Government contracts. Authorizations to subcontractors shall be issued through, and subject to the approval of, the prime contractor. Each authorization (prime or sub) shall be supported by a written finding of the facts which are the basis for the determination to issue the authorization. Such findings shall be retained in the official contract files, along with the related determination and finding required by § 13.201(c).

(b) The authorization to utilize GSA supply sources may be issued only where the contracting officer deems it advisable for a contractor to utilize GSA supply sources in performing:

(i) Government cost-reimbursement contracts; and

(ii) other types of negotiated contracts where it is determined by the contracting officer that a substantial dollar portion of the contractor's contracts are of a Government cost-reimbursement nature.

(c) Subject to the criteria set forth in subparagraph (b) of this paragraph

§ 5.902, written authorizations shall include such limitations or conditions as are deemed necessary in the public interest. For example, the contracting officer may choose to:

(i) authorize purchases from GSA supply sources of any overhead supplies, but no production supplies; or

(ii) limit any authorization requirement to use GSA sources to a specific dollar amount, leaving the contractor free to make smaller purchases from any source he chooses; or

(iii) restrict the authorization to certain plants or facilities. The terms and conditions which may be imposed are not limited to the foregoing examples.

(d) In determining whether to issue such an authorization, consideration should be given, but not necessarily limited to, the following factors:

(i) potential for abuse by contractors authorized access to Federal Supply Sources;

(ii) the administrative cost of placing orders with Government sources, and the program impact of delay factors, if any;

(iii) lower cost of purchased items;

(iv) suitability of items available through GSA supply sources;

(v) delivery factors such as cost and time; and

(vi) recommendations of prime contractors.

(e) The contracting officer shall be responsible for insuring that prime contractors and subcontractors comply with the terms of their authorizations and for insuring that supplies and services obtained from GSA sources of supply are required and properly used.

§5.902-1 Formal and contents of authorization.

(a) Authorizations shall be in writing and shall cite the number of the contract or contracts, specify the applicable limitations of the authority, such as the period of eligibility, and contain any other pertinent information, including requirements relative to ordering, receiving, inspection and payment. The written authorization shall be in substantially the same format as that set forth in § 5.906.

(b) Additional Required Authorization Data.

(i) When the contracting officer authorizes the contractor to use Government supply sources other than, or in addition to, those of the General Services Administration, the written authorization must so state.

(ii) When the contractor is authorized to use the supply sources of the Defense Logistics Agency, the contracting officer's written authorization must contain all data required by (a) above and must cite the contracting NASA installation Department of Defense Activity Address Code (DODAAC) for billing. Such authorization may provide for direct payment by the contractor to the Defense Logistics Agency.

(iii) When the contractor requires a DODAAC so he may use Government supply sources, the contracting officer shall follow the procedures outlined in NMI 4050.2.

§ 5.902-2 Distribution.

Letters of authorization shall be forwarded by the contracting officer to the Installation Supply and Equipment Management Officer; Attention: Activity Address Code Coordinator, who will forward the authorization to the Supply and Equipment Management Division, NASA Headquarters (Attn: Code NES-8), for verification and transmittal to the General Services Administration. Letters of authorization forwarded to Headquarters must include copies of the supporting determination and findings. These latter documents will not be forwarded to GSA.

§5.903 Orders under Federal supply schedule contracts, GSA nonmandatory ADTS/ADP schedule contract, and GSA ADP requirements contract.

(a) Orders placed by Government contractors under Federal Supply Schedule contracts shall be placed in accordance with the provisions of the applicable Federal Supply Schedule and the authorization issued to the contractor. Each order shall be accompanied by a copy of the authorization (unless a copy was previously furnished to the Federal Supply Schedule contractor).

(b) In the event a Federal Supply Schedule contractor refuses to honor an order placed by a Government contractor in accordance with the authorization, the contracting officer shall promptly report the facts and circumstances to the General Services Administration, Federal Supply Service, Office of Customer Service and Support-FF, Washington, D.C. 20406.

(c) Orders under GSA Nonmandatory ADTS/ADP Schedule Contracts and GSA ADP Requirements Contracts shall be placed in accordance with the provisions of the applicable contract and FPR 1-4.1109-6 and 1-4.1109-7 respectively. (See NASA Procurement Notice 81-27.)

§ 5.904 Orders for GSA Stock.

Orders placed by Government contractors with GSA shall be placed in accordance with the authorization. Such orders shall contain the statement set forth in paragraph 2b. of the format for authorization set forth in 5.906.

§ 5.905 Furnishing information to contractors.

The contracting officer shall assist the contractors which they have authorized to use GSA supply sources in obtaining pertinent Federal Supply Schedules and the GSA Supply Catalog, and shall furnish them with any other desired information. Such schedules and catalogs may be obtained by submitting a completed GSA Form 457, FSS Publications Mailing List Application, in accordance with the instructions on the form. GSA Form 457 may be obtained from the GSA regional office serving the area in which the requesting office is located.

§5.906 Format for authorization for contractors to use GSA supply sources.

Subject: Authorization to Lease, Rent or Purchase from General Services Administration Supply Sources

(Contractor's name)

(Address)

1. You are hereby authorized to act for the Government in the following matters:

a. The purchasing of property for acquisition under Contract No. ..... which is available for purchase by Government agencies either directly from the General Services Administration stock or under Federal Supply Schedules, subject to the limitations set forth herein.

b. The leasing or rental of equipment for use on Contract No. ..... which is available for lease or rental by Government agencies under Federal Supply Schedules, subject to the limitations set forth herein.

c. The issuance of tax exemption certificates in lieu of the payment of State or other taxes for which the Government is not liable on property purchased under this authorization.

2. a. *Purchase Orders Under Federal Supply Schedule Contracts.* Orders shall be placed in accordance with the terms and conditions of the attached Federal Supply Schedule and this authorization. A copy of this authorization shall be attached to the order (unless a copy was previously furnished to the Federal Supply Schedule contractor) and shall contain the following statement:

This order is placed on behalf of the National Aeronautics and Space Administration, in furtherance of United States Government Contract No. *(Insert contract number),* pursuant to written authorization dated ..... *[ ]. In the event of any inconsistency between the terms and conditions of this order

and those of the Federal Supply Schedule contract, the latter will govern. *(*Insert "a copy of which is attached," or "a copy of which you have on file," or other suitable language, as appropriate.)*

b. *Orders for Items in the General Services Administration Supply Catalog.* Orders shall be placed in accordance with the attached General Services Administration Supply Catalog and this authorization. Include the address to which billings are to be sent. Bills are not issued by General Services Administration until after shipment has been made, and should therefore be paid promptly. Necessary adjustments, if any, will be made by General Services Administration subsequent to payment. All orders shall contain the following statement:

This order is placed on behalf of the National Aeronautics and Space Administration, in furtherance of United States Government Contract No. *(Insert contract number)*, pursuant to written authorization dated ..... *[ ]. *(*Insert "a copy of which is attached," or "a copy of which you have on file," or other suitable language, as appropriate.)*

3. (Other provisions and restrictions.)

4. This authority hereby granted is not transferable or assignable.

(Contracting Officer's Signature)

PART 7—CONTRACT CLAUSES

§ 7.104-35 [Amended]

11. In Part 7, § 7.104-35 is amended by changing the date of the clauses in paragraphs (a) and (b) to read "(May 1982)" in place of "(June 1981)" and in the introductory paragraph change the word "biweekly" to read "monthly."

12. In Part 7, § 7.104-35 (a) and (b) are amended by changing "eighty-five percent (85%)" or "85 percent" to read "ninety percent (90%)" and by changing the "ninety percent (90%)" to read "ninety-five percent (95%)" wherever they appear in the clauses entitled "Progress Payments for Other Than Small Business Concerns" and "Progress Payments for Small Business Concerns."

§ 7.204-28 [Amended]

13. In Part 7, § 7.204-28 is amended by changing the figure "5.907" to read "5.909."

PART 8—TERMINATION OF CONTRACTS

14. In Part 8, Table of Contents is amended by changing the page numbers for paragraphs 8.202 through 8.208 to read as follows:

* * * * *

8.202	Prior Clearance of Significant Contract Terminations.	8-2:2
8.203	Notice of Termination	8-2:3
8.204	Methods of Settlement	8-2:3
8.205	Duties of Prime Contractor After Receipt of Notice of Termination.	8-2:4
8.206	Duties of Termination Contracting Officer After Issuance of Notice of Termination.	8-2:4
8.206-1	Release of Excess Funds	8-2:4B
8.206-2	Termination Case File	8-2:4B
8.206-50.	Negotiation and Settlement by the Department of Defense or Other Government Agency.	8-2:4B
8.207	Fraud or Other Criminal Conduct	8-2:4C
8.208	Audit of Prime Contract Settlement Proposals and of Subcontract Settlements.	8-2:4C

* * * * *

15. In Part 8, § 8.203(a) is amended by adding paragraph (vi) to read as follows:

§ 8.203 Notice of Termination.

(a) *General.* * * *

(vi) that contractor must set up a separate account to identify and accommodate significant settlement expenses in accordance with § 15.205-42.

16. In Part 8, § 8.205 is amended by adding a paragraph (x) to read as follows:

§ 8.205 Duties of Prime Contractor After Receipt of Notice of Termination.

* * * * *

(x) set up a separate account to identify and accommodate significant settlement expenses in accordance with § 15.205-42.

PART 10—BONDS AND INSURANCE

§ 10.202 [Amended]

17. In Part 10, 10.202 is amended by adding "for Performance and Payment Bonds." to the title "Options in Lieu of Sureties."

PART 15—CONTRACT COST PRINCIPLES AND PROCEDURES

18. In Part 15, Table of Contents is amended by changing the page numbers for §§ 15.205-17, 15.205-45, 15.205-46, 15.205-50, 15.206 and adding 15.205-51 to read as follows:

* * * * *

15.205-17.	Interest and Other Financial Costs	15-2:14A
*	*	*
15.205-45.	Transportation Costs	15-2:24A
15.205-46.	Travel Costs	15-2:24A
*	*	*
15.205-50.	Cost of Money	15-2:29
15.205-51.	Lobbying Cost	15-2:29
15.206	Notice of Intent to Disallow or Not Recognize Costs.	15-2:29

19. In Part 15, § 15.205-16 is revised to read as follows:

§ 15.205-16. Insurance and Indemnification.

(a) Insurance by purchase or by self-insuring includes (i) coverage which the contractor is required to carry, or which is approved, under the terms of the contract, and (ii) any other coverage which the contractor maintains in connection with the general conduct of his business. Any contractor desiring to establish a program of self-insurance applicable to contracts not subject to Cost Accounting Standard (CAS) 416 must comply with the self-insurance provisions of the Standard as well as Part 10 of this Regulation. Approval of a contractor's insurance program in accordance with Part 10 does not constitute a determination as to the allowability of the program's cost. The amount of insurance costs which may be allowed is subject to the cost limitations and exclusions set forth in the following subparagraphs.

(1) Costs of insurance required or approved, and maintained, pursuant to the contract, are allowable.

(2) Costs of other insurance maintained by the contractor in connection with the general conduct of his business are allowable subject to the following limitations:

(i) types and extent of coverage shall be in accordance with sound business practice and the rates and premiums shall be reasonable under the circumstances;

(ii) costs allowed for business interruption or other similar insurance shall be limited to exclude coverage of profit;

(iii) the cost of property insurance premiums for insurance coverage in excess of acquisition cost of the insured assets is allowable *provided* the contractor has a formal written policy assuring that in the event the insured property is involuntarily converted, the new asset shall be valued at the book value of the replaced asset plus or minus adjustments for differences between insurance proceeds and actual replacement cost. If the contractor does not have such a formal written policy, the cost of premiums for insurance coverage in excess of the acquisition cost of the insured asset is unallowable.

(iv) costs of insurance for the risk of loss of or damage to Government property are allowable only to the extent that the contractor is liable for

such loss or damage and such insurance does not cover loss or damage which results from willful misconduct or lack of good faith on the part of any of the contractor's directors or officers, or other equivalent representatives, who has supervision or direction of (A) all or substantially all of the contractor's business, or (B) all or substantially all of the contractor's operations at any one plant or separate location in which the contract is being performed, or (C) a separate and complete industrial operation in connection with the performance of the contract; and

(v) costs of insurance on the lives of officers, partners, or proprietors are allowable only to the extent that the insurance represents additional compensation (see 15.205–6).

(3) Actual losses are unallowable unless expressly provided for in the contract, except:

(i) minor losses not covered by insurance, such as spoilage, breakage, and disappearance of small hand tools, which occur in the ordinary course of doing business are allowable.

(ii) losses incurred under the nominal deductible provisions of purchased insurance, in keeping with sound business practices, are allowable for contracts not subject to CAS 416, when the contractor elected not to establish a self-insurance program. Such contracts are not subject to the self-insurance provisions of CAS 416. Also, for contracts subject to CAS 416, and those made subject to the self-insurance provisions of the Standard as a result of the contractor's having established a self-insurance program (see § 15.205–16(a)), actual losses may be used as a basis for charges under a self-insurance program when the actual amount of losses will not differ significantly from the projected average losses for the accounting period (see 4 CFR 416.50(a)(2)(ii)).

(4) Contracts operating under a program of self-insurance must obtain approval of the program when required by § 10.502.

(b) If purchased insurance is available, the charge for any self-insurance coverage plus insurance administration expenses shall not exceed the cost of comparable purchased insurance plus associated insurance administration expenses.

(c) Insurance provided by captive insurers (insurers owned by or under the control of the contractor) is considered self-insurance and charge therefor must comply with the self-insurance provisions of CAS 416. However, if the captive insurer also sells insurance to the general public in substantial quantities and it can be demonstrated that the charge to the contractor is based on competitive market forces, the insurance will be considered purchased insurance.

(d) The allowability of premiums for insurance purchased from fronting insurance companies (insurance companies not related to the contractor, but who reinsure with a captive insurer of the contractor) shall not exceed the amount (plus reasonable fronting company charges for services rendered) which the contractor would have been allowed had he insured directly with the captive insurer.

(e) Self-insurance charges for risks of catastrophic losses are not allowable.

(f) Late premium payment charges related to employee deferred compensation plan insurance, incurred pursuant to Section 4007 or Section 4023 of the Employee Retirement Income Security Act of 1974, are unallowable.

(g) Indemnification includes securing the contractor against liabilities to third persons and any other loss or damage, not compensated by insurance or otherwise. The Government is obligated to indemnify the contractor only to the extent authorized by law, which authorization is implemented in a provision of the contract, except as provided in subparagraphs (i) and (ii) of (a)(3) above.

(20.) In Part 15, § 15.205–42(f)(1) and (f)(2) are revised to read as follows:

§ 15.205–42 Termination costs.

* * * * *

(f)(1) *Settlement expenses* including the following are generally allowable:

(i) accounting, legal, clerical, and similar costs reasonably necessary for the preparation and presentation to contracting officers of settlement claims and supporting data with respect to the terminated portion of the contract, and for the termination and settlement of subcontracts;

(ii) reasonable costs for the storage, transportation, protection, and disposition of property acquired or produced for the contract; and

(iii) indirect costs related to salary and wages incurred as settlement expenses in (i) and (ii); normally, such indirect costs shall be limited to payroll taxes, fringe benefits, occupancy costs, and immediate supervision.

(2) When settlement expenses of a termination are significant, a separate cost account(s) or work order(s) shall be established to accumulate and identify these expenses separately.

* * * * *

21. In Part 15, § 15.205–51 is added to read as follows:

§ 15.205–51 Lobbying Costs.

(a) For the purpose of this section, lobbying is defined as any activity or communication which is intended or designed to directly influence or to engage in any campaign to encourage others to influence members of the Congress, their staffs, or the staffs of committees of the Congress to favor or oppose legislation, appropriations or other actions of the Congress, its members, or its committees, for the procurement of specific supplies or services by the Federal Government. Except as provided in (c) below, lobbying activity includes, but is not limited to, all forms of communications by the contractor, its employees, or its agents with the Congress, its members, and staffs or members and committees for the above-mentioned purpose.

(b) The costs of lobbying as defined herein, including the applicable portion of the salaries of the contractor's employees and the fees of individuals or firms engaged in lobbying, on behalf of the contractor (whether or not the individuals or firms are registered as lobbyists under any applicable law) are unallowable. In addition, the directly associated costs (see § 15.201–6) of lobbying are unallowable.

(c) Legislative liaison activities, such as attendence at committee hearings, gathering information regarding pending legislation, analysis of the effect of pending legislation, and the like are not lobbying and are allowable. In addition, communications that would be considered lobbying in accordance with (a) above shall be allowable if they are performed after receipt of an invitation or request from a congressional or executive branch source.

PART 16—PROCUREMENT FORMS

22. In Part 16, § 16.001 (a), (b), and (d) are amended by removing NASA Forms 558, 1379 (Reverse) only, and Miscellaneous Form DIB–999 and changing the dates for NASA Forms 417, 419, 604 and U.S. Standard Forms 19–B and 23–A to read as follows:

* * * * *

417	(4–82)	General Provisions for Cost-Reimbursement Research and Development Contract
*	*	* * *
419	(12–80)	General Provisions for Cost-Reimbursement Research and Development Contract with Educational or Nonprofit Institutions
*	*	* * *
604	(6–81)	Additional General Provisions to U.S. Standard Form 23A (10–69 Ed.)
*	*	* * *
19–B	(6–76)	Representations and Certifications (Construction Contracts)

* * * * *

23-A...	(4-75)	General Provisions (Construction Contract)

* * * * *

23. In Part 16, 16.001(d) is amended further by inserting after "DMS-14 (7-59) Allotment Decrease (Construction)" the following list of forms to read as follows:

* * * * *

DOE EV-375	(4-78)	U.S. Department of Energy Isotope Order Blank
GSA-457	(10-66)	Request for Federal Supply Schedules and Contractors Catalogs
GSA-2084		Clearance to Acquire Correspondence Filing Cabinets
ITS-999.	(4-78)	Request for Special Priorities Assistance
NRC 313(I)	(12-81)	U.S. Nuclear Regulatory Commission, Application for By-Product License—Industrial
NRC 313(M).	(9-81)	U.S. Nuclear Regulatory Commission, Application for Materials License—Medical
NRC 313R	(7-77)	U.S. Nuclear Regulatory Commission, Instructions for Preparing Application for By-Product Material License—Use of Sealed Sources in Radiography Form NRC 313R
NRC 374	(12-81)	U.S. Nuclear Regulatory Commission, Materials License

Appendix E—Progress Payments Based on Costs

24. In Appendix E, the Table of Contents is amended by changing the page numbers for paragraphs E.503-1 through E-5-8 to read as follows:

* * * * *

E.503-1.	Uniform Standard Percentages	E-5:2
E.503-2..	Indefinite Quantity Contracts-Basic Ordering Agreements.	E-5:2
E 503-3.	Administration	E-5:3
E. 504.....	Formal Advertising and Small Business Restricted Advertising.	E-5:3
E.504-1..	Progress Payment Provision in Invitations for Bids.	E-5:3
E.504-2..	Small Business Restricted Advertising	E-5:4
E.504-3..	Progress Payments Exclusively for Small Business.	E-5:4
E.504-4..	Notice to Bidders	E-5:4
E.504-5.	Nonresponsive Bids-Uninvited Progress Payment Condition.	E-5:5
E.505	Unusual Progress Payment-Standards-Procedure.	E-5:5
E.506...	Accounting System and Controls	E-5:6
E.507.....	Information Required	E-5:6
E.508 through E.510.	[Reserved]	E-5:6
E.511.....	Instructions for Progress Payment Clauses.	E-5:7
E.511-1..	Contracting Officer	E-5:7
E.511-2..	Uniform Standard Percentages-Firms Not Small Business-Paragraphs (a) and (b) of Clause.	E-5:7
E.511-3.	Uniform Standard Percentages-Small Business Concerns-Paragraphs (a) and (b) of Clause.	E-5:7
E.511-4..	Percentages for Paragraphs (a)(3)(ii) and (a)(4) of Clause-Contracts With Negotiated Profit Rate.	E-5:7
E.511-5.	Unusual Percentages	E-5:7
E.511-6..	Other Protective Provisions	E-5:7
E.512...	Progress Payment Liquidation	E-5:8
E.512-1..	Ordinary Method	E-5:8
E.512-2..	Alternate Method-Contracts With Negotiated Profit Rate.	E-5:8

Appendix E [Amended]

25. In Appendix E, E.503-1 is amended by revising the first two sentences to read as follows:

E.503-1 Uniform Standard Percentages. The uniform standard progress payment rate is ninety percent (90%) of total costs for firms which are not small business concerns, and ninety-five percent (95%) of total costs for small business concerns. This ninety-five percent (95%) rate applies to all contracts awarded to small business concerns, whether or not awarded pursuant to formal advertising. * * *

26. In Appendix E, E.504-1 is amended by revising to read as follows:

E.504-1 Progress Payment Provision in Invitations for Bids. When progress payments are contemplated, the invitations for bids shall include a notice of availability of progress payments as described in E.504-4. The percentage of total costs to be mentioned in these invitations for bids is ninety-five percent (95%) for small business concerns and ninety percent (90%) for firms which are not small business concerns.

* * * * *

27. In Appendix E, E.504-2 is revised to read as folows:

E.504-2 Small Business Restricted Advertising. The above policy and standards also apply to procurement by "Small Business Restricted Advertising" and for procurement pursuant to E.504-3. When progress payments are contemplated in these cases, provision will be made for progress payment percentage at ninety-five percent (95%) of total costs.

E.511-2 [Amended]

28. In Appendix E, E.511-2 is amended by replacing "eighty-five percent (85%)" to read "ninety percent (90%)".

E.511-3 [Amended]

29. In Appendix E, E.511-3 is amended by substituting "ninety-five percent (95%)" for the words "ninety percent (90%)."

Supplement No. 2—File Maintenance, Closeout, and Disposition

30. In Supplement No. 2, S2.102-1 (ix) is revised to read as follows:

S2.102-1 Contract Award File

* * * * *

(ix) The Contract Security Classification Specification (DD Form 254), and evidence of contractor clearance;

* * * * *

31. In Supplement No. 2, S2.301-2 is revised to read as follows:

S2.301-2 Closed Contracts.

Firm Fixed Price Unilateral Purchase Orders are closed when evidence of physical completion is received by the contracting officer. All other contracts are closed when they are physically—complete and when all administrative actions are taken, including the accomplishment of one of the two Contract Completion Statements, DD Form 1594. However, a completed contract cannot be considered closed while it is in litigation, or an appeal is pending before the NASA Board of Contract Appeals.

32. To correct the 1981 Edition of the NPR change clause dates to read as follow:

NPR paragraph	Change date	
	From	To
7.104-53(a).	March 1981	December 1981
7.901-4	October 1981	December 1981
8.701(c)	December 1981	November 1974
9.203-7(a)	January 1977	November 1977

[FR Doc. 82-28624 Filed 10-18-82; 8:45 am]

BILLING CODE 7510-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6333

[CA-7027 WR, CA-7203 WR]

California; Revocation of Executive Order No. 6762 and Public Land Order No. 432

Correction

In FR Doc. 82-24875 beginning on page 39824 in the issue of Friday, September 10, 1982, make the following correction:

On page 39825, first column, insert "September 1, 1982" as the date of signature at the end of the document.

BILLING CODE 1505-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

45 CFR Part 205

General Administration—Public Assistance Programs; Disclosure of Information for Public Audits

AGENCY: Social Security Administration, HHS.

ACTION: Final rule.

SUMMARY: This regulation permits disclosure for audit purposes of information concerning AFDC applicants or recipients to any government entity authorized by law to conduct such audits or similar activity. This regulation reflects the provision of section 403(a) of the Social Security Disability Amendments of 1980 (Pub. L. 96-265) which was effective on September 1, 1980.

EFFECTIVE DATE: This regulation became effective when the interim regulation was published on May 3, 1982 (47 FR 18879).

FOR FURTHER INFORMATION CONTACT: Ms. Helen Hamilton, Office of Family Assistance, Office of Policy, Social Security Administration, Transpoint Building, 2100 Second Street, S.W., Washington, D.C. 20024, telephone (202) 245-3341.

SUPPLEMENTARY INFORMATION: Section 403(a) of the Social Security Disability Amendments of 1980 (Pub. L. 96-265) amended section 402(a)(9) of the Social Security Act to provide another reason for disclosure of information concerning applicants for and recipients of financial assistance under State title IV-A plans. Under this law, disclosure is now permitted for purposes of any audit conducted by any governmental entity authorized by law to conduct such audits or similar activity. To reflect this change, we amended 45 CFR 205.50 by revising clause (C) of paragraph (a)(1)(i) and relocated the revised material in clause (D) of paragraph (a)(1)(i) and in clause (iii) of paragraph (a)(1) to make it easier to read. The basis provision on disclosure for audit purposes is in the new clause (E) of paragraph (a)(1). Disclosure of information to any other committee or legislative body that identifies AFDC applicants or recipients by names or addresses continues to be prohibited. We have also revised paragraph (c) to explain that disclosure for audit purposes is not a requirement of a State plan under title I, X, XIV, or XVI (AABD) of the Social Security Act.

We have also clarified 45 CFR 205.50(a)(1)(iii), which prohibits the publication of lists of names of applicants and recipients, and 45 CFR 205.50(d) which implements the Jenner Amendment. This amendment, which is based on section 618 of the Revenue Act of 1951 (Pub. L. 183, 82nd Congress), provided for a limited exception to the confidentiality rules under section 402(a)(9) of the Social Security Act. Under this amendment, a State may permit public access to disbursement records of public assistance recipients if it is authorized under State law and the State law also prohibits the use of any list or names obtained through such access for commercial or political purposes. We have done this by combining these provisions and redesignated them as a new clause (a)(1)(iv). This is only a technical change for purposes of clarity and does not make any change in Federal policy.

This material does not apply to the adult assistance programs in Guam, Puerto Rico, and the Virgin Islands under title I, X, XIV, and XVI (AABD) of the Social Security Act.

An interim regulation was published on May 3, 1982 (47 FR 18879).

The Social Security Administration found that publication of a Notice of Proposed Rulemaking (NPRM) was "unnecessary" under the Administrative Procedure Act (5 U.S.C. 553(b)(B)). Since the interim regulation only updated existing regulations to reflect the Social Security Disability Amendments of 1980 (Section 403 of Pub. L. 96-265) and since the Secretary had exercised no discretion in implementing, an NPRM would have served no useful purpose. However, to insure that the public had an opportunity to give us their views, we asked interested persons to send us their comments before proceeding with the final rule. The comment period ended July 2, 1982, and we received one comment supporting the regulation.

Regulatory Procedures

Executive Order 12291—This regulation has been reviewed under Executive Order 12291 and does not meet any of the criteria for a major regulation. The regulation has no budgetary impact because it merely permits disclosure of existing AFDC information. Therefore, a regulatory impact analysis is not required.

Paperwork Reduction Act—This regulation imposes no reporting/recordkeeping requirements requiring OMB clearance.

Regulatory Flexibility Act—We certify that this regulation will not, if promulgated, have a significant economic impact on a substantial number of small entities because it affects only the disclosure of information for specific purposes. Therefore, a regulatory flexibility analysis as provided in Pub. L. 96-354, the Regulatory Flexibility Act, is not required.

Accordingly, this regulation is adopted without change as set forth below.

(Secs. 402, 411, 1102, and 1106(a) of the Social Security Act, as amended; 49 Stat. 627, as amended, 91 Stat. 1561, 49 Stat. 647, as amended, 53 Stat. 1398, as amended; 42 U.S.C. 602, 611, 1302, 1306(a) and sec. 403 of Pub. L. 96-265, 94 Stat. 462)

List of Subjects in 45 CFR Part 205

Administrative practice and procedure, Aid to families with dependent children, Family assistance office, Grant programs—social programs, Public assistance programs, Reporting requirements.

Dated: August 25, 1982.

Paul B. Simmons,

Acting Commissioner of Social Security.

Approved: September 27, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

PART 205—GENERAL ADMINISTRATION—PUBLIC ASSISTANCE

Chapter II, Title 45 of the Code of Federal Regulations is amended as set forth below:

1. Section 205.50 is amended Paragraphs (a)(1)(i) (B) and (C) revised; paragraphs (a)(1)(i) (D) and (E) added; paragraphs (a)(1)(iii) and (d) redesignated as (a)(1)(iv) and revised; and a new paragraph (a)(1)(iii) added to read as follows:

§ 205.50 Safeguarding information for the financial assistance programs.

(a) *State plan requirements.* * * *

(1) * * *

(i) * * *

(B) Any investigation, prosecution, or criminal or civil proceeding conducted in connection with the administration of any such plans or programs.

(C) The administration of any other Federal or federally assisted program which provides assistance, in cash or in kind, or services, directly to individuals on the basis of need.

(D) The certification of receipt of AFDC to an employer for purposes of claiming tax credit under Pub. L. 94-12, the Tax Reduction Act of 1975 (see § 235.40 of this chapter).

(E) Any audit or similar activity, e.g., review of expenditure reports or financial review, conducted in connection with the administration of any such plan or program by any governmental entity which is authorized by law to conduct such audit or activity.* * *

(iii) Disclosure of any information that identifies by name or address any applicant or recipient to any Federal, State, or local committee or legislative body other than in connection with any activity under paragraph (a)(1)(i)(E) of this section is prohibited.

(iv) Publication of lists or names of applicants and recipients will be prohibited. *Exception.* In respect to a State plan for financial assistance under title I, IVA, X, XIV, or XVI (AABD) of

the Social Security Act, an exception to this restriction may be made by reason of the enactment or enforcement of State legislation, prescribing any conditions under which public access may be had to records of the disbursement of funds or payments under such titles within the State, if such legislation prohibits the use of any list or names obtained through such access to such records for commercial or political purposes.

2. Paragraph (c) of § 205.50 is amended in the first sentence by adding "with the exception of paragraphs (a)(1)(i) (D) and (E)", to read as follows:

* * * * *

(c) *State plan requirements for programs of financial assistance in Puerto Rico, the Virgin Islands, and Guam.* A State plan under title I, X, XIV, or XVI (AABD) of the Social Security Act must meet all the requirements of paragraph (a) of this section, with the exception of paragraphs (a)(1)(i) (D) and (E), * * *.

* * * * *

§ 205.50 [Amended]

3. Paragraph (d) of § 205.50 is removed and reserved.

[FR Doc. 82-28600 Filed 10-18-82; 8:45 am]

BILLING CODE 4190-11-M

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45 CFR Part 205

General Administration—Public Assistance Programs; Quality Control System Review Completion Requirements

AGENCY: Social Security Administration, HHS.

ACTION: Final rule.

SUMMARY: These regulations revise the quality control sample case completion requirements under the Aid to Families with Dependent Children (AFDC) and adult assistance programs. These regulations require the State agencies administering these programs to complete the review of monthly sample cases and to submit their edited review findings to the Social Security Administration (SSA) within specific time periods. More timely reporting of review data is needed to improve State and Federal management of the programs.

EFFECTIVE DATE: October 1, 1982 except for the following special provisions:

1. Section 205.40(b)(2)(i)—"Submission of the Sampling Plan"—The old requirements for sampling plans remain in effect for the October 1, 1982–March 31, 1983, sampling period. On January 31, 1983, the provisions for submitting sampling plans 60 days prior to the start of the sampling period become effective and are applicable with respect to the April 1, 1983, to September 30, 1983, and subsequent sampling periods.

2. Section 205.40(b)(2)(iv)(A)—"Corrective Action Plan"—The corrective action plan required under the old regulations for the 6-month sampling period from October 1, 1981, to March 31, 1982, will be considered as the initial annual corrective action plan for purposes of the requirements of this rule. The next annual corrective action plan will be due August 15, 1983.

3. Section 205.40(b)(3)(i)—"Alternate Sample Case Completion Plan based on Permanent or Recurring Events"—The requirement that the alternate plan request be submitted at least 60 days prior to the start of the first sampling period covered by the plan is effective with respect to sampling periods beginning on or after April 1, 1983. Thus, alternate plan requests for the April 1, 1983, to September 30, 1983, sampling period must be submitted not later than January 31, 1983. Alternate plan requests covering the October 1, 1982, to March 31, 1983, sampling period may be submitted at any time prior to or during that sampling period.

FOR FURTHER INFORMATION CONTACT: Sean Hurley, Division of AFDC Quality Control, 330 C Street, S.W., Washington D.C. 20201, (202) 245-0976.

SUPPLEMENTARY INFORMATION: These regulations make changes in the quality control (QC) system for the financial assistance programs that are authorized under titles I, IV-A, X, XIV, and XVI (AABD) of the Social Security Act. The QC system is a management tool for monitoring the spending of public assistance funds under these titles. This monitoring is accomplished by a continuous review of a statistically valid and reliable sample of cases to—

(1) Determine the extent to which those persons receiving assistance are eligible, and if eligible, are receiving the right amount of assistance;

(2) Determine the correctness of actions to terminate or deny assistance; and

(3) Reduce or eliminate the incidence of eligibility or payment errors and incorrect denials or terminations.

Under the QC system, State agencies conduct reviews of AFDC and adult assistance cases from a six-month sample period. The State agencies select the cases for review although SSA specifies how many cases the State agencies must review and report on for each six-month sample period. State agencies select their review cases in each month of the six-month sample period.

Our experience in administering the QC system has demonstrated the need for State agencies to complete and submit review findings on a more consistent basis. Without regulations requiring a regular flow of review data to SSA, State agencies have not completed their individual case reviews for sample months according to a consistent schedule. In addition, some agencies delay reporting their case review findings until the end of the 6-month reporting period. The inconsistent flow of case review data causes uneven workloads which hinders efforts to—(1) Identify problems and take corrective action, (2) determine if funds are properly spent, and (3) determine error rates.

We believe these regulations are necessary because administrative measures to obtain timely reporting of case review data have been unsuccessful.

At this time SSA is considering changing from a 6-month sample period to a 12-month sample period. Should such a change take place, the completion requirements for individual case reviews would be appropriately adjusted.

Major Differences Between the Proposed Rule and the Final Rule

A Notice of Proposed Rulemaking (NPRM) on sample case completion requirements under the QC system was published in the **Federal Register** on October 24, 1980 (45 FR 70521). The major differences between the NPRM's provisions and the final rule's provisions are as follows:

(1) The NPRM had left unchanged a rule requiring State agencies to submit their sampling plans to the Department in the form and at the times prescribed by the Department. These final regulations, however, are amending this rule to provide that, effective January 31, 1983, a State agency must submit its sampling plan no later than 60 days before the start of the 6-month sample period except where the State agency does not change its previous sampling plan and that plan meets the Federal sampling requirements. We are establishing this time frame to allow SSA sufficient time to review the sampling plan so that SSA's approval is not delayed until after the start of the sampling period. A delay in approval might also delay the State agency in selecting and completing its reviews of sample cases. Additionally, this new requirement will facilitate the integration of AFDC sample cases with sample cases from the Medicaid and Food Stamps programs into a

comprehensive State agency sample review process.

(2) The NPRM proposed that State agencies must complete review findings from 98 percent of all cases sampled in a month to SSA within 75 days after the end of the month. Based on the objections to this proposal, we have reduced the monthly completion percentage to 90 percent or "all but 5 cases" of the active case sample and 90 percent or "all but 5 cases" of the negative case sample. We made clear that this data must be submitted to us within the 75 day period.

(3) The NPRM proposed that State agencies must complete review findings from 100 percent of their monthly sample within 105 days after the end of the sample month. The final rule extends the time frame and requires the submission of edited review findings within 120 days after the end of the third sample month for sample cases selected in the first, second, and third sample months and 120 days after the sixth sample month for sample cases selected in the fourth, fifth, and sixth sample months.

(4) The NPRM proposed a weekly submission of the review data. Based on the objections to this proposal, we decided to require the submission of edited review findings on a monthly basis instead. These findings must continue to be submitted on prescribed review schedules.

(5) The NPRM extended the due date for State agencies to submit their 6-month summary data reports from 60 days to 75 days after the end of the 6-month sample period. After analyzing the comments we received, we are now planning the future elimination of this requirement from the AFDC/QC program and have deleted the specific requirement for the submission of these reports. However, pending automation of the system to receive edited review findings (see the definition in § 205.40(a)(11)), State agencies will be required to prepare and submit these summary reporting tables under the general submission authority contained in § 205.40(b)(2)(v). These summary tables will be due 120 days after the end of the sample period. We are deleting the specific reference to this requirement from the regulations at this time so that a separate rulemaking action will not be necessary when we actually eliminate the requirement.

(6) The NPRM specified the situations for and the procedures by which State agencies could request approval of an alternate completion schedule if they were unable to meet the completion requirements. An alternate schedule may be approved where the State agency is unable to meet the completion requirements on a long-term, on-going basis for reasons of the State's usual weather conditions, geography, or scattered population. It may also be approved on a short-term, temporary basis when an emergency arises. The final rule made only one change in the NPRM provisions, i.e. under an approved on-going alternate completion plan, a State agency will be required to submit its edited review findings to SSA within 120 days rather than 75 days after the sixth sample month.

(7) The current rules provide that State agencies shall submit their semi-annual corrective action plans within 90 days after the close of each 6-month sample period. The final rule, however, changes the corrective action reporting requirement from a semi-annual to an annual plan with a submission date of August 15 of each year. The first annual corrective action plan, however, will cover only the October 1, 1981–March 31, 1982, sampling period. The corrective action plan which was due on June 30, 1982, under the old rules will be considered as the initial corrective action plan under the new rules. The final rule also provides that State agencies shall submit to SSA on February 15 of each year, a progress report on the effectiveness of corrective actions. Except for the initial report, the report will cover the period since submission of the previous year's progress report. The first progress report will be due on February 15, 1983, and will cover action taken based on the corrective action plan submitted for the October 1981 to March 1982 sample period and any other corrective actions the State has implemented.

Response to Public Comments

We received comments from 22 State welfare agencies, 2 SSA offices, and 2 private organizations. These comments and our responses are discussed below. We indicate where we changed a provision in the proposed rule because of a comment. If we did not adopt a comment we give the reason(s) why.

I. Public Comments That Objected to the Idea of Completion Requirements

Comment: Six commenters opposed the idea of completion requirements. Two commenters felt that imposing requirements would impair a State agency's capacity to manage its QC program. The four other commenters questioned whether establishing a completion and submission requirement in the QC program would help achieve the objectives that were stated in the NPRM preamble.

Response: The reasons for the rule are—

(1) To establish a regulatory basis for requiring the timely completion and submission of review data so that those State agencies, which are consistently late in forwarding their review data, will improve their performance;

(2) To speed up the overall review process since the timely submission of review data to SSA permits more rapid—

(i) Completion of Federal re-reviews; and

(ii) Dissemination of the review data back to the State agencies and to SSA's Office of Assessment for preparing reports, obtaining statistics, and obtaining the data needed for management purposes.

II. Public Comments Objecting to Specific Completion Requirements

(a) Completion rates for monthly sample case reviews.

Comment: Seventeen commenters thought that a 98 percent sample case completion rate within 75 days was too stringent a requirement. Some of the reasons were that—

(1) The sample case review process often gets off to a late start because—

(i) The State agency integrates the AFDC sample with samples from the Medicaid and Food Stamp programs; and

(ii) Computer problems delay generation of the sample case listings;

(2) The verification requirements delay review completions;

(3) Local office review (or other State agency error resolution procedures) would have to be curtailed;

(4) An inflexible 98 percent completion requirement discriminates against State agencies with a smaller number of sample cases; and

(5) Operational problems often arise such as travel, client transfer etc.

Response: We have lowered the completion rate requirement to 90 percent or "all but 5 cases" of the month's active case sample and 90 percent or "all but 5 cases" of the month's negative case sample. Several commenters felt that a 90 percent rate was within their agencies' capabilities. The alternative completion rate of "all but 5 cases" had been suggested by a commenter. An "all but 5 cases" alternative requirement will provide those State agencies with a smaller number of samples with a more reasonable margin for completing difficult cases than would otherwise be provided by a fixed 90 percent completion requirement.

Comment: One commenter suggested that the completion requirement should be a cumulative percentage i.e., for satisfying the monthly sample completion percentage, a monthly sample would include cases carried over from a previous sample month.

Response: We did not adopt this suggestion because it would encourage State agencies to carry over difficult cases for one or more succeeding months. This, in turn, would delay identification of errors in these cases and thus reduce the effectiveness of any trend analyses and the timely implementation of needed corrective actions.

(b) Objections to a fixed starting date and a fixed duration of the sample period.

Comment: Seven commenters wanted State agencies to be able to vary the starting dates or duration (or both) of the sample period. One commenter wanted SSA to allow later completion dates for State agencies' supplemental sample cases e.g. a completion date that is 75 days after the date the supplemental case was selected.

Response: We are unwilling to adopt these suggestions because SSA would then have severe problems coordinating the activities of the 54 jurisdictions in the national QC program. However, to accommodate the concerns that were expressed concerning the duration of the sample period and the necessity of pulling supplemental cases, we extended the 105 day period that was provided in the NPRM for completing each month's sample, to—

(1) 120 days after the third sample month for the first, second, and third sample months; and

(2) 120 days after the sixth sample month for the fourth, fifth, and sixth sample months.

We did not include separate time frames for supplemental cases since the number of these cases should be few and should be easily processed within the final rule's liberalized completion rate and submission time frame requirements.

(c) Different completion requirements for the sixth month.

Comment: One commenter felt that the sixth month's completion requirement should not be different than the completion requirements specified for the other five sample months.

Response: Agreed and adopted.

(d) Dropping cases to meet the completion requirements.

Comment: Three commenters wanted to allow State agencies to drop sample cases, if necessary, to meet the completion requirements. One of the commenters also wanted these dropped cases excluded from the Federal re-review sample.

Response: We have not adopted this suggestion because it would allow State agencies to drop large numbers of cases and, thus, bias the sample. This would lead to inaccurate error rate findings.

III. Objections to Weekly Reports

Comment: Six commenters objected to the weekly reporting of review data. Some of the reasons for objecting were that—

(1) Processing small batches of case review data is an inefficient use of staff time and is a costly method for utilizing time-sharing facilities; and

(2) States with a small number of sample cases should not be forced to report every week.

Response: We changed the requirement for State agencies to report review findings on a weekly basis to a requirement to report review findings at least once a month.

IV. Federal Review Time Frames

Comment: Four commenters felt there was a need to include time frames for completing Federal re-reviews in the regulations.

Response: There are Federal re-review completion standards which are contained in the monitoring guide.

V. Negative Case Corrective Action

Comment: One commenter felt the NPRM had emphasized the review of active sample cases to the exclusion of negative sample cases. Additionally, the commenter noted we had no due date for State agencies to complete the negative case corrective action plan.

Response: We are providing a due date for the corrective action plan on negative cases. As a result, the regulatory provisions for negative cases will parallel the regulatory provisions for active cases.

VI. Other Reporting Requirements

Comment: Several commenters felt that the State agencies need additional time in which to submit the narrative analysis and the corrective action plan. It was mentioned also that the reporting requirements (form numbers, report content, etc.) should be more clearly identified in the regulations.

Response: The attached final rule will modify the current regulatory provisions on the corrective action plan as follows:

(1) State agencies shall now prepare only one corrective action plan per year, to be submitted by August 15 of each year. State agencies will be required to utilize error data from the previous April—September and October—March sample periods in the development of their annual corrective action plan. This will extend the time period for analysis and planning to 135 days after the end of the October—March sample period. Currently, State agencies are allowed 90 days after the end of each sample period to complete the corrective action plans.

However, the first annual corrective action plan will cover the period October 1, 1981—March 31, 1982. The corrective action plan for the 6-month period from October 1, 1981—March 31, 1982, which was due June 30, 1982, under the old regulations will be considered as the initial annual corrective action plan required under the new rules.

(2) State agencies will also have to submit a progress report on the effectiveness of their corrective actions which will be due by February 15 of each year. Each progress report will cover the period that has elapsed since the period reported on in the previous progress report. However, the initial report due on February 15, 1983, shall cover action taken based on the corrective action plan submitted for the October 1981 to March 1982 sample period and any other corrective actions the State has implemented.

We did not adopt the comment on the reporting forms because the reporting requirements (form numbers, report content, etc.) can be found in appropriate sections of the quality control manuals.

VII. Terms To Be Defined

Comment: One commenter thought that the term used in the NPRM—"completed review findings"—should be changed to a term such as—"disposed of sample cases." Another commenter wanted to define the term "completion" to clarify whether completing a sample case occurs when the State agency reviewer finishes with the case or when the subsequent supervisory review, data entry, and editing of the sample case findings has been completed.

Response: The final rule makes clear that "completion" means submitting the sample case review data to SSA. In an effort to make clearer the data to be submitted for a sample case, we substituted a definition "edited review findings" to replace the definition "review findings" to designate the data to be forwarded to SSA. We also added the definition "disposed of case" to the definitions section of the regulations to indicate that the data submitted must include all reviewed cases e.g., dropped cases as well as completed cases.

VIII. Alternate Completion Requirements

Comment: Some commenters felt that the alternate completion requirements were too narrow, that the authority for approval should be placed in the Regional Office, and that SSA response time after a State agency requests an alternate plan should be included in the regulations. Some commenters thought that the contents of this requirement were unclear.

Response: The final rule's provisions contain one change from the NPRM's provisions. This change is that a State agency under an approved on-going alternate plan may submit its edited review findings within 120 days instead of 75 days after the end of the sixth sample month. While we rewrote the NPRM provisions for alternate completion plans, we did so for clarification purposes, and made no other substantive changes. We decided against adopting the comment on vesting alternate plan approval authority with the SSA Regional Office (RO) because approval authority should be centrally located to insure national uniformity. It should be noted that this rule does not restrict redelegation of the Commissioner's approval authority to other SSA officials or receiving RO recommendations on whether or not to approve a plan. Additionally, we did not adopt the suggestion for an SSA response time after State agency submission of a request for approval of an alternate plan. The reason is that SSA's response time is too dependent on the sufficiency of the supporting data and the timeliness of its submission by State agencies.

Regulatory Procedures

Executive Order 12291 and *Regulatory Flexibility Act*—The Secretary certifies that these regulations, if promulgated, will not have a significant economic impact on a substantial number of small entities, and do not meet any of the criteria for a major regulation under Executive Order 12291. While under these regulations the State agencies will be required to conform to a more rigorous schedule for completing their reviews and submitting review data, the number of reviews States will be required to conduct remains unchanged. These regulations require a change in State agency review data submission procedures, but not in actual collection of review data.

Paperwork Reduction Act—The reporting and recordkeeping provisions described in these regulations have OMB approval. The reports and their corresponding OMB approval numbers are:

Title and OMB number

QC in AFDC and Adult Programs—0960-0146
Worksheet for Integrated QC—0960-0176
QC Negative Case Actions—0960-0156
Annual Corrective Action Plan and Progress Report—0960-0279

These regulations are issued under authority of section 1102 of the Social Security Act, as amended, 49 Stat. 647 as amended, 42 U.S.C. 1302.

(Catalog of Federal Domestic Assistance Programs No. 13.808 Public Assistance Maintenance Assistance (State Aid))

List of Subjects in 45 CFR Part 205

Administrative practice and procedure, Aid to families with dependent children, Family assistance office, Grant programs—social programs, Public assistance programs, Reporting requirements.

Dated: July 6, 1982.

John A. Svahn,

Commissioner of Social Security.

Approved: September 27, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

Chapter II, Title 45 of the Code of Federal Regulations is amended as set forth below:

PART 205—[AMENDED]

Section 205.40 is amended by adding new paragraphs (a)(10), (a)(11), and (b)(3), by deleting paragraph (b)(2)(vi), and by revising paragraphs (b)(2), (b)(2)(i), (b)(2)(ii), (b)(2)(iii), (b)(2)(iv), and (b)(2)(v) to read as follows:

§ 205.40 Quality control system.

(a) * * *

(10) "Disposed of case" means that a decision was made on the eligibility and payment status of a case under review or that the case was dropped or listed in error.

(11) "Edited review findings" means that the findings on the review schedule have been screened to insure the data are both accurate and internally consistent.

* * * * *

(b) * * *

(2) The State agency shall submit to the Department, in such form and at such times as it prescribes:

(i) A description of the State agency's sampling plan for active cases and for negative case actions, which is to be submitted to the Department no later than 60 days before the start of each 6-month sampling period unless there has been no change in the State's sampling plan and it continues to meet Federal sampling requirements.

(ii) Edited review findings for the State agency's disposed of active cases and negative case actions. The State agency shall dispose of and submit—

(A) Ninety percent or all but five cases of the cases selected in the active case sample each month, and ninety percent or all but five cases of the cases selected in the negative case sample each month, within 75 days after the end of the sample month;

(B) One hundred percent of the cases selected in the active and negative case samples during the first, second, and third sample months within 120 days after the end of the third sample month; and

(C) One hundred percent of the cases selected in the active and negative case samples during the fourth, fifth, and sixth sample months within 120 days after the end of the sixth sample month.

(iii) On a monthly basis, the edited review findings for the sample cases disposed of in the preceding month.

(iv) The following corrective active material:

(A) A corrective action plan for reducing case error rates for ineligibility, overpayments, and underpayments, including an error analysis and profiles of error and non-error cases by August 15 of each year based on findings from both the active case and negative case samples for the preceding April-September and October-March sample periods.

(B) A progress report on the effectiveness of corrective actions taken since submission of the last report, by February 15 of each year.

(v) Other data and reports that the Commissioner requests.

(3) The State agency may submit an alternate completion plan for the Commissioner's approval if the State is unable to meet the requirements of paragraph (b)(2)(ii) of this section either as a result of circumstances of a permanent or recurring nature or as a result of the occurrence of an unforeseen event during the sample period. Until the Commissioner approves an alternate completion plan, the State must continue to comply with the requirements of paragraph (b)(2)(ii) of the this section.

(i) Alternate sample case completion plan based on permanent or recurring events.

(A) The Commissioner may approve an alternate completion plan where: The State's sample population is dispersed over such great distances that conducting the required number of field interviews needed to meet the

requirements of paragraph (b)(2)(ii) of this section is cost prohibitive; or the State's usual weather conditions or geography make significant numbers of the sample population inaccessible or difficult to contact during certain times of the year making it a hardship for the State to comply with the requirements of paragraph (b)(2)(ii) of this section;

(B) The alternate completion plan request must contain supporting evidence and data which justify the need for an alternate completion plan including a description of the population dispersal or population inaccessibility problems within the State and the reason(s) why the State cannot comply with the requirements of paragraph (b)(2)(ii) of this section;

(C) The alternative completion plan request must contain details on the agency's proposed schedule for completing the sample cases including: the sample period(s) to be covered by the plan; the revised completion dates and completion percentages; and a revised schedule for the submission of the sample case edited review findings. The alternate completion plan request must be submitted no later than 60 days before the start of the first 6-month sampling period covered by the plan; and

(D) Even if the alternate plan is approved, the agency must submit edited review findings on all cases selected in the sample for the six month period within 120 days after the end of the sixth sample month.

(ii) Temporary alternate completion plan based on unforseen events.

(A) The Commissioner may approve an alternate completion plan for a particular sample period where unforseen events occur which temporarily prevent the State from meeting the requirements of paragraph (b)(2)(ii) of this section. These events can include, but are not limited to—floods, earthquakes, computer breakdowns, snowstorms, labor disputes, etc.

(B) The temporary alternate plan request must: briefly describe the event(s) requiring the implementation of the temporary alternate plan; the period the revised schedule will be in effect; the revised completion dates; the revised completion percentages; and the revised schedule for submission of sample case edited review findings;

(C) A temporary alternate plan may allow the State agency to submit the edited review findings on its sample cases at later dates than specified in paragraph (b)(2)(ii).

* * * * *

[FR Doc. 82-28619 Filed 10-18-82; 8:45 am]
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Proposed Rules

Federal Register
Vol. 47, No. 202
Tuesday, October 19, 1982

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.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

1 CFR Ch. III

Limitations on Judicial Review of Rules

AGENCY: Administrative Conference of the United States

ACTION: Request for Public comments

SUMMARY: The Administrative Conference's Committee on Judicial Review has under consideration a draft recommendation concering limitations on judicial review of agency rules in enforcement proceedings. Interested persons are invited to comment on the draft recommendation.

DATE: Comment Deadline: November 3, 1982.

ADDRESS: Comments should be submitted to: Administrative Conference of the United States, 2120 L Street, N.W., Suite 500, Washington, D.C. 20037.

FOR FURTHER INFORMATION CONTACT: Mary Candace Fowler, (202) 254-7065.

SUPPLEMENTARY INFORMATION: The draft recommendation under consideration by the Administrative Conference Committee on Judicial Review deals with limitations on judicial review of agency rules at the enforcement stage. It represents only the tentative views of the Committee and has been agreed to solely for the purpose of soliciting public comment. The draft recommendation identifies types of issues for which judicial review should ordinarily be limited to a brief period after adoption of the rule (*i.e.*, adequacy of rulemaking procedure and adequacy of the rulemaking record before the agency) and other types of issues that should ordinarily remain open for judicial review in later enforcement proceedings (*i.e.*, statutory authority for a rule and application of a rule to a particular respondent). It endorses further limits on the scope of enforcement judicial review when Congress determines that uniform standards must be promptly and finally established. The draft recommendation calls on Congress to implement these principles in any legislation narrowing judicial review of rules or, alternatively, by a general amendment to the Administrative Procedure Act.

The draft recommendation under consideration is based on a report to the Committee by consultant Paul Verkuil, Dean of the Tulane Law School. The report, currently in draft form, reviews relevant statutes, case law, and legal doctrines to determine what limits are now placed, and what limits might properly be placed, on the availability of judicial review of rules in enforcement proceedings. Copies of the draft report may be obtained from the Administrative Conference.

The Committee particularly desires comments on the practical impact of limitations on review like those described in the draft recommendation. Is there usually some party who is both willing and able to raise issues of rulemaking procedure or adequacy of record support in a pre-enforcement review proceeding? Are those who may be affected by rule sufficiently aware of its adoption to challenge the rule at that time? Will parties really be prejudiced if judicial review of these issues is foreclosed in proceedings arising after a limited post-adoption period? Does the draft recommendation put the right issues in each category (review limited/review ordinarily not limited)? Have challenges to rules in enforcement proceedings on the basis of flaws in the rulemaking process proved a problem to agencies and courts?

Comments on the draft recommendation should be submitted to Mary Candace Fowler at the above address no later than November 3, 1982. The Committee will meet on November 8, 1982 to reconsider the proposal in light of the comments received.

Dated: October 14, 1982.

Richard K. Berg,
General Counsel.

Draft Recommendation 82——, Limitations on Judicial Review of Rules

Preamble

A person adversely affected by an agency rule may ordinarily obtain judicial review of that rule either by instituting a direct review proceeding against the agency in an appropriate court (pre-enforcement review) or by asserting the invalidity of the rule as a defense in a civil or criminal proceeding to enforce the rule (enforcement review).[1] Prior to the Supreme Court's decision in *Abbott Laboratories v. Gardner*, 337 U.S. 136 (1967), direct review was generally difficult to obtain because of technical defenses such as lack of ripeness or lack of standing and most review of rules took place in the context of enforcement proceedings.

Under *Abbott Laboratories* and subsequent decisions, direct review of agency rules has become increasingly available. Congress in much recent regulatory legislation has specifically provided for immediate resort to judicial review at the conclusion of the rulemaking proceeding. As a result, direct judicial review of rules has come to be regarded as the norm and review in an enforcement proceeding as something of an exception.

At the same time, and perhaps largely as a result of increasing importance of direct judicial review of rules, courts have intensified their scrutiny of the administrative process proceeding promulgation of the rule. Whereas in the pre-*Abbott Laboratories* era challenges to rules were most frequently based on assertions of lack of agency authority or in inapplicability of the rule to the party's particular circumstances, today the issues in direct review proceedings are usually whether the agency made the proper procedural choices and whether the rule finds adequate support in the administratve record.

The Administrative Procedure Act does not by its terms establish different standards of review for direct review proceedings and enforcement proceedings, and few courts have considered the implications for review in enforcement proceedings of the increasingly intensive standard developed in direct review proceedings. Congress has, however, in a number of major statutes sought to encourage prompt direct review. To do so it has explicitly or impliedly limited the availability of review in enforcement proceedings. However, these preclusion

[1] We use the term "direct review" to refer to judicial review of a rule of general applicability before the rule is applied to a particular person in an adjudicative proceeding. Such review may be by the court of appeals pursuant to a special statutory review procedure or by the district court in the exercise of its power under the Administrative Procedure Act to review agency action not otherwise reviewable. *See* Recommenations Nos. 74-4, 75-3.

provisions have been somewhat unclear and undiscriminating in distinguishing between objections which may be raised only in direct review and those which may be asserted in a subsequent enforcement proceeding.

Sound principles of administrative law favor prompt and dispositive resolution of issues arising from an administrative proceeding, whether that proceeding is rulemaking or adjudication. Agency action should not be open for an indefinite period to challenges based on asserted errors in the administrative process. Objections on procedural grounds should be raised early so that errors may be remedied promptly and the rulemaking process recommenced with a minimum of disruption to the interests of those affected by the rule. And objections based on asserted inadequacy of the administrative record lose their relevance as that record itself becomes cold. These considerations argue for a statutory requirement that objections arising from a rulemaking proceeding be asserted promptly upon the conclusion of the proceeding.

On the other hand, there may be constitutional inhibitions against precluding or restricting at any time challenges based on the asserted unconstitutionality of a rule either on its face or as applied. Even apart from constitutional questions, considerations of fairness and judicial economy may argue for retaining a right to raise in enforcement proceedings those objections based on asserted lack of statutory authority or the inapplicability or unreasonableness of the rule as applied to the facts of the case.

The purpose of this recommendation is to suggest those grounds for review which should ordinarily be available to a person challenging the rule only in the period immediately following the issuance of the rule and those grounds which should ordinarily be available for an indefinite period.[2]

Recommendation

1. Where pre-enforcement judicial review is available, judicial review of issues relating to procedures employed in the rulemaking or the adequacy of factual support for the rule in the administrative record should ordinarily be foreclosed after a brief period (for example, 60 days) following promulgation of the rule.

2. In exceptional situations where Congress concludes that there is a compelling need to establish the legality of uniform standards promptly and with finality, it may appropriately further limit the scope of review available after this period has expired, subject to the minimum level of judicial review required under the Constitution.

3. Judicial review of issues relating to the statutory or constitutional authority for the rule or the application of the rule to a particular respondent or defendant should ordinarily be permitted when raised in subsequent suits or as defenses to subsequent enforcement actions (subject to the principles of collateral estoppel and stare decisis).

4. Congress should implement the principles stated above [by amending the Administrative Procedure Act, 5 U.S.C. ch 7, to narrow the scope of judicial review of rules in enforcement proceedings generally. Absent such general legislation, Congress should implement the principles] in any legislative provision that seeks to narrow the scope of judicial review of particular categories of rules in enforcement proceedings.

5. The Conference expresses no view on whether, in the absence of a statutory provision specifically or impliedly precluding or restricting judicial review, the courts should regard as mooted by the passage of time objections to a rule based on irregularities in the rulemaking proceeding or lack of an adequate factual basis in the administrative record.

[6. If a court finds that in an occasional case foreclosure of issues described in paragraphs 1 and 2 will work a severe hardship or produce a manifestly inefficient outcome, a court should consider dismissing or staying the proceedings and referring the rule to the affected agency for its reconsideration.]

7. Paragraph 4 of Recommendation No. 76-4, Judicial Review Under the Clean Air Act and Federal Water Pollution Control Act, is hereby superseded to the extent that it is inconsistent with this recommendation.

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BILLING CODE 6110-01-M

[2] In this recommenation we distinguish between direct review proceedings which we assume have been instituted within any applicable time limit prescribed by statute or, in the case of non-statutory direct review under the APA, within a relatively short period after promulgation of the rule, and enforcement proceedings which have been instituted by the Government or by a private party at some subsequent time. However, it must be emphasized that the basis of the distinction we propose is the timing rather than the form of the review proceeding. Thus, where an enforcement proceeding is instituted within the relevant statutory period for direct review, the full range of issues should be available for review (subject to any statutory provisions regarding exclusivity of forum for review). Similarly, where there has been a considerable lapse of time between the promulgation of a rule and the initiation of a proceeding for nonstatutory direct review, those issues which under the present formulation would be precluded in an enforcement proceeding should likewise be precluded in the direct review proceeding.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 293

Personnel Records and Files

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management is revising its regulations implementing the Freedom of Information Act (FOIA) and in the process will be eliminating from that section of its regulations the material on the availability of information that may be maintained in the Official Personnel Folders (OPF) of Federal employees. This document proposes to incorporate that material in a revised version of Part 293 of the Office's regulations on personnel records and files.

DATE: Comments must be received on or before December 20, 1982.

ADDRESS: Mail or deliver written comments to: Assistant Director for Workforce Information, Office of Personnel Management (Room 6429), 1900 E Street, N.W., Washington, D.C. 20415. Comments received will be available for public inspection at the above address between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: William H. Lynch, Work Force Records Management Division, (202) 254-9790/9793.

SUPPLEMENTARY INFORMATION: The Office has revised its regulations at 5 CFR 294, which implement the Freedom of Information Act, and is dropping from those regulations specific guidelines on what information is available from various types of personnel records. One section to be dropped from Part 294 is Subpart G, Official Personnel Folder, which describes items of information which if maintained in an Official Personnel Folder (OPF) would be releasable on that employee. The Office has determined that such regulations more appropriately belong in Part 293, Personnel Records, and proposes to incorporate the former 5 CFR 294, Subpart G (except for section 294.703 which will be deleted) into 5 CFR 293, Subpart C. Additionally, since the Office has issued final regulations on performance records (47 FR 3077) which contain a reference to these revised

regulations, this section is also being changed to reflect that those performance-related records discussed are actually being maintained in the Employee Performance File system (including performance folders, envelopes in the OPF, or supervisor's work folders) rather than the OPF.

Proposal

The Office is also proposing several changes to these regulations. These changes would: (1) Provide more detailed instructions on processing Freedom of Information Act requests for data; (2) add "occupational series" and "performance elements and standards" to the list of data elements considered public information for most current and former Federal employees (except where the release of performance elements and standards (or work expectations) would interfere with law enforcement programs, severely inhibit agency effectiveness, or where the elements and standards (or work expectations) are so intertwined with performance appraisals that their disclosure would reveal an individual's appraisal); (3) specifically include reference to data elements which are considered public information for most current and former appointees to the Senior Executive Service (SES), (4) eliminate the section describing release of educational data for historical or research purposes; and (5) make information previously releasable to prospective non-Federal employers a routine use disclosure under the Privacy Act rather than one compelled by the Freedom of Information Act.

Reasons for Proposal

The inclusion of "occupational series" is designed to provide a requester with more meaningful data than mere position titles, since a description of the duties of an incumbent of that series is available in published classification and qualification standards. The inclusion of "performance elements and standards" (except as noted above) among the list of releasable data (both for SES and other employees) is consistent with the Office's past and current policy that the functions of a Federal organizational unit are available to the public; therefore, a job sheet, or a description of a group of duties assigned to an individual to carry out the functions of the unit are also available to the public. The establishment of the SES as a new service, apart from the competitive and excepted services, requires specific mention of information on SES appointees. The description of the release of data pursuant to a request from a person engaged in research for historical, educational, or similar purposes is being deleted in its entirety. release of data to such a requester, and other persons who assert a public interest in the data, will be made on a case-by-case basis consistent with the Freedom of Information and Privacy Acts. The release of data to a prospective non-Federal employer is more appropriately done under a Privacy Act routine use, with the attendant accounting of disclosure.

E.O. 12291, Federal Regulation

OPM has determined that this is not a major rule as defined under Section 1(b) of E.O. 12291, Federal Regulations.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it affects maintenance of records of Government employees only.

List of Subjects in 5 CFR Part 293

Government employees, Privacy, Archives and records.

Office of Personnel Management.

Donald J. Devine,

Director.

Accordingly the Office proposes to amend 5 CFR Part 293 as follows:

(1) The Table of Sections is revised to read as follows:

PART 293—PERSONNEL RECORDS

Subpart A—Basic Policies on Maintenance of Personnel Records

Sec.
293.101 Purpose and scope.
293.102 Definitions.
293.103 Recordkeeping standards.
293.104 Collection of information.
293.105 Restrictions on collection and use of information.
293.106 Safeguarding information about individuals.
293.107 Special safeguards for automated records.
293.108 Rules on conduct.

Subpart B—Personnel Records Subject to the Privacy Act

293.201 Purpose.
293.202 Records subject to Office or agency Privacy Act regulations.
293.203 Review of Office or agency practices.

Subpart C—Official Personnel Folder

293.301 Applicability of regulations.
293.302 Establishment of Official Personnel Folder (OPF).
293.303 Ownership of folder.
293.304 Maintenance and content of folder.
293.305 Type of folder to be used.
293.306 Use of existing folders upon transfer or reemployment.
293.307 Disposition of folders of fomer Federal employees.
293.308 Removal of temporary records from folders.
293.309 Reconstruction of lost folders.
293.310 Response to requests for information.
293.311 Availability of information.

Authority: 5 U.S.C. 552a; Executive Order 12107, (December 28, 1978); 5 U.S.C. 1302, 3 CFR 1954–1958 Compilation; 5 CFR 7.2; Executive Order 9830; 3 CFR 1943–1948 Compilation.

* * * * *

(2) Subpart C is revised to read as follows:

Subpart C—Official Personnel Folder

§ 293.301 Applicability of regulations.

This subpart applies to, and within this subpart "agency" means, each executive department and independent establishment of the Federal Government, each corporation wholly owned or controlled by the United States, and with respect to positions subject to civil service rules and regulations, the legislative and judicial branches of the Federal Government.

§ 293.302 Establishment of Official Personnel Folder.

Each agency shall establish an Official Personnel Folder for each employee occupying a position subject to this part, except as provided in § 293.306. Except as provided in the Federal Personnel Manual, there will be only one Official Personnel Folder maintained for each employee regardless of service in various agencies.

§ 293.303 Ownership of folder.

The Official Personnel Folder of each employee in a position subject to civil service rules and regulations is under the jurisdiction and control of, and is part of the records of, the Office of Personnel Management.

§ 293.304 Maintenance and content of folder.

The head of each agency shall cause to be maintained in the Official Personnel Folder the reports of selection and other personnel actions covered by section 2951 of title 5, United States Code. The folder shall also contain permanent records affecting the employee's status and service, as required by the Office's instructions in the Federal Personnel Manual.

§ 293.305 Type of folder to be used.

Each agency shall use only Official Personnel Folders from Federal Supply Service stock (Standard Form 66) for the folders required by this part.

§ 293.306 Use of existing folders upon transfer or reemployment.

When an agency hires a person who has served on or after April 1, 1947, in a position subject to this part, it shall request the transfer of the Official Personnel Folder pertaining to the person's employment. The folder so obtained shall be used in lieu of establishing a new Official Personnel Folder.

(a) When a person for whom an Official Personnel Folder has been established transfers from one agency to another, the last employing (losing) agency shall, on request, transfer the folder to the new employing agency.

(b) Before transferring the Official Personnel Folder, the losing agency shall:

(1) Remove those records of a temporary nature filed on the left side of the folder; and

(2) Ensure that all permanent documents in the folder are complete, correct, and present in the folder in accordance with Federal Personnel Manual instructions.

§ 293.307 Disposition of folders of former Federal employees.

(a) Folders of persons separated from Federal employment must be retained by the losing agency for thirty working days after separation, and may be retained for an additional sixty days (ninety days where administratively necessary, e.g., where an appeal or an allegation of discrimination is made or where an employee retires or dies in service). Thereafter, the folder must be transferred to the General Services Administration, National Personnel Records Center (Civilian), 111 Winnebago Street, St. Louis, Missouri 63118.

(b) When a former Federal employee is reappointed in the Federal service, the National Personnel Records Center (Civilian) shall, upon request, transfer the folder to the new employing agency.

§ 293.308 Removal of temporary records from folders.

The employing agnecy having possession of an Official Personnel Folder shall remove temporary records from the folder before it is transferred to another agency. For these and also for temporary records of their current employees, maintenance of the records shall be in accordance with General Records Schedule 1, promulgated by the General Services Administration.

§ 293.309 Reconstruction of lost folders.

Agencies will take necessary precautions to safeguard all Official Personnel folders; in the event of a lost or destroyed folder, the current (or last, in the case of a former Federal employee) employing agency shall take the necessary action to reconstruct the essential portions of the folder as specified in Federal Personnel Manual or other Office instructions.

§ 293.310 Response to requests for information.

The Office, or an agency in physical possession of an OPF (for this section, also included are employee performance file system folders and files), in response to a third party Freedom of Information Act (FOIA) request may disclose information as provided in this subpart. A current employee's request for access to his/her own record that cites the FOIA, as with all stated Privacy Act requests made by current employees, shall be processed in accordance with agency Privacy Act procedures consistent with Office regulations in Part 297 of this chapter. All requests for their records from former employees, and FOIA requests for former employee OPFs, shall be referred to the Office's regional or area office nearest to the location of the requester.

§ 293.311 Availability of information.

(a) The following information from both the Official Personnel Folder and employee performance file system folders, their automated equivalent records, or from other personnel record files that constitute an record within the meaning of the Freedom of Information Act and which are under the control of the Office, about most present and former Federal employees (including members of the Senior Executive Service), is available to the public:

(1) Name;

(2) Present and past position titles and occupational series;

(3) Present and past grades;

(4) Present and past annual salary rates (including performance awards or bonuses, incentive awards, merit pay amount, Meritorious or Distinguished Executive Ranks, and allowances and differentials);

(5) present and past duty stations (includes room numbers, shop designations, or other identifying information regarding buildings or places of employment); and

(6) position descriptions, identification of critical and non-critical job elements, and those performance standards (but not actual performance appraisals) the release of which would not interfere with law enforcement programs or severely inhibit agency effectiveness. Performance elements and standards (or work expectations) may be withheld when they are so intertwined with performance appraisals that their disclosure would reveal an individual's performance appraisal.

(b) The Office or agency will generally not disclose this information where the data sought is a list of names, present or past position titles, grades, salaries, performance standards, and/or duty stations of Federal employees which, as determined by the official responsible for custody of the information:

(1) Is selected in such a way as to call for a response that would reveal more about the employee on whom information is sought than the six enumerated items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; or

(2) Would otherwise be protected from mandatory disclosure under an exemption of the Freedom of Information Act.

(c) In addition to the information described in paragraph (a) of this section, a Government official may provide other information from these records (or automated equivalents) of an employee, to others outside of the agency, under a summons, warrant, subpoena, or other legal process; as provided by the Privacy Act (5 U.S.C. 552a (b)(4) through (b)(11)); under those Privacy Act routine uses promulgated by the Office; and as compelled by the Freedom of Information Act.

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5 CFR Part 294

Availability of Official Information

AGENCY: Office of Personnel Management.

ACTION: Proposed rulemaking.

SUMMARY: OPM proposes to revise its regulations on the availability of information to simplify the regulations and effect needed changes.

DATE: Comments by: December 20, 1982.

ADDRESS: Send or deliver written comments to: William C. Duffy, Chief, Information Systems Plans and Policies Branch, U.S. Office of Personnel Management, 1900 E Street, N.W. Room 6410, Washington, D.C. 20415.

FOR FURTHER INFORMATION CONTACT: Charles R. Chesek, (202) 632-6883.

SUPPLEMENTARY INFORMATION: Primarily, these changes would simplify and clarify the regulations for public access to OPM information, by emphasizing active voice and

eliminating redundancy. Except as detailed below, all changes fall in this category.

Section 294.101 would clarify that these regulations apply to obtaining information from the Office of Personnel Management, not from other agencies.

Section 294.103 would delete the previous material which essentially duplicated other portions of the Part, as well as material in other parts; and would substitute wording clarifying an ambiguity resulting from overlapping access laws.

Section 294.105(b) would add several information areas to the list of OPM information subjects and identify the offices responsible for them; (d) would change the sequence of OPM regional offices to conform to the sequence used in most Federal publications; and the old (f) would become (e), replacing material which is included in Part 297, and is amply cited elsewhere in this Part.

Section 204.106(c) would delete the specific instructions for access by persons to their own records, since Part 297 gives them also.

Section 294.107(d) would raise the threshold amount for requiring advance agreement to pay charges for providing information, when appropriate, to $25. This reflects both the higher cost to the Government of an information search, and OPM's experience with the cost of collecting small sums of money versus the cost of complying with information requests. Similarly, (e) would raise the deposit requirement from 20 to 50 percent to provide ample leeway to allow for error in computing the cost estimate. A new paragraph (g) would state that OPM may reduce or waive fees in the public interest.

Section 204.108 would distinguish among differing circumstances of an appeal and provide appropriate guidance for each.

Section 294.109(b) would refer users to Part 297, which has the same guidance and is the proper place for the regulation.

Section 294.110 would be eliminated, in view of common law principles regarding the right to privacy.

Subpart D, Section 204.401(b), would be deleted, since Part 297 covers it, and reference to other agencies would be deleted from the remaining portion.

Subpart F, Section 294.601 (d) and (f), would delete references to other Government agencies.

Subpart G would be deleted, and the material incorporated in Part 293 of this chapter. (The proposed amendment to Part 293 is also published in this issue of the **Federal Register**.) A new Subpart J, Access References, cross-references this material.

Subpart I, Retirement, would be deleted, because it merely referred a reader to § 831.106 of this chapter. The new Subpart J also cross-references this.

Subpart K, Section 294.1101 (renumbered Subpart I, Section 294.901), would be revised to delete reference to other Government agencies.

The Office of Personnel Management is considering relocating Subparts D, E, F, G, H, and I to the parts of its regulations which deal with the subject matter involved. For example, this revision moves material on access to the Official Personnel Folder to the regulations on the Official Personnel Folder, in Part 293.

E.O. 12291, Federal Regulation

OPM has 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 this regulation will not have a significant economic impact on a substantial number of small entities, as it relates entirely to procedures for requesting information from the Office of Personnel Management.

List of Subjects in 5 CFR Part 294

Administrative practice and procedure, Classified information, Freedom of information, Health records, Investigations, Retirement.

U.S. Office of Personnel Management.

Donald J. Devine,

Director.

Accordingly, OPM proposes to revise 5 CFR 294, to read as follows:

PART 294—AVAILABILITY OF OFFICIAL INFORMATION

Subpart A—General Provisions

Sec.

294.101 Purpose.
294.102 Definitions.
294.103 Access to the requester's own records.
294.104 Information available—Indexes of certain records.
294.105 Places to obtain information.
294.106 Procedures for obtaining information.
294.107 Service charges for information.
294.108 Appeal of a denial of information.
294.109 Custody of information; subpoenas.

Subpart B—The Public Information Function

294.201 Public information policy.

Subpart C—Office Operations

294.301 Policy and interpretations.

Subpart D—Medical Information

294.401 Medical information.

Subpart E—Examinations and Related Subjects

294.501 Examinations.

Subpart F—Investigations

294.601 Investigative reports.

Subpart G—Appeals

294.701 Classification appeals.

Subpart H—Classified Information

294.801 Classified information.

Subpart I—Leave Records

294.901 Leave Records.

Subpart J—Access References

294.1001 Access References

Authority: 5 U.S.C. 552, Freedom of Information Act, Pub. L. 92-502.

Subpart A—General Provisions

§ 294.101 Purpose.

This part states the time, place, fees, and procedures to follow in requesting agency records from the Office of Personnel Management.

§ 294.102 Definitions.

In this part: (a) "Information" means books, papers, manuals, records, photographs, and other documentary materials, regardless of physical forms or characteristics, made in or received by or under the control of the Office in pursuance of law or in connection with the discharge of official business;

(b) "Information available to the public" means information, including reasonably-segregable nonexempt portions of information that may lawfully be withheld, which, on request, the public may examine or copy, or obtain copies of, in accordance with this part regardless of interest and without specific justification; and

(c) "Disclose or disclosure" means making information available, on request, for examination and copying, or furnishing a copy of the information.

§ 294.103 Access to the requester's own records.

When a request for a record from a Privacy Act system of records, as defined by 5 U.S.C. 552a(a)(5), comes from the subject of the record, or the subject's duly authorized representative, and the record is retrieved by the subject's name or other personal identifier, then the Office will handle the request under the procedures in 5 CFR 297.

§ 294.104 Information available—Indexes of certain records.

(a) The Office maintains, and revises at least quarterly, an index of materials published and offered for sale or

available for public inspection and copying.

(b) A copy of this index is available at no cost from:

Distribution Services Unit, Office of Personnel Management, 1900 E Street, N.W., Washington, D.C. 20415.

The Office indexes these materials for the convenience of the public. Indexing does not constitute a determination that all of the materials listed are within the category of those required to be indexed by 5 U.S.C. 552(a)(2).

§ 294.105 Places to obtain information.

(a) A requester who believes that the Office headquarters in Washington, D.C., has the desired information should address the request to the associate director or head of other office indicated in the list in paragraph (b) of this section. The address for all such requests is:

Office of Personnel Management, 1900 E Street, N.W., Washington, D.C. 20415.

(b) The following lists the groups and offices of the Office in Washington, D.C., and their principal areas of responsibility:

Submit to	For subject-matter about—
Associate Director for Administration	Senior Executive Service; selection of Federal executives; delegation agreements; and grants to State and local governments.
Associate Director for Compensation	Employee compensation: pay, leave, retirement, insurance, and benefits; and incentive and performance pay guidelines.
Assistant Director for Agency Compliance and Evaluation.	Evaluation of personnel management in agencies; classification and job-grading appeals; reduction-in-force complaint files; appeal of loss of retained grade and rate of pay files; and files for allegations of agency non-compliance with OPM regulations, such as those under the Fair Labor Standards Act.
Assistant Director for Work Force Information	Government-wide statistical personnel information; and information principally in the Official Personnel Folder and the Central Personnel Data File.
Assistant Director for Personnel Investigations	Background investigations of Federal employees and applicants for Federal employment.
Associate Director for Staffing	Nationwide recruiting and job information; examining services for entry and promotion; selection methods; position classification standards; qualification standards; examination rating reviews; test scoring services; reduction-in-force policy; student employment programs; non-competitive case file records; and the Administrative Law Judge program.
Associate Director for Workforce Effectiveness and Development.	Productivity and quality of work life; development of Government-wide occupational health programs; employee relations, discipline, and performance evaluation; incentive awards; job-related training, training information, and training available to Government employees, including developing and training executives; equal employment opportunity and affirmative action; veteran perference; the Presidential Management Intern Program and intergovernmental mobility; and technical information and policy guidance about management and employee unions in the Federal service.
Assistant Director for Planning and Evaluation	Merit System Standards.
Director, Office of Government Ethics	Executive branch policy relating to ethics and conflict of interest.

(c) Direct a request for information on a subject not specifically referred to in this section or in the index, to:

Information Systems Plans and Policies Branch, Office of Personnel Management, 1900 E Street, N.W., Washington, D.C. 20415.

(d) A person who believes that a regional office, area office, or post of duty of the Office has the desired information should send the request to the Regional Director, Office of Personnel Management Regional Office, at the appropriate address indicated in the following list:

John W. McCormack Post Office and Courthouse, Boston, Massachusetts 02109
New Federal Building, 26 Federal Plaza, New York, New York 10278
William J. Green, Jr., Federal Building, 600 Arch Street, Philadelphia, Pennsylvania 19106
Richard B. Russell Federal Building, 75 Spring Street, SW, Atlanta, Georgia 30303
John Kluczynski Building, 230 South Dearborn Street, Chicago, Illinios 60604
1100 Commerce Street, Dallas, Texas 75242
300 Old Post Office Building, 815 Olive Street, St. Louis, Missouri 63101
Denver Federal Center, Building 20, Denver, Colorado 80025
525 Market Street, 23rd Floor, San Francisco, California 94105
Federal Office Building, 26th Floor, 915 Second Avenue, Seattle, Washington 98174

(e) If an OPM group or office receives a request for information it does not have, the recipient office will promptly forward the request to the appropriate group or office and will notify the requester that it has done so. However, for purposes of applying the time limits in section 552 of title 5, United States Code, the request will not be considered received until it arrives in the group or office having possession of the requested information.

§ 294.106 Procedures for obtaining information.

(a) A person may request information under section 552 of title 5, United States Code, by letter directed to one of the groups and other offices listed in § 294.105; or deliver a request in person at the addresses listed in that section during business hours on a regular business day.

(b) Each request for information under section 552 of title 5, U.S.C. should clearly and prominently have a notation onn the first page, such as "Freedom of Information Request." In addition, if sent by mail or otherwise submitted in an envelope or other cover, mark the outside clearly and prominently with "FOIA Request" or "Freedom of Information Act Request."

(c) A request under this part should reasonably describe the information being requested by including revelant data such as name, number, date, subject, title of publication, or other identifying particulars sufficient to enable the Office to identify and locate the information.

(d) If a request includes materials published and offered for sale, e.g., by the Superintendent of Documents, the Office will advise the requester of the appropriate group or other office where the requester may review, and location where the requester may purchase, the materials.

(e) Except in unusual circumstances, the Office will determine whether to disclose or deny the requested information within ten working days after receipt of the request (excluding Saturdays, Sundays, and holidays) and will notify the requester immediately of its determination and the fees required, if any, as prescribed by § 294.107.

§ 294.107 Service charges for information.

(a) The Office will furnish reasonable quantities of information that it has printed or otherwise reproduced for the purpose of making it available to the public without charge.

(b) The Office may furnish information made available to the public, other than that described in paragraph (a) of this section, subject to payment of a fee. Pay the fee by check or money order, payable to the Office of Personnel Management.

(c) Schedule of Fees—When responding to a request for information under section 552 of title 5, U.S.C., the Office will charge fees for searching and duplicating the information at the following rates:

Photocopies per page	$0.10
Printed material per 25 pages or fraction thereof	.25
Manual records search, per hour:	
Professional employees	9.00
Clerical employee	5.00
Automated Records search:	
Programming, per hour	17.00
Keypunching, per 1,000 card-image records	183.00
Duplication, per hour	45.00
Computer time, per quarter-hour	219.00

NOTE.—Charges will be assessed only for actual resources used.

(d) Unless the request specifically states that the requester will accept any cost involved, or specifies an amount acceptable to the requester and sufficient to cover anticipated costs, the Office will not count as received a request which reasonably may exceed $25 in assessed fees until the requester, after prompt notification of the anticipated cost of the request, agrees to bear it.

(e) When the anticipated fees exceed $50, the requester must deposit at least 50 percent of the amount anticipated within 30 days after notification of that fact. The Office will not release the requested information until it has received the deposit.

(f) The Office will assess charges in cases of unproductive or unsuccessful searches unless an appropriate Office official waives charges. Services performed but not required under the Freedom of Information Act, such as formal certification of records as true copies, will be subject to charges under the Federal User Charge Statute (31 U.S.C. 483a) or other applicable statutes, depending upon the services performed.

(g) The Office will furnish information under the Freedom of Information Act without charge or at a reduced charge when the official considering the request for information finds waiver or reduction of fee in the public interest because furnishing the information primarily benefits the general public.

§ 294.108 Appeal of a denial of information.

(a) A person may appeal a denial by an OPM official of a Freedom of Information Act request to: General Counsel, U.S. Office of Personnel Management, Washington, D.C. 20415

(b) A person may appeal denial of a Freedom of Information Act request for information maintained by the General Counsel of the OPM to: Deputy Director, U.S. Office of Personnel Management, Washington, D.C. 20415.

(c) If an official of another agency denies a Freedom of Information Act request for information in one of OPM's Government-wide systems of records (see FPM Chapter 297, Appendix, for a list of these systems), the requestor should consult the agency's regulations for any appeal rights that may apply. An agency may, at its discretion, direct these appeals to OPM's General Counsel.

(d) An appeal should include a copy of the initial request, a copy of the letter denying the request, and a statement why the appellant believes the denying official erred.

§ 294.109 Custody of information; subpoenas.

(a) The Chief, Information Systems Plans and Policies Branch, Office of Management, has official custody of the official records of the Office. A subpoena or other judicial order for an official record from the Office should be served on the:

Chief, Information Systems Plans and Policies Branch, U.S. Office of Personnel Management, 1900 E Street, N.W., Washington, D.C. 20415.

(b) See § 297.505 for the steps other officials should take on receipt of a subpoena or other judicial order for an official personnel record.

Subpart B—The Public Information Function

§ 294.210 Public information policy.

(a) In addition to the basic policies of the Office relative to the disclosure of information when requested by a member of the public, the Office has an independent public information policy for bringing to the attention of the public through news releases, publications of the Office, or other methods, information concerning the functions of the Office as a Federal agency, and the programs administered by the Office.

(b) The Assistant Director for Public Affairs carries out the public information policy of the Office. In addition, each employee of the Office shall cooperate in carrying out this policy.

Subpart C—Office Operations

§ 294.301 Policy and interpretations.

(a) Statements of Office policy and interpretations of the laws and regulations administered by the Office which the Office has adopted, whether or not published in the Federal Personnel Manual or the **Federal Register**, are available to the public.

(b) Generally, memoranda, correspondence, opinions, data, staff studies, information received in confidence, and similar documentary material, when prepared for the purpose of internal communication within the Office or between the Office and other agencies, organizations, or persons, are not available to the public.

Subpart D—Medical Information

§ 294.401 Medical information.

The Office will not disclose to the public medical information about an applicant, employee, or annuitant.

Subpart E—Examinations and Related Subjects

§ 294.501 Examinations.

(a) The Office makes available information that will assist members of the public in undertaking the purpose of, and preparing for, civil service examinations. This includes the types of questions and the categories of knowledge or skill pertinent to a particular examination. The Office does not release the following: (1) Testing and examination materials used solely to determine individual qualifications; and

(2) Test material, including test plans, item analysis data, criterion instruments, and other material the disclosure of which would compromise the objectivity of the testing process.

(b) Each employee entrusted with test material has a positive duty to protect the confidentality of that material and to assure release only as required to conduct an examination authorized by the Office.

(c) An applicant may review his or her own answers in a written test, but only in the presence of an employee of the Office or, for the convenience of the Office and requestor, in the presence of an employee of another agency designated by OPM. The applicant may not review a test booklet in connection with this review.

(d) The Office will release information concerning the results of examinations only to the individuals concerned, or to parties explicitly designated by the individual.

(e) The Office will not reveal the names of applicants for civil service positions or eligibles on civil service registers, certificates, employment lists, or other lists of eligibles, or their ratings or relative standings.

Subpart F—Investigations

§ 294.601 Investigative reports.

(a) The disclosure requirements of the Freedom of Information Act do not apply when criteria established by an Executive order specifically authorize an agency to keep a matter secret in the interest of national defense or foreign

policy, and the agency has assured proper classification under that Executive order.

(b) The Act exempts investigatory records compiled for law enforcement purposes to the extent that the production of such records would (1) interfere with enforcement proceedings, (2) deprive a person of a right to a fair trial or impartial adjudication, (3) constitute an unwarranted invasion of personal privacy, (4) disclose the identity of a confidential source, and in the case of a record compiled by a criminal-law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (5) disclose investigative techniques and procedures, or (6) endanger the life and physical safety of law enforcement personnel.

(c) The Office usually does not release, under the Freedom of Information Act, the records of investigations of individuals. The Office will furnish, on request, a copy of a report of an investigation that it conducted, to the subject of the investigation or to the subject's representative designated in writing, with the exception of any material exempt from disclosure under paragraphs (a) and (b) of this section. If the investigative file maintained by the Assistant Director for Personnel Investigations contains information that originated in another agency, the Assistant Director for Personnel Investigations will refer a copy of the subject's request to that agency for decision concerning release of the information that originated in that agency.

(d) The Office will disclose to the parties concerned the report of an investigation under its control, or an extract, to the extent the report involves a proceeding under Part 771 of this chapter or the negotiated grievance procedures, except when disclosure would violate the proscription against the disclosure of medical information in § 294.401. In this paragraph, "the parties concerned" means the Government employee involved in the proceeding, the employee's representative designated in writing, and the representative of the agency involved in the proceeding.

(e) In suitability rating actions under Part 731 of this chapter, the Office will disclose to an applicant, eligible, appointee, or a representative designated in writing, information from reports of investigation which the Office considers sufficient to enable the person to respond to an interrogatory or other question, without revealing the source of information obtained under an expressed or implied pledge of confidence. The Office will furnish a report of investigation to the Government agency concerned.

(f) The Office does not release a report of investigation, or information from a report under its control, to the public, to witnesses, or, except as provided in paragraphs (a), (b), (c), and (d) of this section, to the parties concerned in the investigation.

Subpart G—Appeals

§ 294.701 Classification appeals.

The Office will disclose to the parties concerned the information contained in an appeal file in proceedings under Part 511 of this chapter, except when the disclosure would violate the proscription against the disclosure of medical information in § 294.401. For the purpose of this section, "the parties concerned" means an applicant for Government employment, or current or former Government employee, involved in the proceedings, that person's representative designated in writing, and the representative of the agency or the Office involved in the proceeding.

Subpart H—Classified Information

§ 294.801 Classified Information.

The Office will not disclose information classified under Executive Order 12356 of April 2, 1982, except to individuals authorized access under terms of that authority.

Subpart I—Leave Records

§ 294.901 Leave Records.

The Office will not disclose the annual and sick leave record of an employee, or information from these records, except as authorized.

Subpart J—Access References

§ 294.1001 Access references.

The table below provides assistance in locating OPM regulations on disclosure of information not covered by Part 294:

Type of information	Location
Official personnel folder	293.301
Protection of privacy and personnel records	297
Retirement	831.106

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BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 51

United States Standards for Grades of Potatoes for Processing [1]

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Agricultural Marketing Service proposes to revise the voluntary U.S. Standards for Grades of Potatoes for Processing. This action is being taken at the request of the Potato Growers of Idaho, Inc., Idaho Association of Commerce and Industry, and Ore-Ida. This revision would provide industry with standards in alignment with current cultural and processing practices.

DATES: Comments must be received on or before December 20, 1982.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in duplicate to the Hearing Clerk, U.S. Department of Agriculture, Rm. 1077, South Building, Washington, D.C. 20250. Comments should reference the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Hearing Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Donald T. Paradis, Fresh Products Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250, telephone (202) 447-2482.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

This action has been reviewed under USDA guidelines implementing Executive Order 12291 and Secretary's Memorandum 1512-1 and has been classified as a non-major rule.

Effect on Small Entities

Eddie F. Kimbrell, Deputy Administrator, Commodity Services, Agricultural Marketing Service, has determined this proposed rule would not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act, Pub. L. 96-354 (5 U.S.C. 601), because it reflects current marketing practices.

[1] Compliance with the provisions of these standards shall not excuse failure to comply with provisions of applicable Federal or State laws.

Background

In 1981 sixteen billion pounds of potatoes were used by the processing industry. More than ten billion pounds were inspected by the Federal-State Inspection Service under grower-processor contract specifications. Industry technological advances as well as significant cultural and marketing changes in recent years have brought about a need for changes in the approach to this phase of industry activity on the part of both industry and the Inspection Service.

The Potato Growers of Idaho, Inc., Idaho Association of Commerce and Industry (representing processors) and Ore-Ida (a multi-state processor), organizations representing a substantial portion of the potato processing industry, have requested a revision of the U.S. Standards for Grades of Potatoes for Processing which became effective in July 1963.

During 1981 a "Market Survey" was developed in cooperation with industry. The Survey outlined a proposed revision of the standards and was widely distributed to growers and processors for review and comment. Also, a Standardization Specialist attended a number of meetings with key state and industry personnel in the effort to provide standards compatible with current industry practices. Comments were generally favorable.

Proposed changes and additions in the standards include the following:

"Usable piece" would be redefined to eliminate several trimming requirements. This redefinition would reduce the number of requirements from ten to three and would eliminate most of the subjective assessments which would significantly reduce the evaluation time of the official sample.

In the application of these standards, tolerances would be provided for lots which are graded or pre-sorted for size or quality. The current standards lack the flexibility in this area to adequately cover changing delivery practices. As a result the usefulness of these standards as a basic part of grower-processor contracts has been diminished.

Tests for specific gravity and fry color would become optional. The use of optional procedures, in lieu of fixed, are preferable in that (1) not all processors use them, and (2) discretionary use of these procedures provides the processors with the opportunity to provide incentives to growers to produce and deliver a better quality product.

Test procedures for glucose determination would be eliminated. Industry has replaced use of this procedure with other more efficient and practical methods.

List of Subjects in 7 CFR Part 51

Fresh fruits, Vegetables and other products (inspection, certification, and standards)

Accordingly, it is proposed that U.S. Standards for Grades of Potatoes for Processing be revised to read as follows:

Subpart—United States Standards for Grades of Potatoes for Processing [1]

Sec.

51.3410 Grades.
51.3411 Usable Piece.
51.3412 Unusable Material.
51.3413 Size.
51.3414 Application of Standards.
51.3415 Definitions.
51.3416 Classification of Defects.
51.3417 Optional Test for Specific Gravity.
51.3418 Optional Test for Fry Color.

§ 51.3410 Grades.

(a) "U.S. No. 1 Processing" consists of potatoes which meet the following requirements:

(1) Basic Requirements:

(i) Similar varietal characteristics;

(ii) Moderately firm; and,

(iii) Fairly well shaped.

(2) Free From:

(i) Freezing or freezing injury;

(ii) Blackheart;

(iii) Late Blight Tuber Rot;

(iv) Southern Bacterial Wilt;

(v) Bacterial Ring Rot;

(vi) Soft rot and wet breakdown; and,

(vii) Loose sprouts, dirt and foreign material.

(3) Free from damage by any cause.

(4) Size. Unless otherwise specified, shall be not less than 2 inches in diameter or 4 ounces in weight. Percentage(s) of a larger size(s) and/or a maximum size may be specified.

(b) "U.S. No. 2 Processing" consists of potatoes or usable pieces of potatoes which meet the following requirements:

(1) Basic Requirements:

(i) Similar varietal characteristics;

(ii) Moderately firm; and,

(iii) Not seriously misshapen.

(2) Free From:

(i) Freezing or freezing injury;

(ii) Blackheart;

(iii) Late Blight Tuber Rot;

(iv) Southern Bacterial Wilt;

(v) Bacterial Ring Rot;

(vi) Soft rot and wet breakdown; and,

(vii) Loose sprouts, dirt and foreign material.

(3) Free from serious damage by any cause.

(4) Size. Unless otherwise specified, shall be not less than 1½ inches in diameter, or usable pieces shall be not less than 4 ounces in weight. Percentage(s) of a larger size(s) and/or maximum size may be specified.

§ 51.3411 Usable piece.

"Usable piece" means that portion of the tuber remaining after trimming, or as it occurs in the sample: Provided, that the remaining portion meets the following requirements:

(a) Shall not have any unusable material;

(b) Unless otherwise specified, shall weigh at least 4 ounces; and,

(c) Must have at least 50% of peel remaining after trimming.

§ 51.3412 Unusable Material.

"Unusable material" consists of defective portions of potatoes, and potatoes which are frozen, affected by freezing injury, soft rot, wet breakdown, Blackheart, Late Blight Tuber Rot, Southern Bacterial Wilt, Bacterial Ring Rot, or which are otherwise seriously damaged by internal defects.

§ 51.3413 Size.

(a) The minimum size, maximum size or range in size may be specified in connection with the grade in terms of diameter or weight.

(b) The diameter means the greatest dimension in terms of inches or fractions of an inch measured at right angles to the longitudinal axis, without regard to the position of the stem end.

(c) Weight means the minimum or maximum weight measured in terms of whole ounces. When a maximum weight is specified, the potato shall not be considered as oversized until it weighs the next higher ounce.

§ 51.3414 Application of Standards.

For lots graded or pre-sorted for size or quality, offered for inspection and required to meet one of the grades, the following specified tolerances, by weight, are provided:

(a) For defects:

(1) U.S. No. 1 Processing: 10 percent for potatoes which fail to meet the requirements of this grade including not more than one-half of this tolerance, or 5 percent, for serious damage by any means, including therein not more than 2 percent for potatoes which are frozen or affected by soft rot or wet breakdown.

(2) U.S. No. 2 Processing: 10 percent for potatoes which fail to meet the requirements of this grade including not more than one-half of this tolerance, or 5 percent, for potatoes which are seriously damaged by internal defects occurring entirely within the vascular ring,

[1] Compliance with the provisions of these standards shall not excuse failure to comply with provisions of applicable Federal or State laws.

including therein not more than 2 percent for potatoes which are frozen or affected by soft rot or wet breakdown.

(b) For loose sprouts, dirt and foreign material: 2 percent.

(c) For off-size:

(1) Undersize: 3 percent when the minimum size specified is less than 2¼ inches in diameter or less than 6 ounces in weight; and 5 percent when the minimum size specified is 2¼ inches or more in diameter or 6 ounces or more in weight.

(2) Oversize: 10 percent.

Note.—In the application of these standards to determine the percentages of potatoes in any lot which meet the requirements of the respective grades or size categories, *the general application of tolerances does not apply.*

§ 51.3415 Definitions

"Damage" means any defect listed in § 51.3416, or an equally objectionable variation of any one of these defects, any other defect, or any combination of defects, which cannot be removed without a loss or more than 5 percent of the total weight of the potato.

"Fairly well shaped" means that the potato is not materially pointed, dumbbell-shaped, or otherwise deformed.[2]

"Loose sprouts, dirt and foreign material" means unattached sprouts or sprouts that become detached during the grading of the sample, stems, vines, adhering dirt, loose dirt, stones, trash and other extraneous material.

"Moderately firm" means that the potato is not seriously shriveled or flabby.[2]

"Not seriously misshapen" means that the potato is not seriously deformed and causing more than 10% waste when determining the non-peelable area directly due to shape.

"Serious Damage" means any defect listed in § 51.3416, or an equally objectionable variation of any one of these defects, any other defect, or any combination of defects, which cannot be removed without a loss of more than 10 percent of the total weight of the potato.

"Similar varietal characteristics" means that the potatoes in any lot have the same general shape, color, and character of skin and color of flesh.

"Soft rot or wet breakdown" means any soft, mushy or leaky condition of the tissue such as leak, slimy soft rot, wet type Fusarium Tuber Rot, or wet breakdown following freezing injury or heat injury.

[2] USDA Visual Aid, POT-L 1 Jan 81. This publication may be examined in the Fruit and Vegetable Division, Fresh Products Branch, AMS, U.S. Department of Agriculture, South Building, Washington, DC 20250, or any field office of the Fresh Fruit and Vegetable Inspection Service. Copies of this visual aid may be purchased from the John Henry Company, P.O. Box 17099, Lansing, MI 48901 or United Fresh Fruit and Vegetable Association, N. Washington at Madison, Alexandria, VA 22314.

§ 51.3416 Classification of Defects.

EXTERNAL DEFECTS

Defects	Maximum allowed for processing	
	U.S. No. 1	U.S. No. 2
Air cracks	5 percent waste	10 percent waste.
Blackleg	do	Do.
Bruises	do	Do.
Cuts	Smooth, not more than 10 percent of surface	Smooth, not more than ⅛ of surface.
Enlarged lenticels, discolored or sunken	5 percent waste	10 percent waste.
Flea beetle	do	Do.
Folded end	do	Do.
Fusarium tuber rot	do	Do.
Grass, wireworm	do	Do.
Greening, light	do	Do.
Growth cracks	See No. 2	Do.
Grub	5 percent waste	Do.
Ingrown sprouts	do	Do.
Nematodes	do	Do.
Rhizoctonia, solid or thick mounded	Not more than 10 percent of surface	Not more than 25 percent of surface.
Rodent, bird damage	5 percent waste	10 percent waste.
Scab, pitted	do	Do.
Scab, russet	25 percent of surface	50 percent of surface.
Scab, surface	do	Do.
Scab, surface (elephant hide)	25 percent of surface or 5 percent waste	25 percent of surface or 10 percent waste.
Scaling, surface cracks—when cracked, thick and has depth	10 percent of surface or 5 percent waste	Do.
Sunburn	5 percent waste	10 percent waste.
Sunken discolored areas	do	Do.

"Internal defects" are defects which cannot be detected without cutting the potato.

INTERNAL DEFECTS

Defects	Maximum allowed for processing	
	U.S. No. 1	U.S. No. 2
Occurring outside of or not entirely confined to the vascular ring		
Internal black spot, internal discoloration, vascular browning, fusarium wilt, net necrosis, other necrosis, stem end browing.	5 percent waste	10 percent waste.
Occurring entirely within the vascular ring		
Hollow heart or hollow heart with discoloration	Area affected not to exceed that of a circle ⅞ inch in diameter on a 10 ounce potato.[1]	Area affected not to exceed that of a circle 1¼ inches in diameter on a 10 ounce potato.[1]
Light brown discoloration (brown center)	Area affected not to exceed that of a circle ⅞ inch in diameter on a 10 ounce potato[1].	Area affected not to exceed that of a circle 1¼ inches in diameter on a 10 ounce potato.[1]
Internal brown spot and similar discoloration (heat necrosis)	Not more than the equivalent of 3 scattered spots ⅛ inch in diameter on a potato 6 ounces in weight or 2½ inches in diameter, or correspondingly lesser or greater number of spots in smaller or larger potatoes.	Not more than the equivalent of 6 scattered spots ⅛ inch in diameter on a potato 6 ounces in weight or 2½ inches in diameter, or correspondingly lesser or greater number of spots in smaller or larger potatoes

[1] Note.—Or correspondingly lesser or greater areas on smaller or larger potatoes.

§ 51.3417 Optional test for specific gravity.

Tests to determine specific gravity shall be made in accordance with the procedures set forth in this section.

(a) The potatoes used for such determinations shall be:

(1) Taken at random from a composite sample drawn from containers representative of the lot.

(2) A comparable sample from a bulk load or storage bin.

(3) From a portion of the divided sample initially drawn or submitted for determination of grade or contract compliance.

(4) Shall be representative of the lot with respect to size and quality. The specific gravity for any lot of potatoes shall be the average of at least 3 corrected readings on separate tests from the composite sample. Specific gravity may also be determined, if requested, in accordance with size classifications or weighted value in proportion to size and/or grade separations in the lot.

(b) Specific gravity shall be determined by either:

(1) Calculation from the weights of the sample in air and in water, made with USDA approved equipment. The reading obtained from each test shall be corrected for temperature variations using Table I.

(2) A hydrometer, specifically designed for determining the specific gravity of potatoes.[4] The pulp temperature of the potatoes and the temperature of water shall be recorded immediately before testing and the specific gravity reading corrected using Table II.

[4] This hydrometer and a Chip Tester, a tape designed for glucose tests, are available from the Potato Chip/Snack Food Association, Crystal Square-3, Suite 903, 1735 Jefferson Davis Highway, Arlington, VA 22202.

TABLE I—CORRECTION FACTORS FOR SPECIFIC GRAVITY OF POTATOES[1]

[Corrected to zero at 50 F tuber temperature and 50 F water temperature]

Tuber temperature	Water temperature (degrees Fahrenheit)									
	38°	40°	45°	50°	55°	60°	65°	70°	75°	80°
38°	−0.0021	−0.0020	−0.0018	−0.0018	−0.0020	−0.0023	−0.0029	−0.0038	−0.0047	−0.0056
40°	−.0017	−.0016	−.0014	−.0014	−.0016	−.0019	−.0025	−.0034	−.0043	−.0052
45°	−.0009	−.0008	−.0008	−.0006	−.0008	−.0011	−.0017	−.0026	−.0035	−.0044
50°	−.0003	−.0002	0000	0000	−.0002	−.0005	−.0011	−.0020	−.0029	−.0038
55°	+.0001	+.0002	+.0004	+.0004	+.0002	−.0001	−.0007	−.0016	−.0025	−.0034
60°	+.0004	+.0005	+.0007	+.0007	+.0005	+.0002	−.0004	−.0013	−.0022	−.0031
65°	+.0005	+.0006	+.0008	+.0008	+.0006	+.0003	−.0003	−.0012	−.0021	−.0030
70°	+.0006	+.0007	+.0009	+.0009	+.0007	+.0004	−.0002	−.0011	−.0020	−.0029
75°	+.0007	+.0008	+.0010	+.0010	+.0008	+.0005	−.0001	−.0010	−.0019	−.0028
80°	+.0008	+.0009	+.0011	+.0011	+.0009	+.0006	0000	−.0009	−.0018	−.0027
85°	+.0009	+.0010	+.0012	+.0012	+.0010	+.0007	+.0001	−.0008	−.0017	−.0026
90°	+.0010	+.0011	+.0013	+.0013	+.0011	+.0008	+.0002	−.0007	−.0016	−.0025
95°	+.0011	+.0012	+.0014	+.0014	+.0012	+.0009	+.0003	−.0006	−.0015	−0024
100°	+.0012	+.0013	+.0015	+.0015	+.0013	+.0010	+.0004	−.0005	−.0014	−.0023

[1] To apply correction factor, change actual specific gravity reading by adding or subtracting the appropriate factor according to the plus or minus sign.

When requested to convert the weight in water of 5000 gram samples used in the weight in air versus weight in water method of specific gravity determinations, the conversion to total solids shall be based on Table II.

TABLE II. SPECIFIC GRAVITY CONVERSION CHART FOR 5,000 GRAMS OF POTATOES

Water weight	Specific gravity	Total solids	Water weight	Specific gravity	Total solids	Water weight	Specific gravity	Total solids
300	1.0638	17.2	358	1.0771	20.1	400	1.0870	22.2
310	1.0661	17.7	360	1.0776	20.2	402	1.0874	22.3
320	1.0684	18.2	362	1.0780	20.3	404	1.0879	22.4
322	1.0688	18.3	364	1.0785	20.4	406	1.0884	22.5
324	1.0693	18.4	366	1.0790	20.5	408	1.0888	22.6
326	1.0697	18.5	368	1.0794	20.6	410	1.0893	22.7
328	1.0702	18.6	370	1.0799	20.7	412	1.0898	22.8
330	1.0707	18.7	372	1.0804	20.8	414	1.0903	22.9
332	1.0711	18.8	374	1.0808	20.9	416	1.0908	23.0
334	1.0716	18.9	376	1.0813	21.0	418	1.0912	23.1
336	1.0720	19.0	378	1.0818	21.1	420	1.0917	23.2

TABLE II. SPECIFIC GRAVITY CONVERSION CHART FOR 5,000 GRAMS OF POTATOES—Continued

Water weight	Specific gravity	Total solids	Water weight	Specific gravity	Total solids	Water weight	Specific gravity	Total solids
338	1.0725	19.1	380	1.0822	21.2	422	1.0922	23.4
340	1.0730	19.2	382	1.0827	21.3	424	1.0926	23.5
342	1.0734	19.3	384	1.0832	21.4	426	1.0931	23.6
344	1.0739	19.4	386	1.0836	21.5	428	1.0936	23.7
346	1.0743	19.5	388	1.0841	21.6	430	1.0941	23.8
348	1.0748	19.6	390	1.0846	21.7	432	1.0946	23.9
350	1.0753	19.7	392	1.0851	21.8	440	1.0965	24.4
352	1.0757	19.8	394	1.0855	21.9	450	1.0989	24.9
354	1.0762	19.9	396	1.0860	22.0	460	1.1013	25.4
356	1.0766	20.0	398	1.0865	22.1	470	1.1040	26.0

Whenever the recorded water weight for an individual reading falls between two sets of numbers as indicated in Table II, the next higher reading shall be used.

§ 51.3418 Optional test for fry color.

Fry color may be determined by using the Munsell Color Standards for Frozen French Fried Potatoes, Third Edition, 1972, 64-1.[5] Select a minimum of twenty (20) potatoes at random from the official sample. Slice each tuber from stem to blossom end into ½ square inch strips. Unless otherwise specified, fry center cut strips in frying oil for a minimum of 3 minutes at 350° F or 2½ minutes at 375°F.

(Agricultural Marketing Act of 1946, Secs. 203, 205, 60 Stat. 1087, as amended, 1090 as amended (7 U.S.C. 1622, 1624))

Done at Washington, D.C. on October 6, 1982.

Eddie F. Kimbrell,

Deputy Administrator, Commodity Services.

[FR Doc. 82-28413 Filed 10-18-82; 8:45 am]

BILLING CODE 3410-02-M

[5] Munsell Color Standards for Frozen French Fried Potatoes, Third Edition, 1972, 64-1, may be purchased from the Munsell Color Co., 2441 North Calvert St., Baltimore, MD 21218.

Rural Electrification Administration

7 CFR Part 1701

Public Information; Appendix A—REA Bulletins REA Specification for Plastic-Insulated Ground Wire, PE-85

AGENCY: Rural Electrification Administration, USDA.

ACTION: Proposed rule.

SUMMARY: REA proposes to amend Appendix A—REA Bulletins by issuing a new REA Bulletin 345-85, Specification for Plastic-Insulated Ground Wire, PE-85.

Presently ground wires used with REA borrower telephone systems are covered by guidelines containing limited requirements which are not stringent enough to continually produce and assure quality products. This new proposed specification will establish improved minimum requirements which will assure the qualtiy of the product.

This document will establish uniform end product ground wire requirements that are consistent with ground wire manufactured and used currently in rural telephone systems.

DATE: Public comments must be received by DREA no later than December 20, 1982.

ADDRESS: Submit written comments to Joseph M. Flanigan, Director, Telecommunications Engineering and Standards Division, Rural Electrification Administration, Room 1355, South Building, U.S. Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Harry M. Hutson, Chief, Outside Plant Branch, Telecommunications Engineering and Standards Division, rural Electrification Administration, Room 1342, South Building, U.S. Department of Agricullture, Washington, D.C. 20250, telephone (202) 382-8667. The Draft Impact Analysis describing the options considered in developing this proposed rule and the impact of implementing each option is available on request from the above office.

SUPPLEMENTARY INFORMATION: Pursuant to the Rural Electrification Act, as amended (7 U.S.C. 901 et seq.), REA proposes to amend Appendix A—REA Bulletins by issuing a new REA Bulletin 345.85, REA Specification for Plastic-Insulated Ground Wire, PE-85. This proposed action has been reviewed in accordance with Executive Order 12291, Federal Regulation. The action will not (1) have an annual effect on the economy of $100 million or more; (2) result in a major increase in costs or prices for consumer, individual industries, Federal, State or local government agencies, or geographic regions; or (3) result in significant adverse effects on competition, employment, investment or productivity and therefore has been determined to be "not major". This action does not fall within the scope of the Regulatory Flexibility Act and is not subject ot OMB Circular A-95 review. This program is listed in the Catalog of Federal Domestic Assistance as 10.851, Rural Telephone Loans and Loan Guarantees.

A copy of the proposed specification is available upon request from the address indicated above. All written submissions made pursuant to this action will be made available for public inspection during regular business hours, above address.

Background

Presently ground wires used with REA borrower telephone systems are covered by guidelines containing limited requirements which are not stringent enough to continually produce and asure quality products. This new propose specification will establish improved minimum requirements which will assure the quality of the product.

This action will establish REA requirements for ground wire without affecting the current designs or manufacturing techniques of wire manufactures. This action will also affect REA borrowers in that they will receive and install an improved quality ground wire without an increase in wire cost. Also these wires will provide better service performance which should result in reduced maintenance cost for our borrowers.

In view of the above, the Administrator is proposing to issue REA Bulletin 345-85, REA Specification for Plastic-Insulated Ground Wire, PE-85.

List of Subjects in 7 CFR Part 1701

Loan programs—communications, Telecommunications, Telephone.

Dated: October 7, 1982.

Jack Van Mark,

Acting Administrator.

[FR Doc. 82-28632 Filed 10-18-82; 8:45 am]

BILLING CODE 3410-15-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 2

[Docket No. PRM-2-11]

Wells Eddleman; Denial of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission is denying a petition requesting that the Commission amend its rules of practice for domestic licensing proceedings to require a separate operating license hearing for each power reactor unit at a nuclear power plant site on the grounds that the requested amendments are unnecessary, contrary to sound administrative practice, and inconsistent with existing law. Despite the provisions of the Atomic Energy Act of 1954, as amended, which permit the Commission, under certain circumstances, to issue an operating license without a hearing, the requested amendments would, if adopted, require a mandatory hearing to be held in connection with the issuance of each license to operate a nuclear power reactor. Based on experience, the Commission has found its present practice of consolidating operating license hearings for nuclear power reactors constructed on the same site to be conducive to the proper dispatch of business and to the ends of justice. Moreover, the Commission's present regulations permit a separate hearing to be held on a single reactor unit in any case in which the Commission finds that a hearing is required in the public interest. The requested amendments are, therefore, unnecessary.

ADDRESS: Copies of correspondence and documents cited below are available for public inspection at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Mr. J. J. Henry, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301-443-5981).

SUPPLEMENTARY INFORMATION: As an enclosure to a letter dated September 23, 1981, Mr. Wells Eddleman of Durham, North Carolina, filed with the Commission petition for rulemaking PRM 2-11.

The Petition

The petitioner requested the following amendments to 10 CFR Part 2:

Add to 10 CFR § 2.101(a) [1] a new paragraph (4) as follows:

* * * * *

(4) For nuclear power reactors, no single operating license hearing shall authorize the operation of more than one power reactor. Instead, a separate operating license hearing including the ability to re-open or introduce any issue including safety, need for power, cost-effectiveness compared to alternatives to meet or eliminate the energy output proposed from the unit, evacuation planning, waste disposal, need for base load power, and other relevant issues, shall be held for each nuclear power reactor.

Add to 10 CFR 2, subpart D, a new § 2.408 as follows:

Section 2.408 Separate operating license hearing required for each power reactor.

For each power reactor at a given site, whether of the same design as other built on that site, or not, a separate operating license hearing shall be held before any operating license for that reactor shall issue. Such separate hearing shall include a *de novo* examination and determination of all relevant safety issues, including unresolved safety problems whether so designated by the Commission or not, especially those difficulties which have occurred in operating plants or have been shown by re-analysis or experiment to be more serious risks than formerly believed. Such separate hearing shall also include a *de novo* determination of the need for power, if any, from the reactor, and a *de novo* determination of the cost-effectiveness of operating the reactor as compared to alternatives, taking fully into account for the reactor and unit, all fixed capital charges, fuel and operating and maintenance costs, including insurance and any tax consequences or benefits of not operating the reactor, or scrapping it or any of its associated systems. Alternatives considered shall include, but not be limited to, any of the following in any combinations: conservation, load management, increased energy efficiency, substitutions of alternative sources of energy and/or efficiency in end-uses of energy, co-generation, development of hydroelectric energy from existing dams, reducing energy waste, avoiding the need for energy use through any measures (including insulation, shading, reflective coatings and air spaces, thermal storage, use of the latent heat of the earth), use of wastes or biomass as fuels, competing sources of electricity including centralized or dispersed solar photovoltaic energy, wind power, more efficient motors or appliances, increased production from existing power plants with lower capital cost, increased electricity production from any other new or existing sources, geothermal energy, wave energy, ocean thermal energy, substitution of solar energy with or without thermal storage for end uses of electricity for heating and/or cooling, waste heat recovery, and microhydroelectric power production. Such separate hearing shall also consider and determine whether the Nuclear Regulatory Commission has in place adequate regulations and sufficient personnel to ensure the safe operation of the unit for its planned operating life, and shall consider the range of probable costs and uncertainties in costs of waste disposal and decommissioning of the unit, in making its cost-effectiveness determination for the nuclear unit compared to alternatives. In the event of conflict between this section and any other part of Chapter 10 of the Code of Federal Regulations or any other regulation, this subsection shall be controlling.

[1] By post card dated February 26, 1982, the petitioner changed the cited paragraph to 10 CFR 2.102(d).

Basis for Request

As the basis for the request, the petitioner stated:

The time lag between in-service dates for individual reactors at multi-reactor nuclear plants has been increasing for many years, since long before Three Mile Island 2's 1979 accident. For 4-unit plants, as much as 9 years or more may now be scheduled to elapse between the first and last unit coming on-line. For 2-unit plants, the second unit is often being scheduled for service 2 or 3 or more more years after the first.

This time lag is partly induced by construction difficulties, partly by additional safety considerations, and considerably by reduced needs for new electrical generating plants, among other factors. However, these time lags provide the opportunity for, and indeed necessitate, more thorough NRC review of the issues involved in licensing a nuclear power unit, with respect to second, third, fourth and even later units of a single plant.

Request for Comments on Petition

A notice of filing of petition for rulemaking was published in the **Federal Register** on January 29, 1982 (47 FR 4310). The comment period expired March 30, 1982. The Commission received 22 letters of comment in response to the notice.

Nine commenters supported the petition primarily for the reasons set out by the petitioner. Responses to those comments are covered in the analysis of PRM 2-11 set out below.

In addition, one commenter observed that "the current practice of simultaneous licensing also has the unfortunate consequence of inhibiting public input to the licensing process" because once the hearing is over, it is difficult to reopen and citizens seeking to address various safety issues concerning successive units have a much higher legal standard to meet. Although litigation has to end sometime, this observation is not entirely accurate. In any case where a subtantive safety issue is raised, the Commission would

respond appropriately, either by reopening the proceeding or by other suitable means, such as, for example, postponing issuance of a full power license until the safety issue is resolved.

Another commenter offered the opinion that if one nuclear plant poses a threat due to accident, radiation releases, etc., it is obvious that two or more nuclear power plants at the same site pose twice the threat. While there may be proportionality between degree of risk and number of units, Commission requirements concerning the exposure risk to individuals residing in the vicinity of a nuclear reactor site are based on siting considerations which are independent of the number of units located at a particular site. Compliance with these requirements is a regularly litigated issue in Commission proceedings and the adoption of the petitioner's approach would not alter the validity nor expand the scope of such contentions.

Thirteen commenters opposed the petition primarily on the basis that the proposed amendments would inject unnecessary issues into the OL proceeding and would lead to a burdensome and duplicative review in the OL proceeding of matters previously raised and resolved in the mandatory construction permit hearing required by section 189 a. of the Atomic Energy Act of 1954, as amended.

One commenter suggested that if serious consideration were given to promulgation of a proposed rule, the petitioner should be required to provide a cost-effectiveness basis for the proposal. This suggestion is without merit. No Commission regulation requires a petitioner for rulemaking to submit cost information in connection with amendments of 10 CFR Part 2.

Another commenter expressed the opinion that the petition is frivolous and defective and should not have been published for public comment. The Administrative Procedure Act (5 U.S.C. 553(e) and 555(e)) and the Commission's rules of practice (10 CFR 2.800–2.809) provide that any interested person may petition to issue, amend, or repeal a rule and that prompt notice shall be given of the denial of a petition in whole or in part, together with a brief statement of the grounds for denial. The Commission's regulations also provide that upon acceptance for docketing, the Commission may publish a notice in the **Federal Register** informing interested persons that the petition has been docketed and requesting public comments. In view of the number of comments received, publication of notice of docketing of PRM 2–11 was not useless act.

Petitioner's First Request

The petitioner's first request is that, for nuclear power reactors, no single OL hearing authorize the operation of more than one power reactor.

The petitioner has provided no compelling reasons—either from the standpoint of issues which must be considered or from the standpoint of participation by interested parties—why it is necessary to confine each OL hearing to a single reactor unit even though the reactor unit may be one of several similar units constructed on a multireactor site. The time lag between in-service dates for individual reactors at multireactor nuclear power plants is the ostensible basis for the petitioner's request. There has been no showing and there is no reason to believe that an amendment to the regulations requiring an exclusive hearing on each reactor unit will result in or enhance the consideration of any issues which could not also have been considered and considered equally well in a hearing on two or more units. Nor is there any reason to believe that the class of persons who could be included or excluded from participating in an OL hearing on two or more units constructed on a multiunit site would be different from the class of persons who could be included or excluded from participating in an OL hearing devoted exclusively to any single reactor unit constructed on the same multiunit site.

The petitioner also overlooks the fact that even though a consolidated hearing is held on several reactor units, a separate OL is issued for each reactor unit constructed on a multiunit site. Before an OL for a reactor unit is issued, the Commission must make the requisite findings and determinations required by the regulations in effect at the time of license issuance. This procedure provides assurance that the reactor unit is licensed to operate in accordance with current safety requirements.

Under the provisions of the Atomic Energy Act of 1954, as amended, and the Commission's rules of practice, the Commission may consider two or more applications in the same licensing review. The Act neither provides for nor precludes the filing of an application for a facility license which covers more than one nuclear power reactor. Section 161 of the Act authorizes the Commission to hold such hearings as it may deem necessary or proper to assist it in exercising any authority provided in the Act and to consider in a single application and combine in a single license one or more of the activities for which a license is required by the Act. Under 10 CFR 50.31, an applicant may combine in one of his several applications for different kinds of licenses under the regulations in 10 CRF Chapter I. Pursuant to 10 CFR 2.716, on motion and for good cause shown or on its own initiative, the Commission may consolidate for hearing or for other purposes two or more proceedings, if it is found that such action will be conducive to the proper dispatch of business and to the ends of justice.

If a hearing is required by the Act or by 10 CFR Part 2, the Commission may submit these applications to an atomic safety and licensing board assigned to hear the case in a consolidated proceeding. In most instances, considerations of administrative efficiency dictate that his precedure be followed.

Although used infrequently, the Commission's rules of practice also provide procedures for severing a proceeding dealing with two or more reactor units and for holding a separate OL hearing on each reactor unit. For example, a party may move at any time to sever the proceedings for the second unit from the proceedings for the first unit and to stay the proceedings for the second unit until further order of an atomic saftey and licensing board (14 NCR 1035, 1981). In addition, the Commission has the authority in any OL proceeding, whether contested or uncontested, to determine on its own initiative that a hearing, including a separate hearing for each separate unit, is required in the public interest. Since the Commission's rules of practice authorize OL hearings on single reactor units, the amendments proposed by the petitioner are unnecessary.

Petitioner's Second Request

The petitioner's second request is that, for each power reactor at a given site, whether of the same design as others built on that site, or not, a separate operating license hearing be held before any operating license for that reactor shall issue.

The requested amendment would, if adopted, have the effect of requiring a mandatory OL hearing in connection with the issuance of an OL for each nuclear power reactor. In this respect, the requested amendment is contrary to the clear intent of Congress, which, in 1962, amended section 189 a. of the Atomic Energy Act of 1954 to eliminate the requirement for mandatory hearings in OL proceedings and to permit the Commission, in any case in which a hearing was not requested, to issue an OL without a hearing. Congress took this action because experience demonstrated that, absent bona fide

intervention, a second hearing at the OL stage was unnecessary and burdensome.

Petitioner's Ancillary Requests

The petitioner also requested that the amendments include the following provisions:

(1) Such separate hearing shall include a *de novo* examination and determination of all relevant safety issues.

The petitioner misconstrues the nature and purpose of the OL hearing which is not intended to duplicate the construction permit hearing or to provide *de novo* review. The OL hearing is limited instead, to examining substantial changes or conditions which have occurred since the issuance of the construction permit and issues which were deferred for consideration at the OL stage of the proceeding. In any initial decision in a contested proceeding on an application for an OL for a production or utilization facility, the presiding officer is required by 10 CFR 2.760a, as amended (44 FR 67088, November 23, 1979) to make findings of fact and conclusions of law on the matters put into controversy by the parties to the proceeding and on matters which have been determined to be the issues in the proceeding by the Commission or the presiding officer. Matters not put into controversy by the parties will be examined and decided by the presiding officer only where he or she determines that a serious saftey, environmental, or common defense and security matter exists.

(2) Such separate hearing shall also include a *de novo* determination of the need for power, if any, from the reactor, and a *de novo* determination of the cost-effectiveness of operating the reactor as compared to alternatives.

On March 26, 1982, the Commission published in the **Federal Register** (47 FR 12940) a final rule amending 10 CFR Part 51, "Licensing and regulatory policy and procedures for environmental protection." In 10 CFR 51.53, *"Hearings—Operating licenses,"* new paragraph (c) states:

> Presiding officers shall not admit contentions proffered by any party concerning need for power or alternative energy sources for the proposed plant in operating license hearings.

In the preamble to the final rule, the Commission stated:

> * * * the purpose of these amendments is to avoid unnecessary consideration of issues that are not likely to tilt the cost-benefit balance by effectively eliminating need for power and alternative energy source issues from consideration at the operating license stage. In accordance with the Commission's NEPA responsibilities, the need for power and alternative energy sources are resolved in the construction permit proceeding. The Commission stated its tentative conclusion that while there is no diminution of the importance of these issues at the construction permit state, the situation is such that at the time of the operating license proceeding the plant would be needed to either meet increased energy needs or replace older less economical generating capacity and that no viable alternatives to the completed nuclear plant are likely to exist which could tip the NEPA cost-benefit balance against issuance of the operating license. Past experience has shown this to be the case.* * * An exception to the rule would be made if, in a particular case, special circumstances are shown in accordance with 10 CFR 2.758 of the Commission's regulations.

(3) Such separate hearing shall also consider and determine whether the Nuclear Regulatory Commission has in place adequate regulations and sufficient personnel to ensure the safe operation of the unit for its planned operating life.

The Commission considered the question of adequacy of its regulations when it restructured its rules of practice in 1972 and adopted 10 CFR 2.758, *"Consideration of Commission rules and regulations in adjudicatory proceedings,"* which states in part:

> (a) * * * any rule or regulation of the Commission, or any provision thereof, issued in its program for the licensing and regulation of production and utilization facilities * * * shall not be subject to attack by way of discovery, proof, argument, or other means in any adjudicatory proceeding involving initial licensing subject to this subpart * * *.

It is inappropriate to consider the issue of sufficient NRC personnel in a licensing proceeding, including a hearing on an OL. The Commission is committed to the effective use of its resources. Furthermore, issues relating to Commission personnel involve the internal organization and management of the agency which is subject to Congressional authorization, and for which the Commission, not a license applicant or an intervenor, has sole responsibility.

(4) Such separate hearing shall consider the range of probable costs and uncertainties in costs of waste disposal and decommissioning of the unit, in making its cost-effectiveness determination for the nuclear unit compared to alternatives.

On March 31, 1982 (47 FR 13750), the Commission amended its regulations in 10 CFR Parts 2 and 50 to eliminate entirely requirements for financial qualifications review and findings for electric utilities that are applying for construction permits or operating licenses for production or utilization facilities.

In the preamble to the March 31, 1982, rule changes, the Commission also determined that any consideration of decommissioning funding should be eliminated from the present licensing process. Instead, the Commission plans to consider financial requirements relating to decommissioning in the context of an ongoing rulemaking proceeding to develop decommissioning regulations.

Denial

Based on the above considerations and careful consideration of the public comments received on petition for rulemaking PRM 2-11, the Commission hereby denies the petition for rulemaking filed by Wells Eddleman as an enclosure to a letter dated September 23, 1981.

A copy of the petition for rulemaking and copies of the letters of comment and the Commission's letter of denial are available for public inspection at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.

Dated at Bethesda, MD, this 30th, day of September, 1982.

For the Nuclear Regulatory Commission.

William J. Dircks,

Executive Director for Operations.

[FR Doc. 82-28714 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

12 CFR Part 7

[Docket No. 82-18]

Data Processing by National Banks

AGENCY: Comptroller of the Currency, Treasury.

ACTION: Proposed rule.

SUMMARY: The Office of the Comptroller of the Currency ("Office") is proposing to revise Interpretive Ruling 7.3500 (12 CFR 7.3500), which states the Office's opinion on the data processing services which a national bank may perform for itself and others. Paragraph (a) of the current ruling sets forth a general analytical framework for deciding questions regarding the permissibility of particular data processing activities and also provides several examples of permissible activities. The Office believes that, although the paragraph's analytical framework remains valid, the specific examples have led to confusior and may be outdated given the great

advances in data processing technology which have occurred in the eight years since the current ruling was last revised. The Office therefore proposes to remove the specific examples from paragraph (a) while retaining the paragraph's analytical framework.

Paragraph (b) of the current ruling sets forth the Office's opinion regarding the applicability to data processing services of the statutory prohibitions against tying arrangements, reciprocal dealing, and price discrimination by national banks. Although there was a need for a codified opinion on the applicability of these statutory prohibitions when paragraph (b) was promulgated in 1974, the Office believes that the experience banks have acquired in the past eight years regarding these issues has ended that need. Therefore, the Office proposes to delete paragaraph (b).

DATE: Written comments must be received on or before December 20, 1982.

ADDRESS: Comments should be sent to Docket No. 82-18, Communications Division, 3rd floor, Office of the Comptroller of the Currency, 490 L'Enfant Plaza East, S.W., Washington. D.C. 20219, Attn: C. Christine Jones. Telephone: (202) 447-1800. Comments will be available for inspection and photocopying.

FOR FURTHER INFORMATION CONTACT: Alan Priest, Attorney, Legal Advisory Services Division, Office of the Comptroller of the Currency, 490 L'Enfant Plaza East, N.W., Washington, D.C. 20219, Telephone: (202) 447-1880.

SUPPLEMENTARY INFORMATION: Special Studies: Because the regulatory Flexibility Act does not apply to interpretive rulings, no regulatory flexibility analysis has been prepared for this proposed interpretive ruling. The Office believes that this proposed interpretive ruling is not a "major rule" under Executive Order 12291 and, therefore, has not prepared a Regulatory Impact Analysis. The proposed interpretive rule will not require national banks to expend any funds or to file reports and will not cause an increase in their prices or costs.

Authority: On June 16, 1980, the Office published an Advance Notice of Proposed Rulemaking ("ANPR") in the **Federal Register** (45 FR 40613-40615) which solicited comments on a series of preliminary issues raised in connection with a possible revision of Interpretive Ruling 7.3500 (12 CFR 7.3500), which sets forth the Office's opinion on the permissible scope of data processing services which may be performed by national banks.[1] The ANPR stated that a re-examination of the ruling was under consideration, "[i]n light of the rapid and significant technological advances in data processing and the growth of electronic funds transfer [EFT] systems in the financial industry," and by virtue of specific interpretive questions which had arisen, partly within the context of litigation, since the ruling was last amended in 1974. All of these factors continue to raise questions as to whether the existing ruling has accommodated technological advances and provided adequate guidance, or whether a revision of the ruling is warranted.

Comments

In the interests of obtaining the full participation of all affected parties, invitations to comment were sent to manufacturers, providers, and users of data processing services and equipment as well as to all national banks. commenters were requested to respond to five suggested alternatives which appeared to cover a broad range of conceptual regulatory approaches and options. In basic form, the alternatives were as follows:

(1) To revise the ruling to reflect changes in technology;

(2) To revise the ruling to reflect current and future needs of financial institutions and other sectors of the economy for data processing capacity and data processing services provided by banks;

(3) To revise the ruling to eliminate differences with Regulation Y of the Federal Reserve Board concerning data processing services provided by bank holding companies;

(4) To retain the ruling but make it more understandable, *e.g.*, through question and answer bulletins or educational sessions;

(5) To implement a formal regulation. In addition to the alternatives which were presented for comment, the Office further requested discussion on a wide range of topics of current interest. These topics essentially focused on three areas: (1) Present data processing operations of national banks, (2) attitudes of banks, users, and data processing competitors regarding the proper role of banks in the providing of data processing services and (3) projections on future applications of EDP technology. These comments were helpful to the instant rulemaking proceeding primarily as background material which served to aid the staff in evaluating the viability of each of the presented alternatives based on the current attitudes, operations, and projected future needs of banks and other processors.

A total of 80 comments were received from banks, non-bank data processing companies, trade associations, and others. The comments were broken down into the following categories:

(1) 62 comments were received from national banks, holding companies, and data processing subsidiaries. 33 commenters identified themselves as providers of data processing services, while an additional 22 comments came from banks which identified themselves as providers and/or users of bank data processing services. 7 banks failed to identify themselves or did not otherwise indicate their status as providers or users of bank EDP services;

(2) 2 comments were received from non-bank users of data processing services;

(3) 4 comments were received from EDP non-bank processors;

(4) 6 comments were received from EDP, user, and banking trade associations;

(5) 6 comments were received from miscellaneous sources, including the Ninth National Bank Region.

In general terms, it would be accurate to conclude that a vast majority of the bank respondents are satisfied with the present ruling and do not favor a revision, although there is some support for issuance of supplemental aids which would make the current ruling more understandable. Bank providers of data processing services also make strong arguments supporting a more relaxed ruling which would permit them to offer a much broader array of data processing

[1] The text of the ruling is as follows:

§ *7.3500 Use of data processing equipment and furnishing of data processing services.*

(a) A national bank may use data processing equipment and technology to perform for itself and others all services expressly or incidentally authorized under the statutes applicable to national banks. For example as part of its banking business and incidental thereto, a national bank may collect, transcribe, process, analyze, and store, for itself and others, banking, financial, or related economic data. In addition, incidental to its banking business, a national bank may (1) market a by-product (e.g., program, output, etc.) of an above-described data processing activity; and (2) market excess time on its data processing equipment so long as the only involvement by the bank is furnishing the facility and necessary operating personnel.

(b) The provision of data processing services by a national bank to others is subject to the prohibitions contained in 12 U.S.C. 1972 concerning tying arrangements, reciprocal dealing, and price discrimination. In particular, a national bank may not require any party who is or proposes to be a customer for any service or product of the bank to utilize any data processing service offered by the bank, and the bank may not fix or vary the consideration for any extension of credit, lease, or sale of property or provision of another service on the condition or requirement that a customer utilize a data processing service offered by the bank.

services to their customers and to the general public. Several of the largest bank providers felt that, legal restrictions aside, the Office should remove all restrictions on their data processing activities.

Non-bank EDP processors, in contrast, favored a rule restricting any further growth of the bank EDP services industry, arguing specifically that banks enjoyed an unfair economic advantage over other competitors because of their inherent power to tie-in the provision of data processing services to other banking services (such as loans) which a prospective customer might desire.

Bank and non-bank users of bank-provided data processing services generally found such services to be superior to those provided by general data processing companies, arguing that banks are in a unique position to assess and to respond to those needs which are related to the areas of banking and finance.

Discussion of the Alternatives Presented

Reaction to the five proposed ANPR alternatives, which were intended to represent a broad range of conceptual regulatory approaches, was mixed. Generally, the majority of the commenters appeared to be comfortable with the current ruling, with many commenters favoring the issuance of supplemental aids. Even those commenters favoring major changes to the ruling did not indicate that the adoption of any of the regulatory approaches embodied in the ANPR options would be preferable. While each of the ANPR options received careful consideration, the Office, upon close examination of each option, has concluded that significant policy and legal obstacles exist which would recommend against adoption of any alternatives proposed by the ANPR.

Option No. 1. Revision of the Ruling To Reflect Changes in Technology

The majority of commenters responding to this option felt that the existing ruling's focus on the type of data that could be processed had been sufficiently flexible to accommodate technological advances in the computer industry. Of those that disagreed with this statement, most felt that the ruling may have been too flexible in respect to the processing of certain types of data, resulting in increased offerings of non-banking services by national banks. Some concern was also voiced that the ruling, which is geared to the provision of banking services, may fail to provide a satisfactory mechanism for encouraging investments in technological innovations which are capable of delivering non-banking as well as banking services, *e.g.*, home television access and "switches" for processing non-banking as well as banking functions.

The Office has decided against this option for two reasons. First, a technologically oriented ruling would quickly become outdated since "state of the art" data processing applications continue to evolve at a rapid rate. Secondly, a technologically oriented ruling would draw focus away from the primary purpose of I.R. 7.3500, *i.e.*, to provide banks with the Office's opinion regarding the legal permissibility of national bank data processing activities. Maintaining the current focus is important given the Office's legal expertise regarding interpretation of the relevant banking laws and the technological expertise of national banks regarding data processing.

Option No. 2. Revision of the Ruling To Reflect Current and Future Needs of Financial Institutions and Other Sectors of the Economy for Data Processing Capability and Data Processing Services Provided by Banks

Generally, the commenters interpreted this alternative to constitutie a method for encouraging banks to expand their data processing capabilities in the future. Bank providers tended to assert that increased data processing capacity would encourage other sectors of the economy to accept data processing and EFT systems. Bank users viewed themselves as the ultimate recipients of the expansion of bank data processing capabilities, while non-bank processors felt they would be futher disadvantaged by an increasing banking presence in the market.

The Office has determined that this alternative is inappropriate since its adoption could be misinterpreted as an endorsement by the Office of bank data processing activities which are not incidental to the business of banking or otherwise permissible under the laws applicable to national banks.

Option No. 3. Revision of the Ruling To Eliminate Differences With Regulation Y of the Federal Reserve Board Concerning Data Processing Services Provided by Bank Holding Companies (12 CFR 225.4(a), 225.123(e))

A significant number of commenters favored a ruling which would be similar, if not identical, to the Federal Reserve Board's provisions on data processing. The primary reasons cited were uniformity, consistency, and competitive equality. (Similar comments were submitted on this same point during the Office's previous rulemaking on I.R. 7.3500 in 1974. While the record regarding the 1974 rulemaking is not adequately documented on this point, it appears that the adoption of a ruling similar to the regulations of the Federal Reserve Board was rejected on legal grounds.)

As in 1974, legal considerations preclude current revision of the ruling to achieve conformity with Federal Reserve Board regulations. The Federal Reserve Board's regulations interpret and apply the provisions of the Bank Holding Company Act, a statute applicable to holding companies and their non-banking subsidiaries. Those entities are not subject to the incidental power provision of the National Bank Act (12 U.S.C. 24 (Seventh)). The primary purpose of Interpretive Ruling 7.3500 is to interpret the applicability of Section 24 (Seventh) to the data processing activities of national banks. This purpose cannot be achieved by revising the Interpretive Ruling to conform to regulations designed to govern the activities of entities which are not even subject to the incidental powers provision.

Option No. 4. To Retain the Ruling but To Issue Supplemental Aids, e.g., in the Form of Question and Answer Bulletins

A significant number of bank providers responding to this question felt that supplementary information would be helpful because the ruling had posed interpretive problems for them. The Office has, from time to time, issued supplementary guidance, often in the form of Banking Issuances, on various subject areas that have caused confusion to some national banks. The Office does not categorically reject this approach at some point in the future regarding data processing. However, at this time, ongoing litigation and the rapid development of data processing capacities and functions make it unlikely that guidelines more specific than those currently provided in the ruling will be possible or desirable in the near future.

As discussed above, the specific examples in the second and third sentences of the current Interpretive Ruling have led to confusion and may be outdated due to advances in the data processing field experienced in the eight years since the rule's last revision. These problems make it undesirable to retain the ruling in its present form. As will be discussed in greater detail below, the Office proposes to solve this problem through deletion of the second and third sentences of the ruling and expansion of the general principles currently enunciated in the ruling's first

sentence. Thus, the option of retaining the ruling in its present form has been rejected.

Option No. 5. To Implement a Formal Ruling

Most of the respondents rejected this option. Three basic reasons were cited: (1) The data processing area is too dynamic to be bound by artificial constraints; (2) a regulation would hamper or retard the development of new banking technologies; and (3) a regulation would encourage an increasing regulatory presence. Only 3 commenters favored the implementation of a regulation.

The Office has determined that no purpose would be served through a regulation that could not be met by an interpretive ruling. Accordingly, this option has been withdrawn.

General Regulatory Approach

The Office has determined that the ruling's present approach, which views bank data processing as a technology, rather than a distinct service or business, is clearly valid. The first sentence of the ruling's paragraph (a) embodies this approach and indicates that the technology of data processing can be used by national banks to provide to themselves and others all services expressly or incidentally authorized under the statutes applicable to national banks. Thus, the first sentence of paragraph (a) provides an analytical framework broad and flexible enough to be applicable to any question regarding the permissibility of particular data processing activities.

Because it believes that this framework is highly useful to national banks, the Office proposes to retain the first sentence of paragraph (a) without change. In addition, the Office proposes to add to paragraph (a) a sentence which will explicitly state the Comptroller's opinion that, in general, data processing is a technology rather than a service distinct or different from the underlying services or functions to which the technology is applied. this opinion is implicit in the current ruling and was stated explicitly in the ruling's preamble when the ruling was last revised in 1974. *See* 39 FR 14192 (1974). It is a fundamental element of the Office's position regarding the data processing activities of national banks. The Office proposes to explicitly state this opinion in the ruling itself because, although adequately emphasized in 1974 through means of the preamble, the opinion is not sufficiently emphasized in the text of the ruling itself.

The Office has faced a number of problems in applying the second and third sentences of paragraph (a) of the current ruling. In an attempt to provide guidance of a more specific nature than that provided in the ruling's first sentence, these sentences cite as permissible activities the marketing of "excess time" and "by-products" and the processing of "banking, financial, or related economic data." The Office believes that many banks have been confused by the subject sentences. Because the specific examples of permissible activities are broadly drafted, they can be misinterpreted as permitting activities that may not be expressly or incidentally related to the business of banking. Accordingly, there may be a significant misunderstanding of the boundaries of those examples, a confusion which was suggested by many of the comments to the ANPR.

One major cause of confusion regarding the meaning of the specific examples in the second and third sentences of the ruling is inherent in any possible listing or examples of permissible data processing services, *i.e.*, the language of the bank data processing field. This language is generally imprecise. It was developed during the course of the evolution of a new technology and is geared to business, rather than legal, needs. Given the imprecision of the basic terms used to describe data processing products, the Office believes it may not be possible to formulate examples of permissible data processing activities which both illustrate the full range of a bank's authority to provide data processing services, yet are not subject to misinterpretation as allowing activities which are not part of the business of banking or incidental thereto. For the same reasons, the Office believes that it may not be possible to draft an acceptable list of impermissible data processing activities.

In addition to being difficult to draft, acceptable specific lists or examples of permissible activities would be very difficult to keep current. This difficulty is due to the rapidly changing nature of the data processing field. The current rate of change virtually ensures that any acceptable list would quickly be rendered obsolete. Thus, any acceptable list or set of examples would require repeated updating. Perhaps more significantly, such a list may discourage the development by national banks of new data processing services which, although part of the business of banking, are not on a list of permitted activities or similar in nature to those in a set of examples of permitted activities.

For the above reasons, this Office has determined that it is inappropriate at this time to include a list of permissible activities, or a set of examples of permissible activities, in Interpretive Ruling 7.3500. This being the case, the Office proposes to delete, rather than amend, the second and third sentences of paragraph (a) of the ruling. In proposing to delete the second and third sentences of paragraph (a), the Office wishes to make clear that it does not intend to indicate any change in its position regarding the permissibility of data processing services. That position, as noted earlier, is expressed in the first sentence of paragraph (a). Under this proposal, that sentence would be retained and amplified.

Paragraph (b) of the Ruling

Paragraph (b) of the Interpretive Ruling expresses the Office's position concerning the applicability to data processing activities of the statutory prohibitions (12 U.S.C. 1972) against tying arrangements, reciprocal dealing, and price discrimination. The Office believes that the position expressed in paragraph (b) is as valid today as it was when promulgated in 1974. However, the Office believes that the need for a codified expression of that position no longer exists.

In 1974 when paragraph (b) was promulgated, many banks were relatively unsophisticated in matters relating to data processing. Many were just beginning to make data processing services available to their customers. Given these circumstances, the Office believed that a codified interpretation of the applicability of 12 U.S.C. 1972 to banks providing data processing services would be helpful. Since 1974, national banks have gained experience in providing data processing services to their customers. Given this experience, the Office believes it is unlikely that there is a present need for a codified opinion regarding the applicability of 12 U.S.C. 1972 to data processing activities. Therefore, the Office proposes to delete paragraph (b) from Interpretive Ruling 7.3500.

List of Subjects in 12 CFR Part 7

National banks, Incidental powers, Data processing.

Proposed Amendment

PART 7—[AMENDED]

Accordingly, the Office proposes to amend 12 CFR Part 7, as follows:

1. The authority citation for Part 7 is as follows:

Authority: 12 U.S.C. 1 *et seq.*

2. Section 7.3500 of 12 CFR Part 7 is proposed to read as follows:

§ 7.3500 Use of data processing equipment and furnishing of data processing services.

It is the opinion of the Comptroller that, in general, data processing is a technology rather than a service distinct or different from the underlying services or functions to which the technology is applied. A national bank may use data processing equipment and technology to perform for itself and others all services expressly or incidentally authorized under the statutes applicable to national banks.

Dated: September 14, 1982.

C. T. Conover,

Comptroller of the Currency.

[FR Doc. 82-28708 Filed 10-18-82; 8:45 am]

BILLING CODE 4810-33-M

DEPOSITORY INSTITUTIONS DEREGULATION COMMITTEE

12 CFR Part 1204

[Docket No. D-0026]

Money Market Deposit Account

AGENCY: Depository Institutions Deregulation Committee.

ACTION: Proposed rulemaking.

SUMMARY: The Depository Institutions Deregulation Committee ("Committee") is required by the Garn-St Germain Depository Institutions Act of 1982 ("Garn-St Germain Act") to authorize a new insured deposit account, available to all depositors, to compete with money market mutual funds. The Garn-St Germain Act requires that this account: (1) Have no limitation on the maximum rate of interest payable; (2) be in effect no later than 60 days from enactment of the Garn-St Germain Act; (3) not be subject to transaction account reserve requirements (as defined by the Board of Governors of the Federal Reserve System, as of August 1, 1982) even though no minimum maturity is required, and even though up to three preauthorized or automatic transfer plus three third-party transfers are permitted per month; and (4) be "directly equivalent to and competitive with money market mutual funds registered with the Securities and Exchange Commission under the Investment Company Act of 1940." No minimum denomination was set forth in the Garn-St Germain Act, although the Conference Report suggested it be no more than $5000. The Committee is requesting comments on features not specifically set forth in the Garn-St Germain Act; *e.g.*, minimum initial denominaiton, maintenance balance, denomination of withdrawals, whether institutions should be required to reserve the right to require seven days' notice of withdrawal, and whether loans should be permitted to meet the minimum denomination requirement.

DATE: Comments must be received by November 3, 1982.

ADDRESS: Interested parties are invited to submit written data, views, or arguments concerning the proposed rules to Gordon Eastburn, Acting Executive Secretary, Depository Institutions Deregulation Committee, Room 1058, Department of the Treasury, 15th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20220. All material submitted should include the Docket Number D-0026 and will be available for inspection and copying upon request, except as provided in § 1202.5 of the Committee's Rules Regarding Availability of Information (12 CFR 1202.5).

FOR FURTHER INFORMATION CONTACT: Alan Priest, Attorney, Office of the Comptroller of the Currency (202/447-1880); Joseph DiNuzzo, Attorney, Federal Deposit Insurance Corporation (202/389-4147); Rebecca Laird, Senior Associate General Counsel, Federal Home Loan Bank Board (202/377-6446); Paul S. Pilecki, Senior Attorney, Board of Governors of the Federal Reserve System (202/452-3281); or Elaine Boutilier, Attorney-Adviser, Treasury Department (202/566-8737).

List of Subjects in 12 CFR Part 1204

Banks, Banking.

SUPPLEMENTARY INFORMATION: The Depository Institutions Deregulation Act of 1980 (Title II of P.L. 96-221; 12 U.S.C. 3501 *et seq.*) ("DIDA") was enacted to provide for the orderly phaseout and ultimate elimination of the limitations on the maximum rates of interest and dividends that may be paid on deposit accounts by depository institutions as rapidly as economic conditions warrant. Under DIDA, the Committee is authorized to phase out interest rate ceilings by any one of a number of methods including the creation of new account categories not subject to interest rate limitations or with interest rate ceilings set at market rates of interest.

Section 327 of the Garn-St Germain Act specifically requires the Committee to authorize a new insured deposit account, which "shall be directly equivalent to and competitive with money market funds." The Garn-St Germain Act prohibits any limitation on the maximum rate of interest payable on the new account. The Garn-St Germain Act also states that the account shall not be subject to reserve requirements on transaction accounts even though no minimum maturity is required and even though up to three preauthorized or automatic transfers and three transfers to third parties are permitted.

The Committee has solicited public comment on short-term deposits previously. After the June 25, 1981 meeting, the Committee requested comments on the desirability of authorizing a new deposit instrument with characteristics similar to money market mutual funds, although the Committee did not put forth a specific proposal at that time. 46 F.R. 36712 (July 15, 1981). After the September 22, 1981 meeting, the Committee requested comments on three specific proposals for short-term time deposits. 46 F.R. 50804 (October 15, 1981).

One of the short-term accounts proposed in the October 15, 1981 notice was a $5000-minimum denomination NOW account, which is similar in concept to the account set forth in the Garn-St Germain Act. Consequently, the Committee has received comments on an instrument that possesses essentially all of the features of the congressionally-mandated account. Certain features are mandated by the Garn-St Germain Act and cannot be changed. However, some features were left by Congress to the Committee's discretion. Accordingly, comment is requested only on features not specified in the Act. Public comment is being requested in view of the interest expressed by competitors of depository institutions for an opportunity to comment on the features the Committee may designate.

The new account proposed by the Committee would have the following features as required by the Garn-St Germain Act and its legislative history: (1) No minimum maturity; (2) no interest rate ceiling; (3) an initial minimum denomination no greater than $5000; (4) allow up to three preauthorized or automatic transfers and three other third-party payments (including drafts) per month without being subject to transaction account reserve requirements; (5) available to all depositors; and (6) insured by the FDIC or FSLIC. The Committee is considering whether or not to impose a minimum initial denomination and/or maintenance balance of less than $5000 and requests comments on this feature. In connection with the minimum balance, the Committee may impose an interest rate limitation (such as the NOW-account rate) on accounts which fall below the minimum maintenance balance, and prohibit loans to meet the minimum initial denomination. The account will permit limited withdrawals

to be made, and certain requirements are being considered by the Committee in regard to these withdrawals, *e.g.* (1) a minimum denomination on drafts; (2) unlimited withdrawals by the depositor by mail, telephone, messenger or in person, except that telephone transfers to third parties or another deposit account of the depositor would be regarded as preauthorized transfers; (3) require an institution to monitor on an *ex post* basis to determine compliance with the withdrawal limitations; and (4) require an institution to reserve the right to require seven days' notice prior to withdrawal. Although the maximum rate of interest paid on the account may not be limited, the Committee is concerned that institutions will circumvent the requirements on other time deposits by guaranteeing a rate of interest for a substantial time period, therefore the Committee is considering a limitation on the time period for which an institution may guarantee an interest rate. The Committee also may restrict overdraft credit arrangements offered in connection with this new account.

The Committee requests comments on the new account as proposed above, and particularly requests comments on the following issues:

(a) What should be the minimum initial denomination? (The Conference Report suggests that it be no more than $5000, and interest has been expressed in a $2500 minimum denomination.)

(b) Should the maintenance balance differ from the initial denomination? If so, what should it be?

What would be the possible consequences of having no maintenance balance? Would it be operationally easier to have the maintenance balance the same as the minimum initial denomination?

(c) Should an institution be required to pay a lower rate of interest, such as the NOW-account rate, for accounts which fall below the maintenance balance,

(d) Should a minimum denomination be set for drafts? If so, should it be $100, $500, or some other amount?

(e) Should depository institutions be required to reserve the right to require seven days' (or some other time span) notice prior to withdrawal?

(f) Should loans be permitted to meet the minimum initial denomination?

(g) Should any restrictions be placed on additional deposits? Should sweeps *from* other accounts be permitted?

(h) Should the time period for which an institution can guarantee an interest rate be limited? If so, what should it be? Or should the account have a maximum maturity?

(i) How should the limitation on the number of withdrawals per month be enforced? For example, should the institution be required to monitor accounts on an *ex post* basis to determine compliance? How should "month" be defined for purposes of this limitation? Should the date of payment by the institution or the date written on the draft control for purposes of compliance with the three drafts per month limitation?

(j) Should any restrictions be placed on overdraft credit arrangments offered in connection with this account?

(k) Should unlimited withdrawals by mail, telephone, messenger, or in person be permitted to the depositor? (The staff believes that telephone transfers should be regarded as preauthorized transfers if the transfer is to a third person or to another deposit account of the same depositor.)

(l) Is thirty days (or some shorter or longer period) adequate lead time for depository institutions to implement operational changes for this account?

The issues set forth above are not intended to limit the area of comment. The Committee requests comments on those questions and on any other aspect of the account which the public wishes to address, particularly with respect to characteristics that would make this account "directly equivalent to and competitive with" money market funds.

The Committee has considered the potential effect on small entities of the proposal to establish a new deposit instrument, as required by the Regulatory Flexibility Act (5 U.S.C. 603 *et seq.*). In this regard, the Committee's action, in and of itself, would not impose any new reporting or recordkeeping requirements. Consistent with the Committee's statutory mandate to eliminate deposit interest rate ceilings, this proposal would enable all depository institutions to compete more effectively in the marketplace for short-term funds. Depositors generally should benefit from the Committee's proposal, since the new instrument would provide them with another investment alternative that pays a market rate of return. If low-yielding deposits shift into the new account, depository institutions might experience increased costs as a result of this action. However, their competitive position *vis-a-vis* nondepository competitors would be enhanced by their ability to offer a competitive short-term instrument at market rates. The new funds attracted by the new instrument (or the retention of deposits that might otherwise have left the institution) could be invested at a positive spread and would therefore at least partially offset the higher costs associated with the shifting of low-yielding accounts.

The Committee is asking for comments for a 15-day period. This short comment period is made necessary by the fact that the Garn-St Germain Act required the new account to be available within 60 days of enactment. Because the Committee desires to give the depository institutions adequate time to prepare and market the account, time for comment must be limited to allow time for compilation and consideration of the comments, a Committee vote on the features and publication of the final rule. Therefore, comments on this account should be submitted promptly.

By Order of the Committee, October 15, 1982.

Gordon Eastburn,

Acting Executive Secretary.

[FR Doc. 82-28847 Filed 10-18-82; 8:45 am]

BILLING CODE 4810-25-M

FEDERAL TRADE COMMISSION

16 CFR Part 13

[Docket 9149]

Ogilvy & Mather International Inc.; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission

ACTION: Proposed Consent Agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would require a New York City advertising agency, among other things, to cease employing the name Aspercreme or any other trade name which erroneously implies that aspirin is an active ingredient of the product. The order would also bar misrepresentations concerning the validity, conclusions, interpretations or results of any test or study; as well as unsubstantiated claims regarding the mode of action by which a drug treats, eases or cures any symptom, condition or disease. Further, the firm would be prohibited from representing without reasonable substantiation that any topically applied drug is faster or more effective than aspirin in the treatment of arthritis, tendonitis, bursitis or rheumatism, or that it involves a new scientific or mechanical principle. Additionally, the order would require the company to retain all data that substantiates or contradicts advertised product claims for a period of three years following dissemination of any advertisement subject to the order.

DATE: Comments must be received on or before December 20, 1982.

ADDRESS: Comments should be directed to: Office of the Secretary, FTC/S, Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: FTC/PA, Melvin H. Orlans, Washington, D.C. 20580. (202) 724–1529.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 3.25(f) of the Commission's Rules of Practice (16 CFR 3.25(f)), notice is hereby give that the following consent agreement containing a consent order to cease and desist and an explanation thereof, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(14) of the Commission's Rules of Practice (16 CFR 4.9(b)(14)).

List of Subjects in 16 CFR Part 13

Advertising, Drugs

United States of America Before Federal Trade Commission

In the Matter of Ogilvy & Mather International Inc., a corporation

Docket No. 9149.

Agreement Containing Consent Order To Cease and Desist

The Agreement herein, by and between Ogilvy & Mather International Inc., a corporation, respondent in the above proceeding initiated by the Federal Trade Commission, is entered into by its duly authorized officer, and its attorney, and counsel for the Federal Trade Commission, in accordance with the Commission's Rules governing consent order procedure.

1. Respondent Ogilvy & Mather International Inc. ("Ogilvy") is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York with its principal offices and place of business located at 2 East 48th Street New York, New York 10017.

2. Respondent has been served with the Commission's Complaint charging it with violations of Sections 5 and 12 of the Federal Trade Commission Act, and has filed an answer to said complaint denying said charges.

3. Respondent admits all jurisdictional facts set forth in the said copy of the Complaint, as amended, of the Commission to the extent they relate to Ogilvy & Mather International Inc.

4. Respondent waives:

(a) Any further procedural steps;

(b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the Order entered pursuant to this Agreement.

5. This Agreement shall not become a part of the public record of the proceeding unless and until it is accepted by the Commission. If this Agreement is accepted by the Commission it, together with the Complaint, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the respondent, in which event it will take such action as it may consider appropriate, or issue and serve its decision, in disposition of the proceeding against respondent.

6. This Agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in the said Complaint of the Commission, as amended, issued in this proceeding.

7. This Agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of §3.25(f) of the Commission's Rules, the Commission may, without further notice to respondent, (1) issue its amended complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding, and issue its decision containing the following Order to cease and desist in disposition of the proceeding, and (2) make information public in respect thereto. When so entered, the Order to cease and desist shall have the same force and effect and shall become final and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The Order shall become final upon service. Delivery by the U.S. Postal Service of the amended complaint and decision containing the agreed-to order to respondent's address as stated in this agreement shall constitute service. Respondent waives any right it might have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or to contradict the terms of the Order.

8. No part or provision of this Order shall become binding upon respondent until the effective date of a final order to cease and desist against Thompson Medical Company, Inc. or its successors or assigns. If a final order against Thompson Medical Company, Inc. in this proceeding contains a provision different from the provision that corresponds to the provision in Part I(A) of this Order or contains a definition of "competent and reliable scientific or medical evidence" that differs from Part II of this Order, then this Order shall be reopened for the sole purpose of conforming said provision or said definition in this Order with the corresponding provision or definition in the Thompson Medical Company, Inc. order. In the event that the Complaint in this matter against Thompson Medical Company, Inc. is dismissed in whole, then the Commission, upon the application of respondent, shall set aside this Order.

9. Respondent has read the Complaint and Order contemplated hereby, and it understands that once the Order has been issued, it will be required to file one or more compliance reports showing that it has fully complied with the Order and that it may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final.

10. The respondent waives any claim under the Equal Access to Justice Act.

Part I

It is ordered that respondent Ogilvy & Mather International Inc., its successors and assigns, and its officers, representatives, agents and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any "drug", as that term is defined in the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do cease and desist from:

A. Employing the trade name "Aspercreme" for any such drug or any other trade name or terms that represents, directly or by implication, that an active ingredient of such drug is aspirin, unless such drug contains aspirin in therapeutically significant quantities.

B. Employing any trade name for any such drug which represents, directly or by implication, that such drug contains an active ingredient which it in fact does not.

C. Representing, directly or by implication, that any such drug is new, or involves a new mechanical or scientific principle, when such drug or one involving such principle has been nationally available for purchase in the United States for more than one year.

D. Representing, directly or by implication, that any such drug has an ingredient when in fact it does not have that ingredient.

E. Misrepresenting the contents, validity, results conclusions or interpretations of any test or study.

F. Representing, directly or by implication, the mode of action by which any such drug treats, mitigates, or cures any symptom, disease, or condition unless respondent possesses and relies upon a reasonable basis substantiating the representation.

Part II

It is further ordered, that respondent Ogilvy & Mather International Inc., its successors and assigns, and its officers, representatives, agents and employees directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any topically applied drug in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, cease and desist from:

A. Representing, directly or by implication, that any such topically applied drug is effective for the treatment or relief of the symptoms of any musculoskeletal disorder (such as arthritis, tendonitis, bursitis, or reheumatic disorders) or any other disease or condition;

B. Representing, directly or by implication, that any such topically applied drug is as fast or faster, or is as effective or more effective, than aspirin in the treatment or relief of the symptoms of any musculoskeletal disorder (such as arthritis, tendonitis, bursitis, or rheumatic disorder) or any other disease or condition;

C. Representing, directly or by implication, that any such topically applied drug will not result in any side effect;

D. Representing, directly or by implication, that any such topically applied drug will result in fewer side effects than any other drug or device; unless at the time of the dissemination of any such representation respondent possesses and relies upon a reasonable basis consisting of competent and reliable scientific or medical evidence substantiating that representation. For the purposes of this Order, competent and reliable scientific or medical evidence shall include at least two well-controlled, double blinded clinical studies which meet the requirements set forth in 21 CFR 314.111(a)(5)(ii) and 21 CFR 330.10(a)(4)(ii), and are conducted by different persons, independently of each other. Such persons shall be qualified by training and experience to conduct such studies. Provided, however, with respect to any representation covered by this Part, if the Food and Drug Administration promulgates any final standard which establishes conditions under which such product is safe and effective, then in lieu of the above, respondent may possess and rely upon scientific evidence which fully conforms to such final standards as a reasonable basis for said representation. Provided further, however, where the evidence relied upon by respondent was not directly or indirectly conducted or controlled by respondent, it shall be an affirmative defense to an alleged violation of this Part for respondent to prove that it reasonably relied on the expert judgment of its client or of an independent third party in concluding that a reasonable basis exists which meets the requirements of this Part. Such expert judgment shall be in writing signed by a person qualified by education or experience to render the opinion. The written opinion shall describe the contents of the evidence upon which the opinion is based and shall set forth the qualifications of the person to render the opinion.

Part III

It is further ordered that respondent Ogilvy & Mather International Inc., its successors and assigns, and its officers, representatives, agents and employees, for a period of three years after respondent last disseminates the advertisements for products covered by this Order, shall retain all test results, data, and other documents or information on which it relied for its representations or any documentation which contradicts, qualifies or calls into serious question any claim included in such advertisements which were in its possession during either their creation or dissemination. Such records may be inspected by the staff of the Commission upon reasonable notice.

Part IV

It is further ordered that respondent notify the Commission at least thirty (30) days prior to the effective date of any proposed change in the corporate Respondent such as dissolution, assignment or sale, resulting in the emergence of a successor.

Part V

It is further ordered that respondent shall distribute a copy of this Order to each of its operating divisions, and to each of its officers who are engaged in the preparation and placement of advertisements for products covered by this order.

Part VI

It is further ordered that the provisions of this Order shall not apply to Scali, McCabe, Sloves, Inc.; Cole & Weber, Inc.; and Rogers, Weiss/Cole & Weber Advertising, three subsidiary corporations wholly owned by respondent, unless a product otherwise covered by this Order is assigned or tansferred from respondent to one of those corporations. However, respondent shall distribute a copy of this Order to the officers of the aforementioned corporations.

Part VII

It is further ordered that the respondent shall, within sixty (60) days after this Order becomes final and annually thereafter for three (3) years, file with the Commission a report, in writing, signed by a responsible officer for respondent, setting forth in detail the manner and form in which it has complied with this Order.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from Ogilvy & Mather International Inc.

The propsed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The complaint charged the respondent with disseminating advertisements containing several false, misleading, or umsubstantiated representations regarding an over-the-counter health care product, namely the topically applied cream known as "Aspercreme". The complaint alleged that Aspercreme advertisements claimed without a reasonable basis that: Aspercreme is an effective drug for the relief of minor arthritis and its symptoms; Aspercreme is as effective a drug, or even more effective, than orally-ingested aspirin for the relief of minor arthritis and its symptoms; Aspercreme is an effective drug for the relief of rheumatic conditions and their symptoms; Aspercreme acts by directly penetrating through the skin to the site of the arthritic disorder; and the use of Aspercreme will result in no side effects

Additionally, the complaint alleged that the Aspercreme advertisements expressly or impliedly represented falsely: (1) That the product Aspercreme contains aspirin; (2) that Aspercreme is a recently discovered or recently developed drug product; and (3) that valid studies have scientifically proven that Aspercreme is more effective than orally-ingested aspirin for the relief of arthritis, rheumatic conditions, and their symptoms.

The consent order contains various provisions designed to remedy the alleged advertising violations.

Part I of the order prohibits the respondent from using the trade name "Aspercreme" in any drug advertising, or from using any other name that represents directly or by implication that aspirin is an active ingredient of such product, unless the drug product actually contains aspirin in therapeutically significant quantities. This Part of the order also prohibits respondent from using any trade name for a drug product which expressly or impliedly represents that the product contains an active ingredient which it in fact does not contain. Part I(D) of the order more generally prohibits respondent from representing in any way (including but not limited to a trade name choice), that a drug product has a particular ingredient when in fact it does not contain that ingredient. Respondent is further prohibited from representing that a drug product is new, or involves a new scientific or mechanical principle, when the drug or one involving the same principle has been available for sale within the United States for longer than one year. Part I(E) prohibits respondent from misrepresenting the contents, validity, results, conclusions or interpretations of any test or study, and Part I(F) requires that in representing a drug's mode of action in treating or mitigating a symptom, disease, or condition, Ogilvy & Mather International Inc. must possess and rely upon a reasonable basis substantiating the representation.

Part II of the order covers the advertising or sale of topically applied drugs specifically. It prohibits the respondent from representing that any topically applied drug is effective for the treatment of the symptoms of arthritis, tendonitis, bursitis, rheumatic disorders, or any other disease or condition, or from representing that such topically applied drug is as fast or faster, or is as

effective or more effective, than aspirin for the symptomatic relief of any such disease or condition, unless at the time of disseminating any such representation respondent possesses and relies on competent and reliable scientific or medical evidence substantiating the representation. Part II of the order also requires that any representation that a topically applied drug will not result in any side effects, or will result in fewer side effects than any other drug or device, must likewise be based upon competent and reliable scientific or medical evidence. For purposes of Part II of the order, "competent and reliable scientific or medical evidence" is defined as including at least two well-controlled, double-blinded clinical studies which are conducted by different persons independently of each other, and which comport with FDA standards for such testing. Finally, Part II of the order provides that where the substantiation evidence relied upon by the respondent was not conducted or controlled by it, either directly or indirectly, then in any suit brought against respondent for violation of this part of the order, it shall be an affirmative defense for respondent to prove that it reasonably relied on its client's judgment or that of an independent third party in concluding that there was a reasonable basis, meeting the requirements of Part II of the order, in support of the product claims being made.

Part III of the order requires respondent to maintain records of its substantiation for its claims for a period of three (3) years after the dissemination of any advertisement subject to this order. The order also requires respondent to retain for such period of time any documents which contradict or call into question any of its advertising claims. Such documentation may be inspected by the Commission's staff.

Parts IV and V of the order require respondent to distribute a copy of the order to each of its operating divisions and to notify the Commission of any change in its corporate structure which might affect compliance obligations. The order exempts from its coverage three subsidiary corporations wholly owned by the respondent, unless a product already covered by the order is transferred to one of those corporations. Finally, the order provides that within sixty (60) days after the effective date of this order, and annually thereafter for three (3) years, respondent must file a report with the Commission detailing its compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Carol M. Thomas,

Secretary.

[FR Doc. 82-28704 Filed 10-18-82; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 4

Vessels in Foreign and Domestic Trade

AGENCY: Customs Service, Treasury.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Customs Regulations relating to cruising licenses. Cruising licenses exempt pleasure vessels from certain countries from formal entry and clearance procedures at all but the first port of entry in the United States. It is proposed to extend the duration of cruising licenses from six months to one year, reducing paperwork for Customs and vessel owners, and to amend the wording of cruising licenses to apprise license-holders under what conditions their vessels may be dutiable.

DATE: Comments must be received on or before December 20, 1982.

ADDRESS: Written comments (preferably in triplicate) should be addressed to the Commissioner of Customs, Attention: Regulations Control Branch, Room 2426, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Harold M. Singer, Carriers, Drawback and Bonds Division (202-566-5706), U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229.

SUPPLEMENTARY INFORMATION:

Background

Section 4.94(a), Customs Regulations (19 CFR 4.94(a)), provides that U.S. vessels documented as yachts, used exclusively for pleasure, not engaged in any trade, and not violating the Customs or navigation laws of the United States, may proceed from port to port in the United States or to foreign ports without entering and clearing, as long as they have not visited hovering vessels.

Generally, foreign-flag yachts entering the United States are required to comply with the laws applicable to foreign vessels arriving at, departing from, and proceeding between ports of the United States. However, as provided in § 4.94(b), Customs Regulations (19 CFR 4.94(b)), pleasure vessels from certain countries may be issued cruising licenses which exempt them from formal entry and clearance procedures (e.g., filing manifests, obtaining permits to proceed and exemptions from the payment of tonnage tax and clearance fees) at all but the first port of entry. Cruising licenses are available to pleasure vessels of countries which extend reciprocal privileges to U.S. pleasure vessels. A list of these countries also is set forth in section 4.94(b).

Cruising licenses may be issued for six-month periods by any district director of Customs in accordance with requirements set forth in § 4.94(c), Customs Regulations (19 CFR 4.94(c)).

Following a management study which solicited opinions from Customs regional and Headquarters offices, Customs has detemined that, in order to reduce paperwork and to facilitate compliance with § 4.94, the duration of cruising licenses should be extended from six months to one year. Customs also has determined that a "warning" concerning dutiability should be included on the license itself to ensure that holders of cruising licenses are aware that, under certain coditions, their vessels may be dutiable.

Presently, when a cruising license expires at the end of six months, a successive cruising license for an additional period of time may be granted at the discretion of the district director. However, in a decision abstracted as T.D. 55218(1), (September 6, 1960), Customs discouraged this practice by stating that successive cruising licenses shall not be issued for extended periods of time as they are not intended as a form of permanent license. In some regions the yachting season extends beyond the six-month limitation, making it necessary for masters of vessels to seek successive licenses. Extension of the duration of cruising licenses from six months to one year should result in fewer requests for renewal of licenses, thereby saving considerable time for both vessel owners and Customs personnel.

The "warning" added to cruising licenses would apprise license-holders of the law concerning dutiability and the consequences of selling, chartering, or offering to sell or charter a vessel at the time of, or within one year of the vessel's arrival, as appropriate. There have been some instances when vessel owners' unfamiliarity with the provisions of the Tariff Schedules of the United States (19 U.S.C. 1202) and Customs long-standing policy on this subject have resulted in the forfeiture of

a vessel when it was sold or chartered, or offered for sale or charter, at the time of, or within one year of, arrival without first paying the required duty.

In view of the above, Customs is proposing to amend § 4.94(c) and (d) to: (1) Extend the duration of cruising licenses from six months to one year; and (2) amend the wording of cruising license to apprise license-holders under what conditions their vessels may be dutiable.

Comments

Before adopting this proposal, consideration will be given to any written comments timely submitted to the Commissioner of Customs. Comments submitted will be available for public inspection in accordance with § 103.11(b)(1), Customs Regulations (19 CFR 103.11(b)(1)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m. at the Regulations Control Branch, Room 2426, Headquarters, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229.

Regulatory Flexibility Act

Customs has determined that the provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604) are not applicable to this proposal because the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The proposal is not expected to; have significant secondary or incidental effects on a substantial number of small entities; impose, or otherwise cause, a significant increase in the reporting, recordkeeping or other compliance burdens on a substantial number of small entities; or generate significant interest or attention from entities through comments, either formal or informal.

Accordingly, it is hereby certified under the provisions of section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Executive Order 12291

It has been determined that the proposed amendment is not a "major rule" within the criteria provided in section 1(b) of E.O. 12291, and therefore no regulatory impact analysis is required.

Authority

This proposal is initiated under the authority of R.S. 251, as amended, section 3, 23 Stat. 119, as amended, section 5, 35 Stat. 425, as amended (5 U.S.C. 301, 19 U.S.C. 66, 624, 46 U.S.C. 3, 104).

Drafting Information

The principal author of this document was Robert J. Pisani, Regulations Control Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 4

Customs inspection and duties, Imports, Vessels, yachts.

Proposed Amendments

PART 4—[AMENDED]

It is proposed to amend § 4.94, Customs Regulations (19 CFR 4.94), in the following manner:

1. The third sentence in § 4.94(c) would be amended to read as follows:

§ 4.94 Yacht privileges and obligations.

* * * * *

(c) * * * Upon approval of the application, the district director will issue a cruising license in the form prescribed by paragraph (d) of this section permitting the yacht, for a stated period not to exceed one year, to arrive and depart from the United States and to cruise in specified waters of the United States without entering and clearing, without filing manifests and obtaining or delivering permits to proceed, and without the payment of entrance and clearance fees, or fees for receiving manifests and granting permits to proceed, duty on tonnage, tonnage tax, or light money. * * *

(2) Paragraph (d) of § 4.94 would be amended by adding the following "warning" at the end of the form:

(d) * * *

Warning: This vessel is dutiable:

(1) If owned by a resident of the United States (including Puerto Rico), or brought into the United States (including Puerto Rico), for sale or charter to a resident thereof, or

(2) If brought into the United States (including Puerto Rico) by a non-resident free of duty as part of personal effects and sold or chartered within one year from date of entry.

Any offer to sell or charter (for example, a listing with yacht brokers or agents) is considered evidence that the vessel was brought in for sale or charter to a resident or, if made within one year of entry of a vessel brought in free of duty as personal effects, that the vessel no longer is for the personal use of the non-resident.

If the vessel is sold or chartered, or offered for sale or charter, in the circumstances described, without the owner first having filed a consumption entry and having paid duty, the vessel may be subject to seizure or to a monetary claim equal to the value of the vessel. See Schedule 8, Part 2, Subpart A, headnote 1(b), Tariff Schedules of the United States ("TSUS"), items 696.05 and 696.10, TSUS, and 19 U.S.C. 1592.

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Alfred R. De Angelus,

Acting Commissioner of Customs.

Approved: September 14, 1982.

John M. Walker, Jr.,

Assistant Secretary of the Treasury.

[FR Doc. 82-28713 Filed 10-18-82; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Parts 404 and 416

[Regs. Nos. 4, 16]

Federal Old-Age, Survivors, and Disability Insurance Benefits

AGENCY: Social Security Administration, HHS.

ACTION: Proposed Rule.

SUMMARY: The Social Security Administration is amending a portion of its regulations which cover Federal Old-age, survivors and disability insurance, and the regulations on supplemental security income for the aged, blind and disabled.

These proposed rules implement section 303 of Pub. L. 96-265, the Social Security Disability Amendments of 1980. Section 303 became effective December 1, 1980. They provide disabled beneficiaries under titles II and XVI of the Social Security Act who have completed 9 months of trial work with a 15-month reentitlement period immediately following the trial work period. During this 15-month reentitlement period, the beneficiary may continue to test his or her ability to do substantial gainful activity (SGA) and will receive cash benefits for any months in which he or she does not perform SGA, without the need for a new application. However, title II disability benefits and title XVI benefits for persons who are disabled generally will not be paid for any month in the period in which the person performs SGA. However, special title XVI benefits can be paid for certain months during the 15-month reentitlement period even if the person performs SGA.

(See 416.260—416.269, 47 FR 15319, April 9, 1982).

DATE: Comments must be received on or before November 18, 1982.

ADDRESSES: Written comments should be sent to the Commissioner of Social Security, Department of Health and Human Services, P.O. Box 1585, Baltimore, Maryland 21203, or delivered to 3-A-3 Operations Building, 6401 Security Boulevard, Baltimore, Md. 21235 between 8:00 a.m. and 4:30 p.m. on regular business days. Comments received may be inspected during these same hours by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Harry J. Short, Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235, telephone 301-594-7337.

SUPPLEMENTARY INFORMATION: Section 303 of Pub. L. 96-265, the Social Security Disability Amendments of 1980, enacted June 9, 1980, affects both the title II and title XVI disability programs. It (1) provides an extended period of 15 months during which beneficiaries with disabling impairments who have completed 9 months of trial work may continue to test their ability to work and remain eligible to have their disability payments reinstated if they do not continue working, (2) provides a "termination month" for the payment of title II benefits and for the period during which a person may be considered disabled for SSI purposes under title XVI, (3) extends the trial work period provisions to disabled widows, disabled widowers, and disabled surviving divorced spouses who are receiving benefits under title II, and (4) revises the ending date of the title II period of disability in certain instances.

Background

Under the law and regulations relating to the title II and title XVI disability programs prior to December 1, 1980, the effective date of section 303 of the Social Security Disability Amendments of 1980, after a person completed a 9-month trial work period and then in a later month was able to perform work at the substantial gainful activity (SGA) level, the person's benefit payments were terminated. The person's disability and any period of disability established under title II ended. (A "trial work period" is a period of 9 months, not necessarily consecutive, during which a beneficiary can test his or her ability to work. Work in those months in not considered in determining whether disability ceased during this period. "SGA" is work activity done for pay or profit that involves significant physical or mental activities. A person who is able to do SGA is, by definition, not disabled. A "period of disability", applicable only in the title II program, is a continuous period during which a person is disabled. Benefits are generally paid during this period and it may favorably affect the way title II benefits may be computed for the person in the future.) Except where other provisions of title II or title XVI reduced or prevented payment of benefits, a person could receive full benefits throughout the trial work period. This is still true. In addition, the person was eligible for benefits for the first month in which he or she was able to perform SGA following the trial work period and for the next 2 months. The period of disability terminated with the month before the month he or she became age 65 or, if earlier, the second month following the month in which disability ceased. Disability would cease because a person was able to do SGA. As a result, anyone whose title II period of disability or whose title XVI benefits terminated and who was unable to continue working had to file a new application which had to be processed as a new claim. Consideration was given to reopening the prior determination that disability ceased on the basis that the work activity that caused the termination of the person's benefits did not show that the person was able to continue to do SGA. Even so, new medical evidence and other documentation had to be obtained. Also, under title II, disabled widow(er)s and disabled surviving divorced spouses were not entitled to a trial work period. Title XVI contains no provisions for disabled widow(er)'s or disabled surviving divorced spouse's benefits.

Regulatory provisions

The proposed regulations will apply to title II disabled worker's insurance benefits, disabled child's benefits, disabled widow(er)'s and disabled surviving divorced spouse's benefits, the period of disability, and title XVI supplemental security income benefits based on disability. They will implement Section 303 of Pub. L. 96-265, the Social Security Disability Amendments of 1980.

The regulations will provide an extended period of time (the reentitlement period) during which a person with a disabling impairment who has completed 9 months of trial work and who engages in SGA will remain eligible to have his or her disability payments reinstated if the work attempt fails.

The reentitlement period, described in §§ 404.1592a and 416.992a, will begin with the first month following completion of the trial work period (but not earlier than December 1, 1980, the effective date of section 303), and will generally end with the 15th month.

During the reentitlement period, a person who has a disabling impairment will be paid benefits for all months in which he or she does not do SGA. In determining whether an employee does SGA in a month in the entitlement period, we consider only work or earnings in that month; we do not consider the average amount of work or earnings over a period of months. In determining whether a self-employed person does SGA in a month in the reentitlement period, we will continue to consider that person's activities and services on a month-by-month basis, as under present rules. We will not average the activities and services over a period of months. Our existing regulations already provide us with sufficient guidance to permit us to make a determination as to whether a self-employed person is doing SGA in the reentitlement period. In certain circumstances, a person may receive special title XVI benefits (§§ 416.260-416.269) even though he or she does SGA, 47 FR 15319, April 9, 1982).

If payments are stopped because a person does not have a medically disabling physical or mental impairment, they will not be automatically resumed. Benefits may be paid after the 15-month period if the person remains unable to do SGA. Under title II of the Social Security Act, a person may have only one trial work period during a period of disability. Under title XVI of the Act, a person may have only one trial work period during a period of entitlement to cash benefits based on the same disability. Since the reentitlement period immediately follows the trial work period, a person may have only one reentitlement period in that same period.

In §§ 404.902 and 416.1402 we have provided that our determinations on whether a person has a disabling impairment are initial determinations and subject to administrative review, and in §§ 404.1511 and 416.911, we have defined the term "disabling impairment".

The proposed amendments also define (in §§ 404.325 and 416.994) the term "termination month" as established by section 303 of Pub. L. 96-265 as a reference point for determining when a person's disability benefits should end under title II and for determining when disability status ends under title XVI.

Sections 404.1574, 404.1575, 416.974, and 416.975 provide that the

unsuccessful work attempt (UWA) policy will not be utilized during the reentitlement period. The UWA policy provides that earnings from work at the SGA level that a person is forced to stop after a short time because of his or her impairment do not show that he or she is able to do SGA. During the reentitlement period, in accordance with section 303, a beneficiary will receive or not receive monthly benefits depending on whether or not he or she does SGA. For this reason, we will not apply the UWA policy during this period. In addition, we have modified the general discussion of the evaluation guides for employees in §§ 404.1574 and 416.974 to make it clear that a person's earnings may show whether or not he or she is able to do SGA.

We have amended §§ 404.1579, 404.1586, 404.1594, and 416.994 to show that a person may be paid benefits for certain months in and after the reentitlement period even though he or she has demonstrated the ability to do SGA.

The proposed amendments also extend (in § 404.1592) the title II trial work period provisions to disabled widows, disabled widowers, and disabled surviving divorced spouses (who, for title II disability program purposes, are considered disabled widow(er)s). A conforming change in section 404.1579 and the revocation of § 404.1580 also reflect this change in the law.

The Social Security Disability Amendments of 1980 also revise the ending date of the title II period of disability in certain instances for persons who have completed 9 months of trial work. These regulations reflect this statutory change (Section 404.321). In § 404.401a, we explain that after the 9-month trial work period, a person cannot be paid disability insurance benefits for months in which he or she does SGA (except for the first month that he or she does SGA and the two succeeding months whether or not he or she does SGA in those two months) even though severely impaired.

Another provision of the Social Security Disability Amendments of 1980 provides for continuation of the payment of cash benefits under certain specific conditions after medical recovery for persons who are enrolled in appropriate vocational rehabilitation programs (section 301). To implement that provision, it was necessary to amend §§ 404.316, 404.337, 404.352, 404.902, 416.1331 and 416.1402. Those amendments were published as a Notice of Proposed Rulemaking, on October 30, 1981 at 46 FR 53684. In this Notice of Proposed Rulemaking we are again amending those sections to implement section 303 of the Social Security Disability Amendments of 1980.

Executive Order 12291

These regulations have been reviewed under E.O. 12291 and do not meet any of the criteria for a major regulation. The regulations merely implement a legislative provision that, overall, should have only a negligible cost impact. While some workers may find it easier to return to the disability rolls because a new application is not required, we believe any resulting costs will be offset by the savings to the Social Security trust funds and general fund as a result of encouraging disabled persons to continue to test their ability to work and come off the disability rolls permanently. Therefore, a regulatory impact analysis is not required.

Paperwork Reduction Act

These regulations impose no new reporting or recordkeeping requirements requiring OMB clearance.

Regulatory Flexibility Act

We certify that these proposed regulations will not, if promulgated, have a significant economic impact on a substantial number of small entities because these rules affect only individuals. Therefore, a regulatory flexibility analysis required under Pub. L. 96–354, the Regulatory Flexibility Act, is not necessary.

(Catalog of Federal Domestic Assistance Program No. 13.802, Disability Insurance; No. 13.807, Supplemental Security Income Program.)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Death benefits, Disabled, Old-Age, Survivors and disability insurance.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disabled, Public assistance programs, Supplemental security income (SSI)

Dated: August 25, 1982.

Paul B. Simmons,

Acting Commissioner of Social Security.

Approved: September 27, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

Part 404 of Chapter III of Title 20 of the Code of Federal Regulations is amended as follows:

PART 404—[AMENDED]

1. The authority citation for Subpart D of Part 404 reads as follows:

Authority: Sec. 202, 205, 216, 223, 228, 1102 of the Social Security Act, 49 Stat. 623, 53 Stat. 1368, 64 Stat. 492, 70 Stat. 815, 80 Stat. 67, 49 Stat. 647; Sec. 5, Reorganization Plan No. 1 of 1953, 67 Stat. 631; 42 U.S.C. 402, 405, 416, 423, 428, and 1302; and 5 U.S.C. Appendix; Sec. 303 of Pub. L. 96–265, 94 Stat. 451 (42 U.S.C. 402, 416, 422, 423).

2. Section 404.316 is amended by revising paragraph (b) and adding new paragraph (d) to read as follows:

§ 404.316 When entitlement to disability benefits begins and ends.

* * * * *

(b) Your entitlement to disability benefits ends with the earliest of these months: (1) The month before the month of your death; (2) the month before the month you become 65 years old; (3) subject to the exception in paragraph (c) of this section, the second month after the month in which your disability ends as provided in § 404.1594(b)(1); or (4) subject to the exception in paragraph (d) of this section, the month before your termination month (§ 404.325).

* * * * *

(d) If, after November 1980, you have a disabling impairment (§ 404.1511), you will be paid benefits for all months in which you do not do substantial gainful activity during the reentitlement period (§ 404.1592a) following the end of your trial work period (§ 404.1592). If you are unable to do substantial gainful activity in the first month following the reentitlement period, we will pay you benefits until you are able to do substantial gainful activity. (Earnings during your trial work period do not affect the payment of your benefit.) You will also be paid benefits for the first month after the trial work period in which you do substantial gainful activity and the two succeeding months, whether or not you do substantial gainful activity during those succeeding months. After those three months, you cannot be paid benefits for any months in which you do substantial gainful activity.

3. Section 404.321 is revised to read as follows:

§ 404.321 When a period of disability begins and ends.

(a) *When a period of disability begins.* Your period of disability begins on the day your disability begins if you are insured for disability on that day. If you are not insured for disability on that day, your period of disability will begin on the first day of the first calendar quarter after your disability began in which you become insured for disability.

Your period of disability may not begin after you become 65 years old.

(b) *When disability ended before December 1, 1980.* Your period of disability ends on the last day of the month before the month in which you become 65 years old or, if earlier, the last day of the second month following the month in which your disability ended.

(c) *When disability ends after November 1980.* Your period of disability ends with the close of whichever of the following is the earliest—

(1) The month before the month in which you become 65 years old;

(2) The month immediately preceding your termination month (§ 404.325); or

(3) If you perform substantial gainful activity during the 15-month period following the end of your trial work period, the last month for which you received benefits.

4. A new § 404.325 is added to read as follows:

§ 404.325 The termination month.

If you do not have a disabling impairment, your termination month is the third month following the month in which your impairment is not disabling even if it occurs during the trial work period or the reentitlement period. If you continue to have a disabling impairment and complete a 9-month trial work period, your termination month will be the third month following the earliest month you perform substantial gainful activity or are determined able to perform substantial gainful activity but in no event earlier than the first month after the 15th month following the end of your trial work period.

Example: You complete your trial work period in December 1980. You are then working at the substantial gainful activity level and continue to do so throughout the 15 months following completion of your trial work period and thereafter. Your termination month will be April 1982, which is the 16th month—that is, the first month in which you performed substantial gainful activity after the 15th month following your trial work period.

Example: You complete your trial work period in December 1980 but you are not able to work at the substantial gainful activity level until December 1982. Your termination month will be March 1983—that is, the third month after the earliest month you perform or are determined able to perform substantial gainful activity.

5. Section 404.337 is amended by revising paragraph (b)(3) and by adding a new paragraph (d) to read as follows:

§ 404.337 When widow's and widower's benefits begin and end.

* * * * *

(b) * * *

(3) If your widow's or widower's benefit is based upon a disability, the second month after the month your disability ends or, where disability ends on or after December 1, 1980, the month before your termination month (§ 404.325). However payments are subject to the exceptions in paragraphs (c) and (d) of this section. You may remain eligible for payment of benefits if you became 65 years old before your termination month and you met the other requirements for widow's or widower's benefits.

* * * * *

(d) If, after November 1980, you have a disabling impairment (§ 404.1511), you will be paid benefits for all months in which you do not do substantial gainful activity during the reentitlement period (§ 404.1592a) following the end of your trial work period (§ 404.1592). If you are unable to do substantial gainful activity in the first month following the reentitlement period, we will pay you benefits until you are able to do substantial gainful activity. (Earnings during your trial work period do not affect the payment of your benefits.) You will also be paid benefits for the first month after the trial work period in which you do substantial gainful activity and the two succeeding months, whether or not you do substantial gainful activity during those succeeding months. After those three months, you cannot be paid benefits for any months in which you do substantial gainful activity.

6. Section 404.352 is amended by revising the first three sentences in paragraph (b)(1) and adding new paragraph (d) to read as follows:

§ 404.352 When child's benefits begin and end.

* * * * *

(b) Your entitlement to benefits ends with the month before the month in which one of the following events first occurs:

(1) You become 18 years old, unless you are disabled or a full-time student. If you become 18 years old and you are disabled, your entitlement to disability benefits ends with the second month following the month in which your disability ends. If your disability ends on or after December 1, 1980, your entitlement to disability benefits continues, subject to the exceptions in paragraphs (c) and (d) of this section, until the month before your termination month (§ 404.325).

* * * * *

(d) If, after November 1980, you have a disabling impairment (§ 404.1511), you will be paid benefits for all months in which you do not do substantial gainful activity during the reentitlement period (§ 404.1592a) following the end of your trial work period (§ 404.1592). If you are unable to do substantial gainful activity in the first month following the reentitlement period, we will pay you benefits until you are able to do substantial gainful activity. (Earnings during your trial work period do not affect the payment of your benefits.) You will also be paid benefits for the first month after the trial work period in which you do substantial gainful activity and the two succeeding months, whether or not you do substantial gainful activity during those succeeding months. After those three months, you cannot be paid benefits for any months in which you do substantial gainful activity.

7. The authority citation for Subpart E of Part 404 reads as follows:

Authority: Secs. 205, 207, and 1102, 53 Stat. 1368, as amended, 79 Stat. 379, as amended, 49 Stat. 647, as amended; sec. 5 of Reorganization Plan No. 1 of 1953, 67 Stat. 18; 42 U.S.C. 405, 427, 1302; Sec. 303 of Pub. L. 96-265, 94 Stat. 451 (42 U.S.C. 402, 416, 422, 423).

8. A new § 404.401a is added to read as follows:

§ 404.401a When we do not pay a disabled person because of work activity.

If you are receiving benefits because you are disabled or blind as defined in title II of the Social Security Act, we will stop your monthly benefits even though you have a disabling impairment (§ 404.1511), if you engage in substantial gainful activity during the reentitlement period (§ 404.1592a) following completion of the trial work period (§ 404.1592). You will, however, be paid benefits for the first month after the trial work period in which you do substantial gainful activity and the two succeeding months, whether or not you do substantial gainful activity in those two months. Earnings from work activity during a trial work period will not stop your benefits.

9. The authority citation for Subpart J of Part 404 reads as follows:

Authority: Secs. 205 and 1102 of the Social Security Act, sec. 5 of Reorganization Plan No. 1 of 1953, 53 Stat. 1368, 49 Stat. 647 (42 U.S.C. 405 and 1302); Section 303 of Pub. L. 96-265, 94 Stat. 451 (42 U.S.C. 402, 416, 422, 423).

10. Section 404.902 is amended by revising paragraphs (q) and (r) and adding a new paragraph (s) to read as follows:

§ 404.902 Administrative actions that are initial determinations.

Initial determinations are the determinations we make that are subject to administrative and judicial review.

The initial determination will state the important facts and give the reasons for our conclusions. In the old age, survivors' and disability insurance programs, initial determinations include, but are not limited to, determinations about—

* * * * *

(q) An offset of your benefits under § 404.408b because you previously received supplemental security income payments for the same period;

(r) Whether your completion of or continuation for a specified period of time in an appropriate vocational rehabilitation program will significantly increase the likelihood that you will not have to return to the disability benefit rolls and thus, whether your benefits may be continued even though you are not disabled; and

(s) Whether or not you have a disabling impairment(s) as defined in § 404.1511.

11. The authority citation for Subpart P of Part 404 reads as follows:

Authority: Secs. 202, 205, 216, 221, 222, 223, 225, and 1102 of the Social Security Act, as amended; 49 Stat. 623, as amended, 53 Stat. 1368, as amended, 68 Stat. 1080, as amended, 68 Stat. 1081, as amended, 68 Stat. 1082, as amended, 70 Stat. 815, as amended, 70 Stat. 817, as amended, 49 Stat. 647, as amended; 42 U.S.C. 402, 405, 416, 421, 422, 423, 425, and 1302. Sec. 303 of Pub. L. 96-265, 94 Stat. 451 (42 U.S.C. 402, 416, 422, 423).

12. A new § 404.1511 is added to read as follows:

§ 404.1511 Definition of disabling impairment.

(a) *Disabled workers and persons disabled since childhood.* If you are entitled to disability cash benefits as a disabled worker or to child's insurance benefits, a disabling impairment is an impairment (or combination of impairments) which, of itself, is so severe that it meets or equals a set of criteria in the Listing of Impairments in Appendix 1 or which, when considered with your age, education and work experience, would result in a finding that you are disabled. In determining whether you have a disabling impairment, earnings are not considered

(b) *Disabled widows, widowers and surviving divorced spouses.* If you are entitled to disability benefits as a disabled widow, widower, or surviving divorced spouse, a disabling impairment is an impairment (or combination of impairments) which, of itself, is so severe that it meets or equals a set of criteria in the Listing of Impairments in Appendix 1 and would result in a finding that you are disabled. In determining whether you have a disabling impairment, earnings are not considered.

13. Section 404.1574 is amended by revising paragraph (a)(1) to read as follows:

§ 404.1574 Evaluation guides if you are an employee.

(a) General. We use several guides to decide whether the work you have done shows that you are able to do substantial gainful activity.

(1) *Your earnings may show you have done substantial gainful activity.* The amount of your earnings from work you have done may show that you have engaged in substantial gainful activity. Generally, if you worked for substantial earnings, this will show that you are able to do substantial gainful activity. On the other hand, the fact that your earnings are not substantial will not necessarily show that you are not able to do substantial gainful activity. Earnings from work that you were forced to stop after a short time because of your impairment will not show that you are able to do substantial gainful activity. However, we will not consider whether or not your impairment forced you to stop working after a short time during the reentitlement period described in § 404.1592a. During that period we will pay you benefits for any months in which you do not engage in substantial gainful activity regardless of whether your impairment forced you to stop working. In determining whether you do SGA in a month during the reentitlement period, we consider only your work in or earnings for that month; we do not consider the average amount of your work or earnings over a period of months.

* * * * *

14. Section 404.1575 is amended by revising paragraph (a) to read as follows:

§ 404.1575 Evaluation guides if you are self-employed.

(a) *If you are a self-employed person.* We will consider your activities and their value to your business to decide whether you have engaged in substantial gainful activity if you are self-employed. We will not consider your income alone since the amount of income you actually receive may depend upon a number of different factors like capital investment, profit sharing agreements, etc. Income from activities that you were forced to stop after a short time because of your impairment will now show that you are able to do substantial gainful activity. However, we will not consider whether or not your impairment forced you to stop working after a short time during the reentitlement period described in § 404.1592a. During that period we will pay you benefits for any months in which you do not engage in substantial gainful activity regardless of whether your impairment forced you to stop working. We will evaluate your work activity on the value to the business of your services regardless of whether you receive an immediate income for your services. We consider that you have engaged in substantial gainful activity if—

* * * * *

15. Section 404.1579 is amended by revising paragraph (a) to read as follows:

§ 404.1579 Why and when we will find that your disability has ended.

(a) *If you are not disabled.* If you are entitled to widow's or widower's benefits as a disabled widow, widower, or surviving divorced spouse, we will find that your disability ended in the earliest of the following months—

(1) The month your impairment, based on current medical evidence, no longer exists or is not an impairment listed in Appendix 1 or is not equal to a listed impairment; or

(2)(i) For months after November 1980, the month in which you do substantial gainful activity following completion of a trial work period; however, we may pay you benefits for certain months in and after the reentitlement period which follows the trial work period. (See § 404.1592a for a discussion of the reentitlement period, and § 404.337 for when your benefits will end.); or

(ii) For months before December 1980, the month in which you do substantial gainful activity.

* * * * *

§ 404.1580 [Removed]

16. Section 404.1580 is hereby removed

17. Section 404.1586 is amended by revising paragraph (a)(1) and (a)(2) to read as follows:

§ 404.1586 Why and when we will stop your cash benefits.

(a) *When you are not entitled to benefits.* If you become entitled to disability cash benefits as a statutorily blind person, we fill find that you are no longer entitled to benefits beginning with the earliest of—

(1) The month your vision, based on current medical evidence, does not meet the definition of blindness (and any remaining impairments do not make you unable to do substantial gainful activity considering your age, education and work experience);

(2) If you are under age 55, the month in which you demonstrated your ability to engage in substantial gainful activity (following completion of a trial work period); however, we may pay you benefits for certain months in and after the reentitlement period which follows the trial work period. (See § 404.1592a for a discussion of the reentitlement period, and § 404.316 for additional information on when your benefits will end.)

* * * * *

18. Section 404.1592 is amended by revising paragraphs (d) and (e) to read as follows:

§ 404.1592 The trial work period.

* * * * *

(d) *Who is and is not entitled to a trial work period.* (1) Those who are receiving disability insurance benefits, child's benefits based on disability and, beginning December 1, 1980, those who are receiving widows' or widowers' benefits based on disability, or surviving divorced spouses' benefits based on disability, generally are entitled to a trial work period.

(2) You are not entitled to a trial work period if—

(i) You are entitled to a period of disability but not to disability insurance cash benefits; or

(ii) You are receiving disability insurance benefits in a second period of disability for which you did not have to complete a waiting period.

(e) *When the trial work period begins and ends.* The trial work period begins with the month in which you become entitled to disability insurance cash benefits, to child's cash benefits based on disability or to widow's, widower's, or surviving divorced spouse's cash benefits based on disability. It cannot begin before the month in which you file your application for benefits and for widows, widowers, and surviving divorced spouses, it cannot begin before December 1, 1980. It ends with the close of whichever of the following calendar months is the earlier:

(1) The 9th month (whether or not the months have been consecutive) in which you have performed services; or

(2) The month in which, based on new evidence, you are not disabled, even though you have not worked a full 9 months.

19. A new section 404.1592a is added to read as follows:

§ 404.1592a The reentitlement period.

(a) *General.* The reentitlement period is an additional period after 9 months of trial work during which you may continue to test your ability to work if you have a disabling impairment. You will not be paid benefits for any month, after the third month, in this period in which you do substantial gainful activity and you will be paid benefits for months in which you do not do substantial gainful activity. (See §§ 404.316, 404.337, 404.352 and 404.401a). If your benefits are stopped because you do substantial gainful activity they may be started again without a new application and a new determination of disability if you discontiue doing substantial gainful activity during this period. In determining whether you do SGA in a month, we consider only your work or earnings in that month ; we do not consider the average amount of your work or earnings over a period of months.

(b) *When the reentitlement period begins and ends.* The reentitlement period begins with the first month following completion of 9 months of trial work but cannot begin earlier than December 1, 1980. It ends with whichever is earlier—

(1) The month before the first month in which your impairment no longer exists or is not medically disabling; or

(2) The last day of the 15th month following the end of your trail work period. (See §§ 404.316, 404.337, and 404.352 for when your benefits end.)

(c) *When you are not entitled to a rentitlement period.* You are not entitled to a reentitlement period if:

(1) You are entitle to a period of disability, but not to disability insurance cash benefits;

(2) You are not entitled to a trail work period;

(3) Your entitlement to disability insurance benefits ended before you completed 9 months of trial work in that period of disability.

20. Section 404.1594 is amended by revising paragraph (b) to read as follows:

§ 404.1594 Why and when we will find that your disability has ended.

(a) *General.* When the medical or other evidence in your file shows that your disability has ended, we will contact you and tell you that the evidence in your file shows that you are able to do substantial gainful activity and that your eligibility for cash benefits and for period of disability will end. Before we stop your benefits or a period of disability, we will give you a chance to give us your reasons why we should not stop your benefits or your period of disability. Section 404.1595 describes your rights and the procedures we will follow. We may also stop payment on your benefits if you have not cooperated with us in getting information about your disability or if we cannot find you (see paragraph (c) of this section).

(b) *Disabled workers and persons disabled since childhood.* If you are entitled to disability cash benefits as a disabled worker or to child's insurance benefits, we will find that your disability ended in the earliest of the following months—

(1) The month your impairment, based on current medical or other evidence, no longer exists or is such that you are able to do substantial gainful activity;

(2) The month in which you demonstrated your ability to engage in substantial gainful activity (following completion of a trial work period); however, we may pay you benefits for certain months in and after the reentitlement period which follows the trail work period. (See § 404.1592a for a discussion of the reentitlement period. If you are receiving benefits on your own earnings record, see § 404.316 for when your benefits will end. See § 404.352 if you are receiving benefits on a parent's earning as a disabled adult child);

(3) The month in which you actually do substantially gainful activity (where you are not entitled to a trial work period).

* * * * *

PART 416—[AMENDED]

Part 416 of Chapter III of Title 20 of the Code of Federal Regulations is amended as follows:

Representative **Reuss. 11.** The authority citation for Subpart I of Part 416 reads as follows:

Authority: Secs. 1102, 1614, and 1631 of the Social Security Act; 49 Stat. 647, as amended, 86 Stat. 1471, as amended by 88 Stat. 52, 86 Stat. 1475; 42 U.S.C. 1302, 1382c, and 1383. Section 303 of Pub. L. 96–265, 94 Stat. 453, (42 U.S.C. 1382, 1383).

2. A new § 416.911 is added to reads as follows:

§ 416.911 Definition of disabling impairment.

A disabling impairment is an impairment (or combination of impairments) which, of itself, is so severe that it meets or equals a set of criteria in the Listing of Impairments in Appendix 1 of Subpart P of Part 404 of this chapter or which, when considered with your age, education and work experience, would result in a finding that you are disabled. In determining whether you have a disabling impairment earnings are not considered.

3. Section 416.974 is amended by revising paragraph (a)(1) to read as follows:

§ 416.974 Evaluation guides if you are an employee.

(a) *General.* We use several guides to decide whether the work you have done shows that you are able to do substantial gainful activity.

(1) *Your earnings may show you have done substantial gainful activity.* The amount of year earnings from work you have done may show that you engaged in substantial gainful activity. Generally, if you worked for substantial earnings, this will show that you are able to do substantial gainful activity. On the other hand, the fact that your earnings are not substantial will not necessarily show that you are not able to do substantial gainful activity. Earnings from work that you were forced to stop after a short time because of your impairment will not show that you are able to do substantial gainful activity. However, we will not consider whether or not your impairment forced you to stop working after a short time during the reentitlement period described in § 416.992a. During that period we will pay you benefits for any months in which you do not engage in substantial gainful activity regardless of whether you impairment forced you to stop working. In determining whether you do SGA in a month during the reentitlement period, we consider only your work in or earnings for that month; we do not consider the average amount of your work or earnings over a period of months. We will also pay you benefits for months in that period in which you engage in substantial gainful activity, if you qualify for the special benefits explained in § 416.261.

* * * * *

4. Section 416.975 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 416.975 Evaluation guides if you are self-employed.

(a) *If you are a self-employed person.* We will consider your activities and their value to your business to decide whether you have engaged in substantial gainful activity if you are self-employed. We will not consider your income alone since the amount of income you actually receive may depend upon a number of different factors like capital investment, profit sharing agreements, etc. Income from activities that you were forced to stop after a short time because of your impairment will not show that you are able to do substantial gainful activity. However, we will not consider whether or not your impairment forced you to stop working after a short time during the reentitlement period described in § 416.992a. During that period we will pay you benefits for any months in which you do not engage in substantial gainful activity regardless of whether your impairment forced you to stop working. We will also pay you benefits for months in that period in which you engage in substantial gainful activity if you qualify for the special benefits explained in § 416.261. We will evaluate your work activity on the value to the business of your services regardless of whether you receive an immediate income for your services. We consider that you have engaged in substantial gainful activity if—

* * * * *

5. A new section 416.992a is added to read as follows:

§ 416.992a The reentitlement period.

(a) *General.* The reentitlement period is an additional period after 9 months of trial work during which you may continue to test your ability to work if you have a disabling impairment. Generally, you will not be paid benefits for any month, after the 3rd month, in this period in which you do substantial gainful activity unless you qualify for the special benefits explained in § 416.261. You will be paid benefits for months in which you do not do substantial gainful activity and you meet all the other eligibility requirements. (See § 416.1331). If your benefits are stopped because you do substantial gainful activity they may be started again without a new application and a new determination of disability if you discontinue doing substantial gainful activity during this period. In determining whether you do SGA in a month during the reentitlement period we only consider your work in or earnings for that month; we do not consider the average amount of your work or earnings over a period of months.

(b) *When the reentitlement periods begins and ends.* The reentitlement period begins with the first month following completion of 9 months of trial work but cannot begin earlier then December 1, 1980. It ends with whichever is earlier—

(1) The month before the first month in which your impairment is determined to no longer exist or not to be disabling: or

(2) The last day of the 15th month following the end of your trial work period (See § 416.1331 for when your benefits end).

6. Section 416.994 is revised to read as follows:

§ 416.994 Why and when we will find that your disability has ended.

(a) *General.* When the evidence in your file shows that you are able to do substantial gainful activity we will contact you and tell you when your disability ended, and also tell you when your benefits will stop.

(b) *Disabled persons age 18 or over.* If you are age 18 or older, we will find that your disability ends in the following month—

(1) For purposes of § 416.1331 (under which benefits can be paid for the month in which disability ends and the two following months), the month in which your impairment is determined, based on current medical or other evidence, to no longer exist or to be such that you are able to do substantial gainful activity or, if earlier, the first month following completion of your trial work period for which it is determined that you have demonstrated the ability to do substantial gainful activity.

(2) For all other purposes, the month preceding the termination month. The termination month, as that term is used in this paragraph, is the first month, after the 15-month reentitlement period (described in § 416.992a), in which you engage in or are determined able to engage in substantial gainful activity or, if earlier, the first month after a trial work period in which your impairment is determined, based on current medical or other evidence, to no longer exist or not to be a disabling impairment as described in § 416.911.

(c) *Disabled persons under age 18.* If you are under age 18, we will find that your disability ends in the following month—

(1) For purposes of § 416.1331, the month your impairment is determined, based on current medical evidence, to no longer exist or not to be an impairment listed in Appendix 1 of Subpart P of Part 404 of this chapter or not to be equal to a listed impairment, or, if earlier, the first month following completion of your trial work period for which it is determined that you have demonstrated the ability to do substantial gainful activity;

(2) For all other purposes, the month preceding the termination month. The termination month, as that term is used in this paragraph, is the first month, after the 15-month reentitlement period (described in § 416.992a), in which you engage in or are determined able to engage in substantial gainful activity or, if earlier, the first month after a trial work period in which your impairment is determined, based on current medical or other evidence, to no longer exist or not

to be a disabling impairment as described in § 416.911.

* * * * *

7. The authority citation for Subpart M of Part 416 reads as follows:

Authority: Secs. 1102, 1611–1615, and 1631 of the Social Security Act, as amended, 49 Stat. 647, as amended, 86 Stat. 1466–1477; 42 U.S.C. 1302, 1382–1382d, 1383; Sec. 303 of Pub. L. 96–265, 94 Stat. 453 (42 U.S.C. 1382, 1383).

8. Section 416.1331 is revised to read as follows:

§ 416.1331 Termination of your disability or blindness payments.

(a) *General.* The last month for which we can pay you benefits based on disability is the earlier of the second month after the first month in which you are able to do substantial gainful activity following a trial work period (described in § 416.992), or the second month after the first month in which you are determined to no longer have a disabling impairment (described in § 416.911). (See § 416.1338 for an exception to this rule if you are participating in an appropriate vocational rehabilitation program, and § 416.261 for an explanation of special benefits to which you may be entitled.) However, benefits may be resumed during the reentitlement period (described in § 416.992a) under certain circumstances. If you have a disabling impairment, you will receive benefits based on disability for any month in which you do not do substantial gainful activity in the reentitlement period and if we determine that you are not able to do substantial gainful activity in the first month following the reentitlement period, we will pay you benefits after the reentitlement period until you are able to do substantial gainful activity. These payments will stop with the earlier of the month before the first month in which you do substantial gainful activity or the month before the month in which you are determined to no longer have a disabling impairment. The last month for which we can pay you benefits based on blindness is the second month after the month in which your blindness ends (see § 416.986 for when blindness ends). You must meet the income, resources, and other eligibility requirements to receive any of the benefits described in this paragraph. We will also stop payment of your benefits if you have not cooperated with us in getting information about your disability or blindness.

(b) *After we make a determination that you are not now disabled.* If we determine that you do not meet the disability requirements of the law, we will send you an advance written notice telling you why we believe you are not disabled and when your benefits should stop. The notice will explain your right to appeal if you disagree with our determination. You may still appeal our determination that you are not now disabled even though your payments are continuing because of your participation in an appropriate vocational rehabilitation program. You may also appeal a determination that your completion of or continuation for a specified period of time in an appropriate vocational rehabilitation program will not significantly increase the likelihood that you will not have to return to the disability benefit rolls and, therefore, you are not entitled to continue to receive benefits.

9. The authority citation for Subpart N of Part 416 reads as follows:

Authority: Sections 1102, 1631(c), and 1633 of the Social Security Act, 49 Stat. 647, 86 Stat. 1475, 86 Stat. 1478 (42 U.S.C. 1302, 1383, and 1383b); Section 301 of Pub. L. 96–265, 94 Stat. 450 (42 U.S.C. 1382c, 1383).

10. Section 416.1402 is amended by revising paragraphs (j) and (k) and adding a new paragraph (l) to read as follows:

§ 416.1402 Administrative actions that are initial determinations.

Initial determinations are the determinations we make that are subject to administrative and judicial review. The initial determination will state the important facts and give the reasons for our conclusions. Initial determinations regarding supplemental security income benefits include, but are not limited to, determinations about—

* * * * *

(j) Your disability;

(k) Whether your completion of or continuation for a specified period of time in an appropriate vocational rehabilitation program will significantly increase the likelihood that you will not have to return to the disability benefit rolls and thus, whether your benefits may be continued even though you are not disabled; and

(l) Whether or not you have a disabling impairment as defined in § 416.911.

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Food and Drug Administration

21 CFR Parts 182 and 184

[Docket No. 80N-0388]

Niacin and Niacinamide; Proposed Affirmation of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to affirm that niacin and niacinamide are generally recognized as safe (GRAS) as direct human food ingredients. The safety of these ingredients has been evaluated under a comprehensive safety review conducted by the agency. The proposal would take no action on the listing of these ingredients as GRAS substances for use in dietary supplements.

DATE: Comments by December 20, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive review of human food ingredients classified as GRAS or subject to a prior sanction. The agency has issued several notices and proposals (see the **Federal Register** of July 26, 1973 (38 FR 20040)) initiating this review, under which the safety of niacin and niacinamide has been evaluated. In accordance with the provisions of § 170.35 (21 CFR 170.35), the agency proposes to affirm the GRAS status of these ingredients as nutrient supplements in conventional food [1] and infant formula.

The GRAS status of the use of niacin and niacinamide in dietary supplements (i.e., over-the-counter vitamin preparations in forms such as capsules, tablets, liquids, wafers, etc.) is not affected by this proposal. The agency did not request consumer exposure data on dietary supplement uses when it initiated this review. Without exposure data, the agency cannot evaluate the safety of using these ingredients in dietary supplements. The use of these ingredients in dietary supplements will continue to be permissible under Subpart F of Part 182 (21 CFR Part 182).

The term "niacin" is used as the name for nicotinic acid (pyridine-3-carboxylic acid) and as a generic term to refer to niacinamide and other derivatives of nicotinic acid that qualitatively exhibit the biological activity of nicotinamide. Thus, phrases such as "niacin activity" and "niacin deficiency" are commonly used.

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[1] FDA is using the term "conventional food" to refer to food that would fall within any of the 43 categories listed in § 170.3(n) (21 CFR 170.3(n)).

The International Union of Nutrition Sciences and the American Institute of Nutrition have recommended use of the term "nicotinic acid" instead of "niacin" and the term "nicotinamide" instead of "niacinamide." However, to be consistent with FDA's nutrition labeling regulations, the agency has decided to retain the traditional names for these ingredients, "niacin" and "niacinamide." Additionally, FDA will continue to use the name "niacin" when describing the biological effects of nicotinic acid and its derivatives. In other instances, the specific chemical names will be used.

Niacin (nicotinic acid) occurs naturally in a number of food sources. In the pure form it exists as nonhygroscopic, colorless, odorless, sour-tasting, needle-shaped crystals, which melt at 236° C and sublime above this temperature. Nicotinic acid is soluble in alcohol and in water but is insoluble in ether. It is stable to heat and oxidation. Niacin is readily converted in the body to niacinamide (nicotinamide).

Niacinamide (nicotinamide) occurs naturally in conjugated forms; e.g., nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). These biological conjugates are required by numerous enzyme systems. Pure nicotinamide exists as colorless, bitter-tasting, needle-shaped crystals with a melting point of 129°C. It is soluble in alcohol, in water, in glycerol, and in ether.

Both niacin and niacinamide are recognized as sources of the essential micronutrient vitamin B_3. The recommended daily allowances (National Academy of Sciences/National Research Council (NAS/NRC) (1980)) of vitamin B_3, range from 6 milligrams (mg) for infants to 24 mg for young lactating mothers. The average U.S. diet provides 16 to 33 mg of pre-formed niacin or its biological equivalents (precursors). Pellagra is the dietary deficiency disease that results from insufficient intake of this vitamin or its precursors.

Niacin and niacinamide were listed as GRAS nutrients in a regulation published in the **Federal Register** of November 20, 1959 (24 FR 9368). Subsequently, they were listed as GRAS nutrients/dietary supplements in a regulation published in the **Federal Register** of January 31, 1961 (26 FR 938). However, in a final rule published in the **Federal Register** of September 5, 1980 (45 FR 58837), FDA divided the nutrient/dietary supplement category into separate listings for GRAS dietary supplements (21 CFR Part 182, Subpart F) and for GRAS nutrients (21 CFR Part 182, Subpart I). As a consequence, niacin and niacinamide are currently listed in §§ 182.5530 and 182.5535 (21 CFR 182.5530 and 182.5535), respectively, for use as dietary supplements. They are also listed in §§ 182.8530 and 182.8535 (21 CFR 182.8530 and 182.8535), respectively, as GRAS for use as nutrients in conventional human food.

Section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) lists niacin as a required nutrient in infant formula, subject to level restrictions. FDA is reviewing all nutrient levels in infant formulas under a contract with the American Academy of Pediatrics. Any necessary modifications in the nutrient levels of niacin in infant formula will be proposed by a separate rulemaking under section 412(a)(2) of the act. Niacin and niacinamide also may be used to fortify foods as described in Part 104 (21 CFR Part 104).

In 1971, NAS/NRC surveyed a representative cross-section of food manufacturers to determine the specific foods in which niacin and niacinamide were used and the levels of usage. NAS/NRC combined information from this survey of consumer consumption with the information on the amount of these substances manufactured for food use to obtain an estimate of consumer exposure to these ingredients. The survey found that niacin and niacinamide were used to enrich various foods such as bakery, cereal, and pasta products. Reports from manufacturers responding to poundage surveys in both 1970 and 1975 indicate that the 1975 food use of both ingredients was about three times the 1970 use. On the basis of these data, FDA estimates from the NAS/NRC survey that 1,390,000 pounds of niacin and 2,590,000 of niacinamide were used in food in 1975. However, the per capita daily intake calculated from these poundage data represents less than half of the estimated total daily intake of niacin from all dietary sources.

Niacin and niacinamide have been the subjects of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavioral effects, (12) detection, and (13) processing. A total of 4,778 abstracts was reviewed, and 69 particularly pertinent reports from the literature survey have been summarized in a scientific literature review.

Information from the scientific literature review and other sources has been summarized in a report to FDA by the Select Committee on GRAS Substances (the Select Committee), which is composed of qualified scientists chosen by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (FASEB). The members of the Select Committee have evaluated all the available safety information on niacin and niacinamide.[2] In the Select Committee's opinion:

The term niacin as adopted by the American Institute of Nutrition, is a generic form including both nicotinic acid and its amide, nicotinamide (or niacinamide), to which it is readily converted in the body. However, niacin as employed by the Code of Federal Regulations refers only to nicotinic acid. Nicotinamide is a component of two essential coenzymes, nicotinamide adenine dinucleotide and nicotinamide adenine dinucleotide phosphate. The body is also able to form nicotinamide from tryptophan (60 mg of tryptophan provide 1 mg of niacin equivalent) and much of the total niacin equivalents of the diet are supplied in this manner.

Disappearance data suggest that per capita daily intakes of nicotinic acid and nictinamide added to foods are less than 7.5 and 2.2 mg, respectively. Thus the amount added to foods (about 0.15 mg per kg body weight) is approximately one half the total dietary intake of these substances from both added and natural sources. The LD_{50} for various laboratory animals given the substances parenterally has generally been found to be more than 1 g per kg per day. Limited data on oral ingestion by mice nd rats suggest that the LD_{50} may be more than 4 g per kg per day. Young laboratory animals fed diets containing 1 or 2 percent nicotinic acid or nicotinamide (1 to 2 g per kg body weight per day) have demonstrated growth depression in some but not all studies. At levels of 0.1 percent in the diet, fatty livers may occur, reflecting an induced choline deficiency.

Because large doses of nicotinic acid are known to reduce serum concentration of cholesterol, administration of nicotinic acid has been employed in management of patients with hypercholesterolemia. Dosage commonly employed is 3 to 9 g daily (50 to 150 mg per kg). Initially experenced side effects, including cutaneous flushing, pruritis.

[2] "Evaluation of the Health Aspects of Niacin and Niacinamide as Food Ingredients," Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1979, pp. 11–22. In the past, the agency presented verbatim the Select Committee's discussion of the biological data it reviewed. However, because the Select Committee's report is available at the Dockets Management Branch and from the National Technical Information Service, and because it represents a significant savings to the agency in publication costs, FDA has decided to discontinue presenting the discussion in the preamble to proposals that affirm GRAS status in accordance with current good manufacturing practice.

and nausea, usually subside with continued therapy and the great majority of subjects then appear to experience no adverse effects. However, abnormal values in liver function tests have been detected rather frequently and at least a few subjects have developed jaundice. These manifestations generally subside promptly after discontinuation of treatment. Pathologic changes in the liver, possibly irreversible, have been associated with treatment with large daily doses in a few instances.

Although there have been no short- or long-term animal studies defining the greatest no-adverse-effect level of intake of nicotinic acid or nicotinamide, the adverse effects reported in animals and man have been associated with intakes at least a hundredfold greater than those likely to be achieved from fortification of foods. [3]

The Select Committee concludes that no evidence in the available information on niacin (nicotinic acid) or niacinamide (nicotinamide) demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or that might reasonably be expected in the future.[4]

FDA has undertaken its own evaluation of the available information, and insofar as niacin and niacinamide are used as nutrient supplements in conventional food, concurs with the conclusion of the Select Committee. The agency concludes that no change in the current GRAS status of these ingredients is justified. Therefore, the agency proposes to affirm that niacin and niacinamide are GRAS when used as nutrient supplements in conventional foods. However, because the NAS/NRC survey did not specifically request data on dietary supplement use, FDA does not have adequate data upon which to judge exposure from the use of niacin and niacinamide as dietary supplements. Without such exposure data, the agency cannot evaluate the safety of the use of these substances in dietary supplements and therefore can take no action on the GRAS status of this use of niacin and niacinamide.

Additionally, FDA is proposing not to include in the GRAS affirmation regulation for niacin and niacinamide the food categories and levels of use reported in the NAS/NRC 1971 survey for these ingredients. Both FASEB and the agency have concluded that a large margin of safety exists for the use of these substances, and that a reasonably foreseeable increase in the level of consumption of niacin and niacinamide will not adversely affect human health. Therefore, the agency is proposing to affirm the GRAS status of niacin and niacinamide when they are used under current good manufacturing practice conditions of use in accordance with § 184.1(b)(1) (21 CFR 184.1(b)(1)). To make clear, however, that the affirmation of the GRAS status of niacin and niacinamide is based on the evaluation of currently known uses, the proposed regulation sets forth the technical effects that FDA evaluated.

In the **Federal Register** of September 7, 1982 (47 FR 39199), FDA proposed to adopt a general policy restricting the circumstances in which it will specifically describe conditions of use in regulations affirming substances as GRAS under 21 CFR 184.1(b)(1) or 186.1(b)(1). The agency proposed to amend its regulations to indicate clearly that it will specify one or more of the current good manufacturing practice conditions of use in regulations for substances affirmed as GRAS with no limitations other than current good manufacturing practice only when the agency determines that it is appropriate to do so.

Copies of the scientific literature review on niacin and niacinamide, a literature update, mutagenic studies, and the report of the Select Committee are available for review at the Dockets Management Branch (address above). All of these studies, reviews, and reports may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161, as follows:

Title	Order No.	Price code	Price [1]
Nicacin (scientific literature review)	PB 241-952/AS	A18	$21.00
Niacin and niacinamide (scientific literature review update).	PB 275-752/AS	A02	5.00
Niacin (mutagenic evaluation)	PB 278-472/AS	A03	6.00
Niacinamide (mutagenic evaluation)	PB 278-473	A03	6.00
Niacin and niacinamide (Select Committee report).	PB 80-112030	A03	6.00

[1] Price subject to change.

This proposed action does not affect the current use of niacin and niacinamide in pet food or animal feed.

The format of the proposed regulations is different from that in previous GRAS affirmation regulations. FDA has modified paragraph (c) of §§ 184.1530 and 184.1535 to make clear the agency's determination that GRAS affirmation is based upon current good manufacturing practice conditions of use, including the technical effects listed. This change has no substantive effect but is made merely for clarity.

The agency has determined under 21 CFR 25.24(d) (6) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 the effect of this proposal is to maintain current known uses of the substances covered by this proposal by both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Excutive Order 12291, FDA has carefully analyzed the economic effects of this proposal, and the agency has determined that the final rule, if promulgated, will not be a major rule as defined by the Order.

List of Subjects

21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients; Spices and flavorings.

21 CFR Part 184

Direct food ingredients; Food ingredients; Generally recognized as safe (GRAS) food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), it is proposed that Parts 182 and 184 be amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. Part 182 as amended:

§ 182.8530 [Removed]

a. By removing § 182.8530 *Niacin.*

§ 182.8535 [Removed]

b. Be removing § 182.8535 *Niacinamide.*

[3] *Ibid.*, p. 23.
[4] *Ibid.*, p. 24.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

2. Part 184 is amended:

a. By adding new § 184.1530, to read as follows:

§ 184.1530 Niacin.

(a) Niacin ($C_6H_5NO_2$, CAS Reg. No. 59-67-6) is the chemical 3-pyridinecarboxylic acid (nicotinic acid). It is a nonhygroscopic, stable, white, crystalline solid that sublimes without decomposition at about 230° C. It is soluble in water and alcohol. It is insoluble in ether.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 205, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the act or with regulations promulgated under section 412(a)(2) of the act.

b. By adding new § 184.1535, to read as follows:

§ 184.1535 Niacinamide.

(a) Niacinamide ($C_6H_6N_2O$, CAS Reg. No. 98-92-0) is the chemical 3-pyridinecarboxylic acid amide (nicotinamide). It is a white crystalline powder that is soluble in water, alcohol, ether, and glycerol. It melts between 128° and 131° C.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 205, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washigton, D.C. 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the act or with regulations promulgated under section 412(a)(2) of the act.

The agency is unaware of any prior sanction for the use of these ingredients in foods under conditions different from those identified in this document. Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The action proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), and the failure of any person to come forward with proof of an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on it later. Should any person submit proof of the existence of a prior sanction, the agency hereby proposes to recognize such use by issuing an appropriate final rule under Part 181 (21 CFR Part 181) or affirming it as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

Interested persons may, on or before December 20, 1982, 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: September 22, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-28638 Filed 10-18-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 184

[Docket No. 80N-0245]

Nickel; Proposed Affirmation of GRAS Status

AGENCY: Food and Drug Administration

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to affirm that nickel is generally recognized as safe (GRAS) for use as a catalyst in the hydrogenation of fats and oils for human consumption. The safety of this ingredient has been evaluated under a comprehensive safety review conducted by the agency.

DATE: Written comments by December 20, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary C. Custer, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive review of human food ingredients classified as GRAS or subject to a prior sanction. The agency has issued several notices and proposals (see the **Federal Register** of July 26, 1973 (38 FR 2040)) initiating this review, under which the safety of nickel has been evaluated. In accordance with the provisions of § 170.35 (21 CFR 170.35), the agency proposes to affirm the GRAS status of this ingredient.

Nickel is a silver-white metal with high electrical and thermal conductivities and a melting point of 1452° C. It is moderately electropositive. Nickel occurs in nature mainly in combination with arsenic, antimony, sulfur, and magnesium silicates of variable composition.

The metallurgy of nickel compounds is complicated, varying a good deal with the particular ore being processed. In general, the ore is transformed to nickel sulfide (Ni_3S_2), which is roasted in air to give nickel oxide (NiO). The oxide is then reduced with carbon to give the metal which can be electrolytically refined.

Nickel is listed by the U.S. Department of Agriculture (USDA) for use as a hydrogenation catalyst for animal fats and vegetable oils under 9 CFR 318.7. it is also regulated as an indirect food additive under 21 CFR 176.180 for use as a component of paper and paperboard in contact with dry

food. Nickel has a prior sanction from the Meat Inspection Division of the USDA for use as a catalyst in rendered animal fats (or a combination of such fat and vegetable fats), in amounts sufficient for the purpose. FDA has issued an opinion letter stating that the use of nickel to hydrogenate vegetable fats is considered to be GRAS provided no more than 0.1 part per million (ppm) of the catalyst is present in the finished product.

In 1971, the national Academy of Sciences/National Research Council (NAS/NRC) surveyed a representative cross-section of food manufacturers to determine the specific foods in which selected GRAS substances were used and the levels of usage. No information on nickel was reported in this survey. In 1975, FDA requested additional information on some GRAS substances, including nickel. A few manufacturers responded to this request and the data indicated a weighted mean level of 0.55 ppm nickel was present in some fat and oil products. Assuming that 0.55 ppm nickel was present in all margarine, shortening, and edible oils marketed in 1978, the per capita daily intake of nickel from its use as a catalyst in the hydrogenation of edible oils and fats was estimated by the Select Committee on GRAS Substances (the Select Committee) of the Federation of American Societies for Experimental Biology (FASEB) to be about 30 μg.

Nickel has been the subject of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazard, (3) metabolism, (4) reaction products, (5) degradation products, (6) carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavioral effects, (12) detection, and (13) processing. A total of 888 articles on nickel was reviewed, and 137 particularly pertinent reports from the literature survey have been summarized in a scientific literature review.

Information from the scientific literature review and other sources has been summarized in a report to FDA by the Select Committee, which is composed of qualified scientists chosen by the Life Sciences Research Office of FASEB. The members of the Select Committee [1] have reviewed all the available safety information on nickel. In the Select Committee's opinion:

This opinion concerns the only GRAS use of nickel, that as a catalyst in the hydrogenation of edible oils and fats. According to industry, a residue of 0.1 to 1.5 ppm nickel may be present in the hydrogenated oils. There are few data on the amount of nickel actually consumed by humans from this source, but at the average level of 0.55 ppm reported by industry in 1975 it can be estimated that per capita daily intake from the residual in hydrogenated oils was about 30 μg. This amount is about an order of magnitude lower than that ingested in the diet from natural sources, which is estimated at 300 to 600 μg per day.

Most of the nickel ingested is excreted in the feces; a small proportion is absorbed and excreted in urine and sweat. Nickel and nickel salts when administered orally to various species of animals have relatively low toxicities. Granulocytic hyperplasia of the bone marrow was observed in dogs fed high levels (60 mg per kg body weight) of nickel as the sulfate, but carcinogenicity has not been reported for nickel and nickel salts administered orally to experimental animals; however, tumors have resulted following parenteral administration. Adverse effects on reproductive performance have been reported in mice fed nickel acetate; daily intake of nickel was estimated to be 335 mg per kg body weight. Daily ingestion of 9.4 mg nickel as nickel sulfate per kg body weight, has caused infertility in rats. However, no effect on the reproductive performance of rats resulted from feeding up to 100 mg per kg body weight of catalytic nickel powder. The existence of nickel dermatitis from occupational contact with nickel or nickel salts as well as in the general population is recognized. No data are available indicating the occurrence of allergic reactions to the oral ingestion of nickel and nickel salts.[2]

The Select Committee concludes that there is no evidence in the available information on elemental nickel that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used at levels that are now current and in the manner now practiced or that might reasonably be expected in the future.[3]

FDA has undertaken its own evaluation of the available information on the use of nickel as a catalyst in the hyrogenation of edible oils and fats and concurs with the conclusion of the Select Committee. The agency concludes that no change in the current GRAS status of this ingredient is justified. Therefore, the agency proposes that nickel be affirmed as GRAS.

Although the Select Committee evaluated only the use of nickel as a catalyst in the hydrogenation of fats and oils, the agency recognizes that nickel is also used as a catalyst in the manufacture of some food additives and GRAS ingredients. However, such uses of nickel are not affected by this proposed rule. Any potential safety problem associated with the use of nickel in the manufacture of a food additive or GRAS ingredient would be addressed in the applicable food-grade specifications for the substance.

The agency is also aware of a number of published reports of the carcinogenicity of certain nickel compounds. Although not mentioned in the opinion section of its report, these studies were also available to the Select Committee. The Select Committee evaluated the potential carcinogenicity of nickel and stated that it was aware of no evidence that nickel or nickel salts administered orally are carcinogenic.[4] The agency agrees with this finding.

Because no food-grade specifications exist for nickel at the present time, the agency will work with the Committee on Food Chemicals Codex of the National Academy of Sciences to develop acceptable specifications for this ingredient. If acceptable specifications are developed, the agency will incorporate them into this regulation at a later date. Until specifications are developed, FDA has determined that the public health will be adequately protected if commerical nickel complies with the description in the proposed regulation and is of food-grade purity (21 CFR 170.30(h)(1) and 182.1(b)(3)).

The agency is proposing not to include in this GRAS affirmation regulation the levels of use reported for nickel. Both FASEB and the agency have concluded that a large margin of safety exists for the use of this substance, and that a reasonably foreseeable increase in the level of consumption of nickel will not adversely affect human health. Therefore, the agency is proposing to affirm the GRAS status of nickel when it

[1] "Evaluation of the Health Aspects of Nickel as a Food Ingredient," Life Sciences Research Office, Federation of American Societies for Experimental Biology, 1979, pp. 7–14. In the past, the agency presented verbatim the Select Committee's discussion of the biological data it reviewed. However, because the Select Committee's report is available at the Dockets Management Branch and from the National Technical Information Service, and because it represents a significant savings to the agency in publication costs, FDA has decided to discontinue presenting the discussion in the preamble to proposals that affirm GRAS status in accordance with current good manufacturing practice.

[2] *Ibid.*, p. 15.

[3] *Ibid.*

[4] *Ibid.*, p. 13.

is used under current good manufacturing practice conditions of use in accordance with § 184.1(b)(1) (21 CFR 184.1(b)(1)). To make clear, however, that that affirmation of the GRAS status of this substance is based on the evaluation of limited uses, the proposed regulation sets forth the technical effect and food category that FDA evaluated.

In the **Federal Register** of September 7, 1982 (47 FR 39199) FDA proposed to adopt a general policy restricting the circumstances in which it will specifically describe conditions of use in regulations affirming substances as GRAS under 21 CFR 184.1(b)(1) or 186.1(b)(1). The agency proposed to amend its regulations to indicate clearly that it will specify one or more of the current good manufacturing practice conditions of use in regulations for substances affirmed as GRAS with no limitations other than current good manufacturing practice only when the agency determines that it is appropriate to do so.

Copies of the scientific literature review on nickel and the report of the Select Committee are available for review at the Dockets Management Branch (address above), and may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161, as follows:

Title	Order No.	Price code	Price[1]
Nickel (scientific literature review)	PB 241-972/AS	A10	$13.00
Nickel (Select Committee report)	PB 80-104 623	A03	6.00

[1] Price subject to change.

This proposed action does not affect the current use of nickel in pet food or animal feed.

The format of the proposed regulation is different from that in previous GRAS affirmation regulations. FDA has modified paragraph (c) of § 184.1537 to make clear the agency's determination that GRAS affirmation is based upon current good manufacturing practice conditions of use, including both the technical effect and food category listed. This change has no substantive effective but is made merely for clarity.

The agency has determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 the effect of this proposal is to maintain current known uses of the substance covered by this proposal by both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal, and the agency has determined that the final rule, if promulgated, will not be a major rule as defined by the Order.

List of Subjects in 21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), it is proposed that Part 184 be amended by adding new § 184.1537, to read as follows:

§ 184.1537 Nickel.

(a) Elemental nickel (CAS Reg. No. 7440-02-0) is obtained from nickel ore by transforming it to nickel sulfide (Ni_3S_2). The sulfide is roasted in air to give nickel oxide (NiO). The oxide is then reduced with carbon to give elemental nickel.

(b) The Food and Drug Administration is developing foodgrade specifications for nickel in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a catalyst as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in the hydrogenation of fats and oils as defined in § 170.3(n)(12) of this chapter at levels not to exceed current good manufacturing practice. Current good manufacturing practice includes the removal of nickel from fats and oils following hydrogenation.

The agency is unaware of any prior sanction for the use of this ingredient in foods under conditions different from those identified in this document. Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The action proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), and the failure of any person to come forward with proof of an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on it later. Should any person submit proof of the existence of a prior sanction, the agency hereby proposes to recognize such use by issuing an appropriate final rule under Part 181 (21 CFR Part 181) or affirming it as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

Interested persons may, on or before December 20, 1982 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: September 22, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-28722 Filed 10-18-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 310, 314, and 431

[Docket No. 79N-0021]

Adverse Drug Experiences With Approved New Drugs and Antibiotics Reporting Requirements; Withdrawal of Proposed Rule

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a proposed rule that would have revised its adverse drug experience reporting requirements for approved new drugs and antibiotics for human use. Elsewhere in this issue of the **Federal Register**, FDA is proposing comprehensive revisions to all of its regulations governing applications for FDA approval to market new drugs and antibiotics. That proposal supersedes the proposal being withdrawn.

EFFECTIVE DATE: October 19, 1982.

FOR FURTHER INFORMATION CONTACT: Michael C. McGrane, National Center for Drugs and Biologics (HFN-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 3, 1979 (44 FR 19434), FDA published a proposal to revise its adverse drug experience reporting requirements for approved new drugs and antibiotics for human use. Elsewhere in this issue of the **Federal Register**, FDA is proposing comprehensive revisions to all of FDA's regulations governing applications to market new drugs and antibiotics. The new proposal includes revised adverse drug experience reporting requirements with respect to approved applications and, thus, supersedes the April 3, 1979 proposal. The agency prepared the adverse drug experience reporting provisions in the new proposal in part on the basis of comments on the 1979 proposal and the provisions reflect FDA's current view of appropriate reporting requirements.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Medical devices, Reporting requirements.

21 CFR Part 314

Administrative practice and procedure, Drugs.

21 CFR Part 331

Administrative practice and procedure; Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 505, 507, 701(a), 52 Stat. 1052-1053 as amended, 1055, 59 Stat. 463 as amended (21 U.S.C. 355, 357, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and under 21 CFR 10.4(c), the proposed rule published in the **Federal Register** of April 3, 1979 (44 FR 19434) is withdrawn, effective October 19, 1982.

Dated: October 12, 1982.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-28759 Filed 10-18-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 314

[Docket No. 75N-0054]

Revision of Requirement for Information in Abbreviated New Drug Applications; Withdrawal of Proposed Rule

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a proposed rule that would have revised its manufacturing and controls information requirements for abbreviated new drug applications. Elsewhere in this issue of the **Federal Register**, FDA is proposing comprehensive revisions to all of its regulations governing applications for FDA approval to market new drugs and antibiotic drugs for human use. That proposal supersedes the proposal being withdrawn.

EFFECTIVE DATE: October 19, 1982.

FOR FURTHER INFORMATION CONTACT: Michael C. McGrane, National Center for Drugs and Biologics (HFN-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 20, 1975 (40 FR 26156), FDA published a proposal to revise its requirements for manufacturing and controls information in an abbreviated new drug application (ANDA) to conform them to the requirements for a full new drug application (NDA). After the proposal was published, FDA began initial deliberations on an overall plan to improve the efficiency of the agency's drug approval process. Because those deliberations contemplated a comprehensive revision of all of FDA's regulations on the drug approval process, the agency deferred further action on the June 20, 1975 proposal. Elsewhere in this issue of the **Federal Register**, FDA is proposing comprehensive revisions to all of FDA's regulations governing applications to market new drugs and antibiotics. The new proposal includes revised content requirements for ANDA's regarding manufacturing and controls information and, thus, supersedes the June 20, 1975 proposal. The agency prepared the content requirements for ANDA's in the new proposal in part on the basis of comments on the 1975 proposal, and the requirements reflect FDA's current view of appropriate manufacturing and controls information for ANDA's.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure; Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 502(a) and (f), 505, 701(a), 52 Stat. 1050-1053, 1055 as amended (21 U.S.C. 352(a) and (f), 355, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and under 21 CFR 10.40(c), the proposed rule published in the **Federal Register** of June 20, 1975 (40 FR 26156) is withdrawn, effective October 19, 1982.

Dated: October 12, 1982.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-28760 Filed 10-18-82; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

Paroling, Recommitting, and Supervising Federal Prisoners

AGENCY: Parole Commission, Justice.

ACTION: Proposed rule.

SUMMARY: The Parole Commission is proposing two amendments to its conditions of release permitting limited search and seizure by U.S. Probation Officers. These amendments would allow supervising probation officers to conduct reasonable searches of releasees for detection of drug use and to seize contraband observed in plain view. These amendments are intended as supervision tools to aid in the early detection of parole violations and crime prevention.

DATE: Comments must be submitted on or before December 20, 1982.

ADDRESS: Send comments to Joseph A. Barry, General Counsel, U.S. Parole Commission, 5550 Friendship Boulevard, Chevy Chase, Maryland 20815.

FOR FURTHER INFORMATION CONTACT: Joseph A. Barry, General Counsel, U.S. Parole Commission, 5550 Friendship Boulevard, Chevy Chase, Maryland 20815; telephone: (301) 492-5959.

SUPPLEMENTARY INFORMATION: In its continuing study of the need and desirability of permitting some types of

searches and seizures by U.S. Probation Officers in supervision of releasees, the Commission has decided to publish for comment two proposed amendments to its rule on the conditions of release. This first proposed amendment would modify the parole condition which proscribes narcotics activity to require the parolee to submit to a reasonable search of his person for detection of drug use when so directed by supervising probation officers. Resort to or resumption of drug activity by a parolee has been found to be a reliable indicant of imminent failure on parole. Early confirmation of the supervising probation officer's suspicions permits likelier salvage of the releasee through immediate treatment of the problems involved and possible circumvention of criminal episodes.

Many releasees will already be performing under drug aftercare conditions which provide for urinalysis tests; the search permitted by the proposed amendment (e.g., for fresh needle marks) will be an additional and much quicker method of detecting indications of drug use. It is contemplated that enhanced training procedures for probation officers will enable them accurately to interpret physical indications of use of drugs. Such training has been successfully used in probation work in State and Federal programs.

The second proposed amendment would permit seizure of contraband materials which are observed by the supervising probation officer in plain view in his contact with the parolee. This seizure provision refers only to plain view contraband materials such as drugs and firearms. It will constitute a supervision tool, and in practice it is anticipated that this provision will also function as a crime preventive measure.

In both of the proposed amendments to the conditions of parole, no use of force would be permitted if the parolee refused cooperation, though refusal could constitute a basis for revocation.

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, Probation and parole, Prisoners.

PART 2—[AMENDED]

Therefore pursuant to the provisions of 18 U.S.C. 4203(a)(1) and 4204(a)(6), it is proposed that 28 CFR § 2.40 be amended by revising (a)(9) and adding (a)(12) as follows:

§ 2.40 Conditions of release.

(a) * * *

(9) The parolee shall not drink alcoholic beverages to excess. He shall not purchase, possess, use or administer marijuana or narcotics or other habit-forming drugs unless prescribed or advised by a physician. The parolee shall not frequent places where such drugs are illegally sold, dispensed, used or given away. At the probation officer's direction, the parolee shall submit to reasonable examination of his person by the probation officer (or qualified drug treatment personnel) for detection of drug abuse.

* * * * *

(12) The parolee shall permit confiscation by his probation officer of any contraband materials which he observes in plain view in the parolee's apparent possession in his residence, place of business or occupation, vehicle(s), or on his person.

* * * * *

I certify that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Dated: September 28, 1982.

Benjamin F. Baer,

Chairman, U.S. Parole Commission.

[FR Doc. 82-28627 Filed 10-18-82; 8:45 am]

BILLING CODE 6820-95-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-10-FRL 2193-1]

Approval and Promulgation of State Implementation Plan, Washington

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rulemaking.

SUMMARY: The purpose of this Notice is to present the results of EPA's review of the 1982 Seattle-Tacoma, Washington, carbon monoxide/ozone (CO/O_3) State Implementation Plan (SIP) revision. This SIP revision was developed to satisfy the provisions of Part D of the 1977 Clean Air Act, as amended, which requires plans for CO and O_3 nonattainment areas with approved attainment date extensions to be submitted by July 1, 1982.

Today's action proposes approval of the final plan which was subject to a joint State and local public hearing and which was submitted to EPA on July 16, 1982. EPA is requesting public comments on its proposed actions for a period of 30 days.

DATE: Comments must be received on or before November 18, 1982.

ADDRESSES: Comments should be addressed to: Laurie M. Kral, Air Programs Branch, M/S 532, Environmental Protection Agency, 1200 Sixth Avenue, Seattle, WA 98101.

Copies of the materials submitted to EPA may be examined during normal business hours at:

Air Programs Branch, M/S 532, Environmental Protection Agency, 1200 Sixth Avenue, Seattle, WA 98101.

State of Washington, Department of Ecology, 4224 Sixth Avenue SE., Lacey, WA 98503.

FOR FURTHER INFORMATION CONTACT: Richard F. White, Air Programs Branch, M/S 532, Environmental Protection Agency, 1200 Sixth Avenue, Seattle, WA 98101, Telephone No. (206) 442-4016, FTS: 399-4016.

SUPPLEMENTARY INFORMATION:

Table of Contents

II. Background
III. Plan Review Discussion
A. Ozone—Specific
B. Carbon Monoxide—Specific
C. Carbon Monoxide/Ozone—Joint Elements

I. Introduction

This Notice is divided into three sections entitled "Introduction," "Background" and "Plan Review." The "Background" section briefly recaps the history of the development of the CO/O_3 nonattainment plan from the initial stage or "plan-for-a-plan" stage, through the second and final stage which resulted in the July 1982 SIP revision submittal. The "Plan Review" section discussion separately the plan requirements for CO and O_3. This discussion is based on the requirements for CO and O_3 SIPs published on January 22, 1981 (46 FR 7182) and describes the design value, the emission reduction required, the type of modeling used, the transportation control measures (TCMs) selected and the required commitments for TCM implementation and the projected attainment dates for each area. In addition, the procedures for public and elected official participation and the methodology for determining (1) conformity of transportation projects with the SIP, (2) reasonable further progress (RFP) and (3) basic transportation needs for the nonattainment areas will be presented. At the end of Subparts A, B and C of the plan review section EPA describes what rulemaking action is being proposed. Public comment is being sought on each action proposed by EPA.

Today's **Federal Register** action has been developed in parallel with action on the State and local level to adopt and submit a revision to the currently

approved SIP. This process enabled EPA to comment on the SIP in the early stages of SIP development. It also allows EPA to carry out its administrative rulemaking process concurrent with that of the State so that final EPA action could be completed shortly after the State completed its adoption process.

II. Background

The Clean Air Act Amendments of 1977 added a new Part D to Title I of the Act which required States to revise the SIPs for all nonattainment areas and submit the revisions to EPA by January 1, 1979 (Sections 171–178 of the Clean Air Act; Section 129(c) (uncodifed) of Pub. L. 95–95). The revised plan had to provide for attainment by December 31, 1982, unless the State demonstrated that it would not be possible to attain either the O_3 or CO standard by that date (Sections 172(a)(1), 172(a)(2)). If EPA approved this demonstration, the attainment date for O_3 or CO could be extended up to December 31, 1987, and the State could defer compliance with certain of the Part D planning requirements. However, the Amendments also require States which have received attainment date extensions to submit a second SIP revision which provides for attainment by the approved attainment date and complies with all the Part D requirements (Section 172(c)). This second SIP revision must be submitted by July 1, 1982 (Section 129(c) (uncodified), Pub. L. 95–95).

On January 22, 1981 (46 FR 7182) EPA published a final policy containing criteria to be used in reviewing the SIP revisions due in July 1982. This policy supplements the "General Preamble" for SIP revisions for nonattainment areas published on April 4, 1979 (44 FR 20372).[1]

The State of Washington submitted an initial SIP revision for the Seattle-Tacoma CO/O_3 nonattainment area in April 1979. The State requested EPA to extend the attainment date for the O_3 standard in this area beyond 1982 but no later than 1987. In addition, due to attainment problems in the Seattle portion of the Seattle-Tacoma CO nonattainment area, the State requested a similar extension for CO. EPA approved the extension request for O_3 in the entire Seattle-Tacoma nonattainment area and for CO in the Seattle portion and conditionally approved the initial plan revision on June 5, 1980 (45 FR 37821). EPA gave final approval to this initial plan revision on September 14, 1981 (46 FR 45607) after the conditions had been fulfilled.

Since EPA's final approval of the initial plan, the single Seattle-Tacoma CO nonattainment area boundary was eliminated, and five much smaller nonattainment areas were established (46 FR 61655). The remainder of the original CO nonattainment area is now designated either "unclassifiable" or "attainment."

Recent data indicates that the original SIP control measures for the Tacoma CO nonattainment problem have successfully brought the original nonattainment monitor into attainment. The current nonattainment area, a four-block section along the main arterial in the Tacoma Control Business District (CBD), was defined on the basis of data from a monitoring site established after the original round of Part D SIP revisions. The Puget Sound Air Pollution Control Agency (PSAPCA), the lead agency, has submitted a specific schedule for development of a plan, which is currently under review and which will be the subject of separate Federal rulemaking action at a later date. Therefore, for purposes of CO SIPs, this notice is specific to the nonattainment areas located in the Seattle-Bellevue urban area.

The SIP subject to proposal today is the second phase of the version submitted in April 1979. Since that date the local agencies have been updating the emission inventories, refining the air quality modeling, holding additional public hearings and meetings with their advisory and policy making committees, reviewing all the candidate transportation control measures for CO and O_3 and selecting those that are reasonably available, and finally, obtaining commitments to implement TCMs from the local governmental jurisdictions involved. The resulting draft SIP revision was submitted to EPA and the State on February 24, 1982. Concurrently, the State requested EPA to process this SIP revision in parallel with the State and local approval procedure.

The SIP revision was adopted by the local agency Board of Directors at an April 8, 1982 public hearing and was forwarded to the State for final submission to EPA. On July 16, 1982, after public hearings and adoption, the State submitted the SIP revision to EPA.

III. Plan Review

The general requirements for CO/O_3 SIPs were described in the **Federal Register** published on January 22, 1981 (46 FR 7182). EPA reviewed the draft Seattle-Tacoma CO/O_3 SIP in accordance with those requirements and developed a technical support document which briefly describes the elements of the SIP, their location in the SIP and EPA's conclusions regarding approvability. The following discussion briefly describes the SIP in terms of the major review points and indicates what action EPA proposes. The discussion is divided into two sections each describing O_3- and CO-specific portions of the SIP and a third section describing portions of the SIP that deal with CO and O_3 simultaneously.

A. Ozone-Specific

1. *Data Base and Modeling Results:*

The Seattle-Tacoma O_3 nonattainment area extends north to Marysville, east to Issaquah, south to Spanaway and west to Puget Sound. The SIP was developed using a baseline design concentration of 0.14 parts per million (ppm). The design value was derived from data collected over the past three years and represents the concentration that can be expected to be exceeded once each year.

The strategy for attaining the O_3 standard (i.e., bringing air quality levels from the design concentration of 0.14 ppm to the standard of 0.12 ppm) centers around reducing emissions of volatile organic compounds (VOC), one of the major precursors to the formation of O_3. To determine the reduction needed for attainment, the "city-specific Empirical Kinetic Modeling Approach" model was utilized. Based on this analysis a 22 percent reduction in 1981 VOC emissions is required for attainment. Using the stationary and mobile source control measures described below, the required emission reduction is expected to be achieved by mid-1984.

2. *Control Measures:*

a. *Stationary Sources.*—Stationary source controls for VOC in the Seattle-Tacoma nonattainment area are embodied in the Puget Sound Air Pollution Control Agency's (PSAPCA) Regulation II, which includes controls for petroleum solvent dry cleaners, and the State Department of Ecology Regulation WAC 173–490. The State regulations, adopted in 1979 and 1980 to satisfy guidance published in the EPA Control Techniques Guidelines, were approved as SIP revisions on September 14, 1981 (46 FR 45607) and April 14, 1982 (47 FR 16018). The State regulations were revised to (1) add controls for surface coating of aerospace components, (2) provide clarifications requested in the April 14, 1982 EPA approval and (3) to assure consistency with the local regulations, on which the

[1] EPA published four additional notices supplementing the general preamble in 1979: July 2, 1979 (44 FR 38583); August 28, 1979 (44 FR 50371); September 17, 1979 (44 FR 53761); and November 23, 1979 (44 FR 67182).

SIP emission reductions are based. The EPA technical support document further describes the levels of VOC controls inherent in the State and local regulations.

b. *Mobile Sources.*—Measures for controlling VOC emissions from mobile sources include the Federal Motor Vehicle Emission Control Program (FMVECP), vehicle inspection and maintenance (I/M) and regional TCM's. The initial plan included a proposed vehicle inspection and maintenance (I/M) program, which was required for the Seattle nonattainment area (Section 172(a)(2) of the Clean Air Act). EPA's evaluation of and approval action on the I/M portion is documented in the June 5, 1980 **Federal Register** (45 FR 37821).

Further evaluation of the I/M program, including rules and regulations (WAC 173–422), is contained in the I/M technical support document, located at the addresses listed earlier. That document describes how the I/M program, now in full operation, meets all the criteria in the January 22, 1981 I/M policy. The regional TCMs that have been committed to are listed in Table 1 (numbers 2–14). More detailed information concerning implementation schedules and specific TCM descriptions is available in the SIP.

3. *EPA Proposed Action:*

EPA proposes to approve the foregoing data base and modeling results. In addition to those control measures for mobile and stationary sources of VOC previously approved, EPA proposes to fully approve (1) the I/M program, including WAC 173–422 (Motor Vehicle Emission Inspection) and the public awareness program; (2) Section 208 of WAC 173–490 (surface coating of aerospace components) for control of VOC; (3) PSAPCA Regulation II and its attendant applicability clarifications for control of VOC and (4) the commitments to implement regional TCMs.

B. Carbon Monoxide-Specific

1. *Data Base and Modeling Results:*

The Seattle CO nonattainment area is comprised of four small areas, formerly called "hotspots," located in downtown Bellevue, the Seattle CBD, the University District and Northgate. The design values, percent reductions needed for attainment and projected attainment dates are described in Table 2.

To determine the projected attainment dates, the rollback model was applied to the 1981 emissions and ambient air quality data and the CO reductions needed to attain standard were determined. Then, using the 1981 projected emission reductions, the actual attainment dates were determined for each nonattainment area.

2. *Control Measures:*

Control measures to achieve the emission reduction include the FMVECP, I/M and regional TCMs. Since the contribution from stationary sources is less than 3 percent for the four nonattainment areas (with no 1,000 tons per year sources) and does not appear to impact ground level air quality, only mobile source controls are being considered in the SIP.

The I/M program, previously discussed in paragraph A.2.b of this section, was implemented on a mandatory basis January 2, 1982. It is operating in the Seattle nonattainment areas as indicated in Table 1.

Table 1 also shows the geographical coverage of adopted TCMs. These TCMs, which account for approximately 3 percent of the emission reductions in the nonattainment areas, are region-wide in some instances and nonattainment area-specific in others. They were proposed in the 1979 SIP as potential regional control strategies which would contribute to attaining the standards in "hot spot" areas, now designated as the nonattainment areas. For the 1982 SIP, commitments to implement selected strategies are an integral part of the control plan.

3. *EPA Proposed Action:*

EPA proposes to approve the foregoing data base and modeling results and the control measures for mobile sources of carbon monoxide for the four hotspots in Bellevue and Seattle.

C. Carbon Monoxide/Ozone—Joint Elements

Some elements of the CO and O_3 SIPs will be discussed on a joint basis, since they are the same for both SIPs. They include (1) determination of reasonable further progress (RFP), (2) description of basic transportation needs, (3) conformity of highway projects with the SIP and (4) procedures for public and elected official participation.

1. *Reasonable Further Progress:*

The plan includes RFP analyses for the nonattainment areas. RFP is enforceable through the VOC control, I/M and TCM commitments that are being proposed for approval. Reasonable further progress will be assessed in terms of the expected reductions described for each nonattainment area. The plan includes a TCM monitoring procedure whereby the Puget Sound Council of Governments will prepare an annual report summarizing data from each committing agency concerning progress in implementing TCMs and verification of credit for transportation emission reductions. The Puget Sound Air Pollution Control Agency will then use this report in combination with air quality data to assess reasonable further progress toward meeting air quality standards.

2. *Basic Transportation Needs:*

The SIP discusses "basic transportation needs" in relation to the ongoing transportation planning function carried out by the Puget Sound Council of Governments. The transportation needs for the region have been assessed and transportation control measures have been developed including commitments to implement regional public transportation plans and to use Federal, State and local funding to the extent they are available in meeting the commitments.

3. *Conformity of Federal Actions with the SIP:*

Existing State rules already ensure that Federal action will be reviewed for conformity with the SIP in a manner consistent with the criteria contained in the April 1, 1980 **Federal Register** (45 FR 21590). Procedures for specifically evaluating Department of Transportation plans, programs and projects were developed by a work group with representation from EPA, DOE, PSAPCA, PSCOG, and the Washington State Department of Transportation and have been adopted by PSAPCA. The work group and the Transportation Technical Committee have developed draft criteria against which individual projects will be evaluated for conformance with all provisions and requirements of the SIP. Specifically, this includes the provision that the project must not cause new violations or delay attainment of the NAAQS. The locally adopted conformity procedures and criteria have been submitted to DOE and EPA. Local adoption of the analysis criteria will take place at a public hearing October 14, 1982, after which DOE will adopt and submit the conformity procedures and analysis criteria as a SIP revision. EPA's final action will be contingent upon receipt of finally adopted analysis criteria which are consistent with those being proposed for approval today.

4. *Public and Elected Official Participation:*

Participation in the SIP development process extended to a wide range of public and elected officials. There were two major committees involved: the Transportation Technical Committee representing Federal, State and local government and the Citizens Committee on Air Quality and Transportation Control Planning representing twenty

organizations including the Washington Lung Association, Northwest Pulp and Paper Association, Auto Club of Washington, Puget Sound Chamber of Commerce, etc. These committees interacted over a period of four years to develop recommendations on reasonably available transportation control measures, which were finally acted upon by the lead agency's Board of Directors. The completed SIP was then forwarded to the State Department of Ecology after the joint State-local public hearing April 8, 1982.

5. *Proposed EPA Action:*

EPA proposes to approve these procedural elements of the SIP dealing with "reasonable further progress," "basic transportation needs," "conformity" and "public and elected official participation." With regard to conformity, final EPA action is contingent upon receipt of adopted conformity analysis creiteria that are consistent with those being proposed for approval today.

Under 5 U.S.C. Section 605(b), the Administrator has certified that SIP approvals do not have a significant impact on a substantial number of small entities (46 FR 8709 (January 27, 1981)).

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

Interested parties are invited to comment on all aspects of this proposed approval of the Washington SIP. Comments should be submitted, preferably in triplicate, to the address listed in the front of this Notice. Public comments postmarked by November 18, 1982 will be considered in any final action EPA takes on this proposal.

(Section 110, 172, Clean Air Act (42 U.S.C. 7410(b) and 7502)).

List of Subjects in 40 CFR Part 52

Air Pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, Hydrocarbons, Intergovernmental relations.

Dated: August 13, 1982.

John R. Spencer,

Regional Administrator.

TABLE 1.—GEOGRAPHICAL COVERAGE OF ADOPTED CONTROL MEASURES

Control Measures	Seattle CBD	University District	Northgate	Bellevue	Tacoma [a]	Region
1. Motor vehicle emission inspection and maintenance.	X	X	X	X		X [b]
2. Improved public transit.	X	X	X	X	X	X
3. Bus/carpool lanes and area wide carpool programs.	X	X	X	X	X	X
4. Road access limitations to private vehicles.	X			X		
5. Long range transit improvements.	X					
6. On-street parking controls.	X	X		X		
7. Park and ride lots.	X				X	X
8. Pedestrian bike lanes.	X	X		X	X	
9. Employer programs for ride sharing, bicycling, etc.	X	X	X			
10. Secure bicycle facilities.	X	X		X	X	X
11. Staggered work hours.	X	X	X	X	X	X
12. Road user charges to discourage SOV's.		X				
13. Idling control programs.		X				
14. Traffic flow improvements.			X			
15. FMVECP	X	X	X	X	X	
16. VOC stationary source controls.	X	X	X	X	X	X

(a) EPA approval is specific to the SIP for O_3 attainment. Approval relative to CO will be addressed in a separate rulemaking action.

(b) 1—I/M coverage includes zip codes areas as follows: 98004-98009 (Bellevue), 98011 (Bothell), 98020 (Edmonds), 98027 (Issaquah), 98028 (Kenmore), 98033 (Kirkland), 98036 (Lynnwood), 98039 (Medina), 98040 (Mercer Is.), 98043 (Mountake Terrace), 98052 (Redmond), 98055-98057 (Renton), 98062 (Seahurst), 98063 (Seattle Heights), 98072 (Woodinville), 98101-98199 (Seattle Except 98110 (Bainbridge Island)).

TABLE 2.—EMISSION REDUCTION TARGETS AND ATTAINMENT PROJECTIONS

	Baseline design concentration (ppm)	Percent emission reduction to reach attainment (from 1981 base)	Projected attainment date
Carbon monoxide:			
Bellevue	12.00	25	January 1986
Seattle CBD	13.30	32	January 1986
University district	14.20	36	November 1985
Northgate	17.00	36	January 1986
Ozone:			
Region	.14	22	July 1984

[FR Doc. 82-28561 Filed 10-18-82; 8:45 am]

BILLING CODE 6560-50-M-

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 83

[PR Docket No. 82-677; FCC 82-421]

Deletion or reduction of requirements for spare parts for ship radio stations in the maritime mobile service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This action proposes to eliminate the requirement to carry specific spare parts, tools, test equipment and instruction manuals aboard compulsory ship stations. This change would relieve licensees of an unnecessarily detailed regulation and be more consistent with actual statute and treaty requirements. These rules should provide an economic benefit to licensees. This action was staff initiated.

DATES: Comments are due by November 8, 1982 and replies by November 23, 1982.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Robert P. DeYoung, Private Radio Bureau, (202) 632-7175.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 83

Communications equipment, Ship stations, Radio.

FCC 82-421

Adopted: September 23, 1982.

Released: October 1, 1982.

In the matter of Amendment of Part 83 of the rules to delete and simplify requirements governing spare parts, tools, test equipment, instruction books and circuit diagrams for compulsory ship stations in the maritime mobile service, PR Docket No. 82-677.

1. In this proceeding, the Commission proposes to amend or delete §§ 83.474, 83.475, 83.476, 83.477, 83.478, 83.479 and 83.499. These rule provisions govern spare parts, tools, test equipment, instruction books and circuit diagrams for compulsory ship stations in the maritime mobile service.

2. Pursuant to the Regulatory Flexibility Act of 1980 [1] and to its own deregulatory program, the Commission is systematically reviewing its regulations with the objective of eliminating unnecessary regulations and of simplifying necessary regulations. In a recent action in General Docket 80-108, for example,[2] the Commission reduced from "requirements" to "recommendations" extremely detailed provisions relating to spare parts, tools, test equipment and technical manuals relating to compulsory radar carried on board ships by operation of the Safety of Life at Sea Convention, 1974 (SOLAS 74). Part of the rationale for doing so was the Commission's conclusion that it could rely on the operational experience of individual shipowners and operators to decide the spares, test equipment, tools and so forth necessary to maintain the radar equipment.

3. In reviewing similar rule provisions governing compulsory ship radio stations, we have reached a similar conclusion. Accordingly, we are proposing to delete or amend these provisions, as set forth in the attached appendix, to make them consistent with the language of the Communications Act and with SOLAS.

4. Because these rule amendments relax existing requirements and because, these provisions constitute a minor cost of operating a ship radio station, the Commission has determined that Sections 603 and 604 of the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) do not apply to this rule making proceeding. The rules will not, if promulgated, have a significant economic impact on a substantial number of small entities.

5. Accordingly, it is ordered, that this Notice of Proposed Rule Making is adopted.

6. Authority for this Notice of Proposed Rule Making is contained in Sections 1, 4(i) and 303(b), (c), (e), (f), (g), and (r) of the Communications Act of 1934, as amended. Pursuant to procedures set out in § 1.415 of the Commission's rules, 47 CFR 1.415, interested persons may file comments on or before November 8, 1982, and reply comments on or before November 23, 1982.

All relevent and timely comments will be considered by the Commission before final action is taken in this proceeding. In reaching its decision, the Commission may take into consideration information and ideas not contained in the comments, provided that such information or a writing indicating the nature and source of such information is placed in the public file, and provided that the fact of the Commission's reliance on such information is noted in its Report and Order.

7. In accordance with the provisions of § 1.419 of the Commission's rules, 47 CFR 1.419, formal participants shall file an original and 5 copies of their comments and other materials. Participants wishing each Commissioner to have a personal copy of their comment should file an original and 11 copies. Members of the general public who wish to express their interest by participating informally man do so by submitting one copy. All comments are given the same consideration, regardless of the number of copies submitted. All findings will be available for public inspection during regular business hours in the Commission's Public Reference Room at its headquarters in Washington, D.C.

8. For purposes of this non-restricted notice and comment rulemaking proceeding, members of the public are advised that *ex parte* contacts are permitted from the time the Commission adopts a notice of proposed rulemaking until the time a public notice is issued stating that a substantive disposition of the matter is to be considered at a forthcoming meeting or until a final order disposing of the matter is adopted by the Commission, whichever is earlier. In general, an *ex parte* presentation is any written or oral communication (other than formal written comments/pleadings and formal oral arguments) between a person outside the Commission and a Commissioner or a member of the Commission's staff which addresses the merits of the proceeding.

[1] Public Law 96-354, 94 Stat. 1164, 5 U.S.C. 601 et seq.

[2] See Memorandum Opinion and Order; Docket 18949; General Docket 80-108; released October 9, 1981 (FCC 81-456); 87 F.C.C. 2d 30.

Any person who submits a written *ex parte* presentation must serve a copy of that presentation on the Commission's Secretary for inclusion in the public file. Any person who makes an oral *ex parte* presentation addressing matters not fully covered in any previously-filed written comments for the proceeding must prepare a written summary of that presentation; on the day of oral presentation, that written summary must be served on the Commission's Secretary for inclusion in the public file, with a copy to the Commission official receiving the oral presentation. Each *ex parte* presentation described above must state on its face that the Secretary has been served, and must also state by docket number the proceeding to which it relates. See generally, § 1.1231 of the Commission's rules, 47 CFR 1.1231.

9. For questions on matters covered in this document contact Robert P. DeYoung at 202/632-7175.

(Secs. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission.

William J. Tricarico,

Secretary.

Appendix

Part 83 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

PART 83—STATIONS ON SHIPBOARD IN THE MARITIME SERVICES

1. Section 83.474 is revised to read as follows:

§ 83.474 Ship station spare parts, tools, instruction books, circuit diagrams and testing equipment.

(a) Each ship station shall be provided with such spare parts, tools, testing equipment, instruction books and circuit diagrams as will enable the radiotelegraph installation and survival craft station to be maintained in efficient working condition while at sea.

(b) The testing equipment shall include an instrument or instruments for measuring A.C. volts, D.C. volts and ohms.

§ 83.476 [Reserved]

2. Section 83.476 is Removed and designated reserved.

§ 83.477 [Reserved]

3. Section 83.477 is removed and designated reserved.

§ 83 478 [Reserved]

4. Section 83.478 is removed and designated reserved.

§ 83.479 [Reserved]

5. Section 83.479 is removed and designated reserved.

6. Section 83.499 is revised to read as follows:

§ 83.499 Ship station spare parts, tools, instruction books, circuit diagrams and testing equipment.

(a) Each ship station shall be provided with such spare parts, tools, testing equipment, instruction books and circuit diagrams as will enable the radiotelephone installation to be maintained in efficient working condition while at sea.

(b) The testing equipment shall include an instrument or instruments for measuring A.C. volts, D.C. volts and ohms.

[FR Doc. 82-28610 Filed 10-18-82; 8:45 am]

BILLING CODE 6712-01-M

Notices

Federal Register
Vol. 47, No. 202
Tuesday, October 19, 1982

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

Rural Electrification Administration

Matanuska Electric Association, Inc.; Finding of No Significant Impact

AGENCY: Rural Electrification Administration, USDA.

ACTION: Notice of Finding of No Significant Impact.

SUMMARY: Notice is hereby given that the Rural Electrification Administration (REA), pursuant to the National Environmental Policy Act of 1969, the Council on Environmental Quality Regulations (40 CFR Part 1500) and REA Bulletin 20-21:320-21, Environmental Policies and Procedures, has made a Finding of No Significant Impact (FONSI) with respect to a request for financing assistance by Matanuska Electric Association, Inc., (Matanuska) of Palmer, Alaska, for the construction of two 500 kW diesel electric generating units and associated facilities in the village of Unalakleet, Alaska.

FOR FURTHER INFORMATION CONTACT: REA's FONSI And Environmental Assessment (EA) and Matanuska's Borrower's Environmental Report (BER) may be reviewed at or obtained from Mr. William E. Davis, Director, Distribution Systems Division, Room 3304, South Agriculture Building, Washington, D.C. 20250, telephone (202) 382-8848, or Mr. James F. Palin, Manager, Matanuska Electric Association, Inc., Palmer, Alaska 99645, telephone (907) 745-3231, during regular business hours.

SUPPLEMENTARY INFORMATION: REA, in connection with a request for financing assistance by Matanuska, has reviewed the BER submitted by Matanuska and has determined that it represents an accurate assessment of the environmental impacts of the proposed project. The proposed project consists of adding two 500 kW diesel electric generating units, one 150,000 gallon fuel storage tank with dike, adding three overhead distribution transformers and replacing three poles on the existing power distribution lines. Based on the BER and other support documents, REA prepared an EA concerning the proposed project and its environmental impacts. REA concluded that the proposed construction will not be a major Federal action significantly affecting the quality of the human environment.

The BER and EA adequately consider potential impacts of the project on resources including air quality, water quality, important farmlands, wetlands and floodplains, threatened and endangered species, and cultural resources.

Alternatives considered include no action, rebuilding the existing plant, use of alternative forms of energy, and energy management and conservation. After reviewing these alternatives, REA determined that the proposed project is an acceptable alternative because it meets Unalakleet's long-term needs and results in minimal adverse environmental impacts and costs.

This program is listed in the Catalog of Federal Domestic Assistance as 10.850—Rural Electrification Loans and Loan Guarantees.

Dated: October 13, 1982.

Jack Van Mark,

Acting Administrator.

[FR Doc. 28-666 Filed 10-18-82; 8:45 am]

BILLING CODE 3410-15-M

CIVIL AERONAUTICS BOARD

Announcement of Approval of Reporting and Information Requirements by the Office of Management and Budget Under the Paperwork Reduction Act (44 U.S.C. 35)

On October 1, 1982, the Office of Management and Budget approved the extension of the following reporting and information requirements: Reporting and information requirements under the U.S.-Canada Nonscheduled Air Services Agreement—approved through June 30, 1985, under OMB No. 3024-0059.

Dated: October 12, 1982.

Robin A. Caldwell,

Chief, Information Management Division, Office of Comptroller.

[FR Doc. 82-28675 Filed 10-18-82; 8:45 am]

BILLING CODE 6320-01-M

[Docket 40962]

Lone Star Certificate Amendment and Transfer Case; Prehearing Conference

Notice is hereby given that a prehearing conference in the above-titled proceeding will be held on December 2, 1982, at 10:00 a.m. (local time), in Room 1012, Universal Building, 1825 Connecticut Avenue, N.W., Washington, D.C., before the undersigned.

In order to facilitate the conduct of the conference, parties are instructed to submit one copy to each party and six copies to the Judge of (1) proposed statements of issues; (2) proposed stipulations; (3) proposed request for information and evidence; (4) statements of position; and (5) proposed procedural dates. The staff Bureau concerned will circulate its material on or before November 5, 1982. The other parties will circulate theirs on or before November 24, 1982.

Dated at Washington, D.C., October 14, 1982.

William A. Kane, Jr.,

Administrative Law Judge.

[FR Doc. 82-28671 Filed 10-18-82; 8:45 am]

BILLING CODE 6320-01-M

[Dockets 40837 and 40838]

Sun Country Airlines, Inc. Fitness Investigation; Prehearing Conference

Notice is hereby given that a prehearing conference in the above entitled matter is assigned to be held on October 26, 1982, at 10:00 a.m. (local time) in Room 1012, Universal Building, 1825 Connecticut Avenue, N.W., Washington, D.C., before the undersigned administrative law judge.

Dated at Washington, D.C., October 13, 1982.

John M. Vittone,

Administrative Law Judge.

[FR Doc. 82-28674 Filed 10-18-82; 8:45 am]

BILLING CODE 6320-01-M

COMMISSION ON CIVIL RIGHTS

Alaska Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Alaska Advisory Committee to the Commission will convene at 9:30 p.m., and will end at 5:00 p.m., on November 6, 1982, at the Alaska Native Foundation, 411 West 4th, Anchorage, Alaska 99501. The Advisory Committee will review Alaska-Washington Seafood Study and discuss program planning.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Mr. Donald Peter 108 Stewart Street, Anchorage, Alaska 99504 (907) 272-9531 or the Northwestern Regional Office 915 Second Avenue, Room 2852 Seattle, Washington 98174 (206) 442-1246.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., October 12, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-28651 Filed 10-18-82; 8:45 am]

BILLING CODE 6335-01-M

Louisiana Advisory Committee; Cancellation

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights that a meeting of the Louisiana Advisory Committee of the Commission originally scheduled for October 28, 1982, at the Warwick Hotel, New Orleans, Louisiana [FR Doc. 82-26757, on page 42767 has been cancelled].

Dated at Washington, D.C., October 14, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-28645 Filed 10-18-82; 8:45 am]

BILLING CODE 6335-01-M

Maine Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given pursuant to the provisions of the the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Maine Advisory Committee to the Commission will convene at 6:00 p.m., and will end at 9:00 p.m., on November 10, 1982, at the Maine Teachers Association, 35 Community Drive, Augusta, Maine 04330. The Advisory Committee will discuss proposed project on block grant; Annual Civil Rights Development Report; Affirmative action in Maine.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Ms. Lois G. Reckitt, 38 Myrtle Avenue, So. Portland, Oregon 04106 (207) 827-7776 or the New England Regional Office, 55 Summer Street, 8th Floor, Boston, Massachusetts 02110 (617) 223-4671.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., October 12, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-28648 Filed 10-18-82; 8:45 am]

BILLING CODE 6335-01-M

Massachusetts Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Massachusetts Advisory Committee to the Commission will convene at 4:00 p.m., and will end at 6:00 p.m., on November 10, 1982, at the U.S. Commission on Civil Rights, New England Regional Office, 55 Summer Street, 8th Floor, Boston, Massachusetts 02110. The Subcommittee will meet to discuss program planning.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Dr. Bradford E. Brown, 17 Roberta Jean Circle, P.O. Box 93 E. Falmouth, Massachusetts 02536 (617) 548-5123 or the New England Regional Office, 55 Summer Street, 8th Floor, Boston, Massachusetts 02110 (617) 223-4671.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., October 12, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-28650 Filed 10-18-82; 8:45 am]

BILLING CODE 6335-01-M

Massachusetts, Connecticut, Maine, New Hampshire, Rhode Island and Vermont Advisory Committees; Agenda and Notice of Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Massachusetts Advisory Committee to the Commission will convene at 4:00 p.m. and will end at 6:00 p.m., on November 18, 1982, at the U.S. Commission on Civil Rights, New England Regional Office 55 Summer Street, 8th Floor, Boston, Massachusetts 02110. The purpose is a regional conference to plan programs for fiscal year 1983 in the New England Region.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Dr. Bradford E. Brown, 17 Roberta Jean Circle, P.O. Box 93, E. Falmouth, Massachusetts 02536, (617) 548-5123; or the New England Regional Office, 55 Summer Street, 8th Floor, Boston MA 02110, (617) 2230-4671.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., October 12, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-28652 Filed 10-18-82; 8:45 am]

BILLING CODE 6335-01-M

New Hampshire Advisory Committee; Agenda and Notice of Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the New Hampshire Advisory Committee to the Commission will convene at 10:00a and will end at 12Noon, on November 16, 1982, at the Norris Cotton Federal Building, 3rd Floor Conference Room, 275 Chestnut Street, Manchester, New Hampshire 03103. The Committee will hold a news conference to release its report on bilingual education in Manchester.

Persons desiring additional information or planning a presentation to the Commitee, should contact the Chairperson, Mr. Andrew T. Stewart, Moose Mountain, Enfield, New Hampshire 03748, (603) 632-7543; or the New England Regional Office, 55 Summer Street, 8th Floor, Boston MA 02110, (617) 223-4671.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., October 14, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-28646 Filed 10-18-82; 8:45 am]

BILLING CODE 6335-01-M

New Hampshire Advisory Committee; Agenda and Notice of Public Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the New Hampshire Advisory Committee to the Commission

will convene at 7:30p and will end at 9:30p, on November 15, 1982, at the Carpenter Center, 323 Franklin Street, Manchester, New Hampshire 03103. The Advisory Committee will discuss final preparations for the November 16 news conference, and release of its report on bilingual education in Manchester.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Mr. Andrew T. Stewart, Moose Mountain, Enfield, New Hampshire 03748, (603) 632-7543; or the New England Regional Office, 55 Summer Street, 8th Floor, Boston, Massachusetts 02110, (617) 223-4671.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., October 12, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-28647 Filed 10-18-82; 8:45 am]

BILLING CODE 6335-01-M

Washington Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the the rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Washington Advisory Committee to the Commission will convene at 9:00 a.m., and will end at 5:00 p.m., on November 5, 1982, at the Federal Building, 915 Second Avenue, Seattle, Washington 98174 (206) 442-1246. The Advisory Committee will review draft report on Discrimination in the Seafood Processing Industry; report on SAC Chair Conference; Update on monitoring activities.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Ms. Katharine M. Bullitt, 1125 Harvard Avenue E, Seattle, Washington 98102 (206) 447-9800, or the Northwestern Regional Office, 915 Second Avenue, Room 2852, Seattle, Washington 98174 (206) 442-1246.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., October 12, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-28649 Filed 10-18-82; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping Investigation; Portland Hydraulic Cement From Australia

AGENCY: International Trade Administration, Commerce.

ACTION: Initiation of Antidumping Investigation.

SUMMARY: On the basis of a petition filed with the United States Department of Commerce, we are initiating an antidumping investigation to determine whether portland hydraulic cement from Australia is being, or is likely to be, sold in the United States at less than fair value. We are notifying the United States International Trade Commission (ITC) of this action so that it may determine whether there is a reasonable indication that imports of portland hydraulic cement from Australia are materially injuring, or are threatening to materially injure, a United States industry. If the investigation proceeds normally, the ITC will make its preliminary determination on or before November 8, 1982, and we will make ours on or before March 2, 1983.

EFFECTIVE DATE: October 19, 1982.

FOR FURTHER INFORMATION CONTACT: Terry Link, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230; telephone (202) 377-0189.

SUPPLEMENTARY INFORMATION:

Petition

On September 23, 1982 we received a petition filed by counsel on behalf of Kaiser Cement Corporation, Gifford-Hill Cement Company, Monolith Portland Cement Company, Nevada Cement Company, the Stone, Glass and Clay Coordinating Committee, AFL/CIO, and the United Cement, Lime, Gypsum and Allied Workers International Union, AFL/CIO; CLC. In compliance with the filing requirements of § 353.36 of the Commerce Regulations (19 CFR 353.36), the petition alleges that imports from Australia of portland hydraulic cement are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Tariff Act of 1930, as amended (19 U.S.C. 1673) (the Act) and that these imports are materially injuring, or are threatening to materially injure, a United States industry. The allegation of sales at less than fair value is supported by comparisons of United States price based on published export prices with foreign market value based upon offered prices for comsumption in the Australian home market.

Initiation of Investigation

Under section 732(c) of the Act, we must determine, within 20 days after a petition is filed, whether a petition sets forth the allegations necessary for initiation of an antidumping investigation and whether it contains information reasonably available to the petitioner supporting the allegations. We have examined the petition on portland hydraulic cement and have found that it meets these requirements.

Therefore, in accordance with section 732 of the Act, we are initiating an antidumping investigation to determine whether portland hydraulic cement from Australia is being, or is likely to be, sold in the United States at less than fair value. If the investigation proceeds normally, we will make our preliminary determination by March 2, 1983.

Scope of the Investigation

For purposes of this investigation, the term "portland hydraulic cement" covers portland hydraulic cement, other than white, non-staining portland cement, as currently provided for in item 511.1440 of the *Tariff Schedules of the United States Annotated.*

Notification of ITC

Section 732(d) of the Act requires us to notify the ITC of this action and to provide it with the information we used to arrive at this determination. We will notify the ITC and make available to it all nonprivileged and nonconfidential information. We will also allow the ITC access to all privileged and confidential information in our files, provided that the ITC confirms it will not disclose such information either publicly or under an administrative protective order without the written consent of the Deputy Assistant Secretary for Import Administration.

Preliminary Determination by ITC

The ITC will determine by November 8, 1982 whether there is a reasonable indication that imports of portland hydraulic cement from Australia are materially injuring, or are threatening to materially injure, a United States industry. If its determination is negative, this investigation will terminate; otherwise, the investigation will proceed according to statutory procedures.

Dated: October 13, 1982.

Gary N. Horlick,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 82-28670 Filed 10-18-82; 8:45 am]

BILLING CODE 3510-25-M

Initiation of Antidumping Investigation: Portland Hydraulic Cement From Japan

AGENCY: International Trade Administration, Commerce.

ACTION: Initiation of antidumping investigation.

SUMMARY: On the basis of a petition filed with the United States Department of Commerce, we are initiating an antidumping investigation to determine whether portland hydraulic cement from Japan is being, or is likely to be, sold in the United States at less than fair value. We are notifying the United States International Trade Commission (ITC) of this action so that it may determine whether there is a reasonable indication that imports of portland hydraulic cement from Japan are materially injuring, or are threatening to materially injure, a United States industry. If the investigation proceeds normally, the ITC will make its preliminary determination on or before November 8, 1982, and we will make ours on or before March 2, 1982.

EFFECTIVE DATE: October 19, 1982.

FOR FURTHER INFORMATION CONTACT: Terry Link, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone (202) 377-0189

SUPPLEMENTARY INFORMATION:

Petition

On September 23, 1982 we received a petition filed by counsel on behalf of Kaiser Cement Corporation, Gifford-Hill Cement Company, Monolith Portland Cement Company, Nevada Cement Company, the Stone, Glass and Clay Coordinating Committee, AFL/CIO, and the United Cement, Lime, Gypsum and Allied Workers International Union, AFL/CIO; CLC. In compliance with the filing requirements of § 353.36 of the Commerce Regulations (19 CFR 353.36), the petition alleges that imports from Japan of portland hydraulic cement are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Tariff Act of 1930, as amended (19 U.S.C. 1673) (the Act) and that these imports are materially injuring, or are threatening to materially injure, a United States industry. The allegation of sales at less than fair value is supported by comparisons between United States prices based on F.O.B. port of exportation prices obtained from the Japan Cement Exporters Association with foreign market values based on delivered prices for consumption in Japan published by Keizai Chosakin, a price monitoring body in Japan.

Initiation of Investigation

Under section 732(c) of the Act, we must determine, within 20 days after a petition is filed, whether a petition sets forth the allegations necessary for initiation of an antidumping investigation and whether it contains information reasonably available to the petitioner supporting the allegations. We have examined the petition on portland hydraulic cement and have found that it meets these requirements.

Therefore, in accordance with section 732 of the Act, we are initiating an antidumping investigation to determine whether portland hydraulic cement from Japan is being, or is likely to be, sold in the United States at less than fair value. If the investigation proceeds normally, we will make our preliminary determination by March 2, 1983.

Scope of the Investigation

For purposes of this investigation, the term "portland hydraulic cement" covers portland hydraulic cement, other than white, non-staining portland cement, as currently provided for in item 511.1440 of the *Tariff Schedules of the United States Annotated.*

Notification of ITC

Section 732(d) of the Act requires us to notify the ITC of this action and to provide it with the information we used to arrive at this determination. We will notify the ITC and make available to it all nonprivileged and nonconfidential information. We will also allow the ITC access to all privileged and confidential information in our files, provided that the ITC confirms it will not disclose such information either publicly or under an administrative protective order without the written consent of the Deputy Assistant Secretary for Import Administration.

Preliminary Determination by ITC

The ITC will determine by November 8, 1982 whether there is a reasonable indication that imports of portland hydraulic cement from Japan are materially injuring, or are threatening to materially injure, a United States industry. If its determination is negative, this investigation will terminate; otherwise, the investigation will proceed according to statutory procedures.

Dated: October 13, 1982.

Gary N. Horlick,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 82-28669 Filed 10-18-82; 8:45 am]

BILLING CODE 3510-25-M

[Case No. 626]

Piher Semiconductores, S.A.; Order Amending Temporary Denial of Export Privileges

By Orders of June 2, 1982, 47 FR 24765 (June 8, 1982) and August 3, 1982, 47 FR 35808 (August 17, 1982), the Order of February 25, 1982, 47 FR 9044 (March 3, 1982) Temporarily Denying Export Privileges was amended so as to authorize certain exports by Piher International Corp. Avda San Julian, s/n Apartado Correos 177 Granallers (Brancelona), Spain. The Order of August 3, 1982 further provided that Piher International Corp. could apply for an extension of such authorization to export if serious economic hardship would be caused by a failure of such extension coupled with a continuing consideration of a motion filed by Piher International Corp. that requested exception from the provisions of Paragraph III of the Order of February 25, 1982.

Consideration of this motion is still continuing, and Piher International Corp. has now applied for an extension of its authorization to make certain exports, asserting that failure to obtain the extension will entail serious economic hardship.

Based on the representations made by Piher International Corp., I find that its application for an extension of its authorization to make certain exports is justified, and that granting this extension will not jeopardize the purpose of the Order of February 25, 1982.

Accordingly, it is hereby ordered that the Order of February 25, 1982 is further amended by excepting, from its denial of export privileges, Piher International Corp., with addresses at 565 W. Golf Road, Arlington Heights, Illinois 60005 and at Post Office Box 91969, Chicago, Illinois 60680, insofar as Piher International Corp. exports variable resistors and potentiometers to its customers in Canada and Singapore in fulfillment of shipments scheduled through November 1982 in the shipment release documents filed by Piher International Corp. in support of its application for this extension, provided

all such exports are G–DEST under the Export Administration Regulations (15 CFR Part 368, *et seq.* (1981)). Piher International Corp. may apply for an extension of this Amendment to shipments scheduled after November 1982 should a continuing consideration of its aforesaid motion entail serious economic hardship if such an extension is not issued.

This Amendment of the Order is effective immediately.

Dated: October 12, 1982.

Thomas W. Hoya,

Hearing Commissioner.

[FR Doc. 82-28688 Filed 10-18-82; 8:45 am]

BILLING CODE 3510-25-M

Electronic Instrumentation Technical Advisory Committee; Closed Meeting

AGENCY: International Trade Administration, Commerce.

Federal Register Citation of previous announcement: 47 FR 43009 October 5, 1982.

Previously announced time and date of the meeting: 9:30 a.m., October 20–21, 1982.

Changes in the meeting: 9:30 a.m., November 18–19, 1982.

Dated: October 14, 1982.

John K. Boidock,

Director, Office of Export Administration.

[FR Doc. 82-28715 Filed 10-18-82; 8:45 am]

BILLING CODE 3510-25-M

Petitions by Producing Firms for Determinations of Eligibility To Apply for Trade Adjustment Assistance

Petitions have been accepted for filing from the following firms: (1) The Toy Works, Inc., Fiddler's Elbow Road, Middle Falls, New York 12848, producer of dolls, towels, pillows, aprons and handbags (accepted September 21, 1982); (2) Duro Metal Products Company, 2649 North Kildare Street, Chicago, Illinois 60639, producer of hand tools (accepted September 21, 1982); (3) Wenczel Tile Company, 200 Enterprise Avenue, Trenton, New Jersey 08638, producer of ceramic floor and wall tile (accepted September 22, 1982); (4) Audiophonics Corporation, 95 Rantoul Street, Beverly, Massachusetts 01915, producer of cables (accepted September 22, 1982); (5) Quinault Pacific Corporation, P.O. Box X, Shelton, Washington 98584, producer of cedar shakes and shingles, and softwood lumber (accepted September 23, 1982); (6) Simpsonville Mills, Inc., 301 West Curtis Street, Simpsonville, South Carolina 29681, producer of fabrics (accepted September 23, 1982); (7) V.S.D. Clothing Company, Inc., 102 S. William Street, Newburgh, New York 12550, producer of women's coats (accepted September 24, 1982); (8) Super Glass Corporation, 1020 East 48th Street, Brooklyn, New York 11203, producer of glass lamp parts and giftware (accepted September 27, 1982); (9) New-Stan Dyeing and Finishing Company, Inc., P.O. Box 2566, Newburgh, New York 12550, producer of fabrics (accepted September 27, 1982); (10) Dexter Knitting Mills, Inc., 500 Main Avenue, Wallington, New Jersey 07057, producer of women's sweaters (accepted September 27, 1982); (11) B. Bennett Company, Inc., 518 Common Street, New Orleans, Louisiana 70130, producer of men's, women's and children's pants (accepted September 27, 1982); (12) Manhattan Fashions, Inc., 1620 Manhattan Avenue, Union City, New Jersey 07087, producer of women's coats and jackets (accepted September 28, 1982); (13) KWB/Calco Manufacturing Company, 1801 South Main Street, Los Angeles, California 90015, producer of uniforms and linens (accepted September 28, 1982); (14) New Ringgold Mills, Inc., P.O. Box 182, New Ringgold, Pennsylvania 17960, producer of women's blouses and other tops (accepted September 30, 1982); (15) Diana Originals, inc., 1050 Kastrin Street, El Paso, Texas 79907, producer of women's jackets, vests and skirts; men's jackets, coats and pants (accepted September 30, 1982); (16) Brevonne Creations, Inc., 98 Greenville Avenue, Johnston, Rhode Island 02919, producer of jewelry (accepted October 1, 1982); (17) Leemar Corporation, 1407 S. 6th Street, Camden, New Jersey 08104, producer of women's dresses (accepted October 4, 1982); (18) Lanan Products, Inc., 3909 W. Harrison Street, Chicago, Illinois 60624, producer of materials handling equipment (accepted October 4, 1982); (19) Hall Ski-Lift Company, Inc., P.O. Box 869, Watertown, New York 13600, producer of ski lifts and accessories (accepted October 4, 1982); (20) Lambert Furniture Corporation, 1301 New York Avenue, Trenton, New Jersey 08638, producer of furniture (accepted October 4, 1982); (21) De Francisci Machine Corporation, 280 Wallabout Street, Brooklyn, New York 11206, producer of food processing machines (accepted October 4, 1982); (22) Smoke Signal Broadcasting, 31336 Via Colinas, Westlake Village, California 91362, producer of microcomputers (accepted October 6, 1982); (23) Union Special Corporation, 400 North Franklin Street, Chicago, Illinois 60610, producer of sewing machines (accepted October 6, 1982); (24) Spademan Sports, Inc., P.O. Box 6410, Incline Village, Nevada 89450, producer of ski bindings (accepted October 6, 1982); (25) Oregon Metallurgical Corporation, P.O. Box 580, Albany, Oregon 97324, producer of titanium ingots, bars, plates and other products (accepted October 6, 1982); (26) Albin Manufacturing Corporation, P.O. Box 346, Farmington, Michigan 48024, producer of copiers (accepted October 6, 1982); and (27) California Steel and Tube, 16049 Stephens Street, City of Industry, California 91745, producer of steel tubing and other shapes (accepted October 7, 1982).

The petitions were submitted pursuant to Section 251 of the Trade Act of 1974 (Pub. L. 93–618) and § 315.23 of the Adjustment Assistance Regulations for Firms and Communities (13 CFR Part 315). Consequently, the United States Department of Commerce has initiated separate investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each firm contributed importantly to total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

Any party having a substantial interest in the proceedings may request a public hearing on the matter. A request for a hearing must be received by the Director, Certification Division, Office of Trade Adjustment Assistance, International Trade Administration, U.S Department of Commerce, Washington, D.C. 20230, no later than the close of business of the tenth calendar day following the publication of this notice. The Catalogue of Federal domestic Assistance official program number and title of the program under which these petitions are submitted is 11.309, Trade Adjustment Assistance. In as far as this notice involves petitions for the determination of eligibility under the Trade Act of 1974, the requirements of Office of Management and Budget Circular No. A–95 regarding review by clearinghouses do not apply.

Charles L. Smith,

Acting Director, Certification Division, Office of Trade Adjustment Assistance.

[FR Doc. 82-28667 Filed 10-18-82; 8:45 am]

BILLING CODE 3510-25-M

National Oceanic and Atmospheric Administration

Notice of Issuance of Permit

On June 24, 1982, Notice was published in the **Federal Register** (47 FR 27400), that an application had been filed with the National Marine Fisheries Service by Drs. Warren M. Zapol and Robert C. Schneider, Massachusetts General Hospital to take up to 25

Weddell seals over a period of two years for the purpose of scientific research.

Notice is hereby given that on October 13, 1982, and as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407), the National Marine Fisheries Service issued a Scientific Research permit for the above taking subject to certain conditions set forth therein.

The Permit is available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, N.W., Washington, D.C.; and

Regional Director, National Marine Fisheries Service, Northeast Region, 14 Elm Street, Federal Building, Gloucester, Massachusetts 01930.

Dated: October 13, 1982.

R. B. Brumsted,

Acting Deputy Director, Office of Marine Mammals and Endangered Species, National Marine Fisheries Service.

[FR Doc. 82-28657 Filed 10-18-82; 8:45 am]

BILLING CODE 3510-22-M

Working Group on Commercialization Land Remote Sensing Satellite Advisory Committee

AGENCY: National Environmental Satellite Service, NOAA.

ACTION: Notice of closed meeting.

SUMMARY: The Land Remote Sensing Satellite Advisory Committee was established on August 12, 1981 by the Secretary of Commerce to advise on matters pertinent to the Department's responsibilities for the establishment and management of the civil operational land remote sensing satellite program. The Working Group on Commercialization was formed to review and evaluate sensitive submissions from U.S. industry potentially interested in acquiring the U.S. civil remote sensing satellites.

DATES: The meeting will convene November 1, 1982, at 9:30 a.m. and adjourn at approximately 12:00 noon on November 4, 1982.

ADDRESS: U.S. Department of Commerce, Washington, D.C.

AGENDA: The entire meeting is being closed to discuss proposals by U.S. industry, including potential contractors, to acquire or operate elements of the U.S. Civil Remote Sensing Satellites including the Landsat system. These proposals will include trade secrets and commercial and financial data submitted to the Government in confidence.

FOR FURTHER INFORMATION CONTACT: Committee Control Officer, Richard J. Keating, (301) 763-5904, or the Committee Staff Officer, Ms. Peggy Harwood, (301) 763-7822. They are located in the Office of External Relations, National Earth Satellite Service, NOAA, (Sx3) Washington, D.C. 20233.

SUPPLEMENTARY INFORMATION: The Assistant Secretary for Administration of the Department of Commerce, with the concurrence of the delegate of the General Counsel, formally determined on October 15, 1982, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended by Section 5(c) of the Government in the Sunshine Act, Pub. L. 94-409, that the matters to be discussed at this meeting should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings and public participation therein, because the discussions are likely to disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential, matters that are within the purview of 5 U.S.C. 552b(c)(4). (A copy of the determination is available for public inspection and copying in the Public Reading Room, Central Reference and Records Inspection Facility, Room 6628, Department of Commerce.)

Dated: October 15, 1982.

S. A. Lawrence,

Assistant Administrator for Management and Budget.

[FR Doc. 82-28858 Filed 10-18-82; 8:45 am]

BILLING CODE 3510-12-M

DEPARTMENT OF DEFENSE

Office of the Secretary

DOD Advisory Group on Electron Devices; Advisory Committee Meeting

Working Group C (Mainly Imaging and Display) of the DOD Advisory Group on Electron Devices (AGED) will meet in closed session 28 October 1982, at the Palisades Institute for Research Services, AGED at 1925 N. Lynn Street, Arlington, Virginia 22209.

The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group C meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. This special device area includes such programs as infrared and night sensors. The review will include classified program details throughout.

In accordance with Section 10(d) of Pub. L. 92-463, as amended, (5 U.S.C. App 1, 10(d) (1976)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552(b)(c) (1976), and that accordingly, this meeting will be closed to the public.

M. S. Healy,

OSD Federal Register Liaison Officer, Department of Defense.

October 14, 1982.

[FR Doc. 82-28616 Filed 10-18-82; 8:45 am]

BILLING CODE 3810-01-M

DOD Advisory Group on Electron Devices; Notice of Advisory Committee Meeting

Working Group A (Mainly Microwave Devices) of the DoD Advisory Group on Electronic Devices (AGED) will meet in closed session on November 5, 1982 at the Naval Research Laboratory, Underwater Sound Reference Detachment, 755 Gatlin Avenue, Orlando, Florida 32805.

The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group A meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. This microwave device area includes programs on developments and research related to microwave tubes, solid state microwave, electronic warfare devices, millimeter wave devices, and passive devices. The review will include classified program details throughout.

In accordance with Section 10(d) of Pub. L. No. 92-463, as amended (5 U.S.C. App 1, 10(d) (1976)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1976), and that

accordingly, this meeting will be closed to the public.

M. S. Healy,

OSD Federal Register Liaison Officer, Department of Defense.

October 14, 1982.

[FR Doc. 82-28660 Filed 10-18-82; 8:45 am]

BILLING CODE 3810-01-M

DoD Advisory Group on Electron Devices; Notice of Advisory Committee Meeting

Working Group D (Mainly Laser Devices) of the DoD Advisory Group on Electronic Devices (AGED) will meet in closed session December 7-8, 1982, at the U.S. Army Communications Electronics Command, Room 3C121, Hexagon Building, Fort Monmouth, N.J. 07703.

The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group D meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. The laser area includes programs on developments and research related to low energy lasers for such applications as battlefield surveillance, target designation, ranging, communications, weapon guidance and data transmission. The review will include classified program details throughout.

In accordance with Section 10(d) of Pub. L. No. 92-463, as amended, (5 U.S.C. App 1, section 10(d)(1976), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1976), and that accordingly, this meeting will be closed to the public.

M. S. Healy,

OSD Federal Register Liaison Officer, Department of Defense.

October 14, 1982.

[FR Doc. 82-28661 Filed 10-18-82; 8:45 am]

BILLING CODE 3810-01-M

Department of the Navy

Final Notice of Decision To Construct and Purchase Navy Family Housing Projects; San Diego, Calif., Area

Pursuant to the regulations implementing the procedural provisions of the National Environmental Policy Act (NEPA) (§ 1505.2 of Title 40, *Code of Federal Regulations*), the Department of the Navy announces its decision to construct the FY 1982 increment of 290 units at two sites, the Carroll Canyon Fire Fighting School and on the south side of Home Avenue in San Diego, and to purchase existing family housing units available in the City of San Diego.

The Department of the Navy has decided to construct and purchase urgently needed family housing for active-duty Department of Defense (DoD) personnel and their dependents stationed in the San Diego area. The initial phase of 290 units is scheduled for FY 1982. Subsequent phases totaling 1,222 units have been planned for the short-term period of five to six years; however, a potential total of 3,500 units have been approved for study.

Adequate housing is deemed essential for the morale, well-being, and retention of the approximately 130,000 DoD personnel and their dependents in the San Diego area. Many of these persons are housed on-base at military facilities; several thousand other individuals reside off-station and compete for housing in the civilian community. While many find adequate housing, many others are unable to do so, frequently because of problems in either housing availability or personal finances. Studies have revealed a serious shortage of adequate housing for members of the U.S. Armed Forces and their dependents. Family housing requirements surveys in this area have identified a current DoD housing deficit of 9,000 units, increasing to a possible 14,000 units in five years. Currently, over 5,000 eligible military families are on the waiting list for military quarters, of which 4,465 or 86 percent are enlisted personnel. The average waiting period for a two bedroom unit can exceed three years and, in consideration of enlistment periods, such is unacceptable.

Initially, and at the time of the filing of the Draft Environmental Impact Statement (DEIS) in February of 1982, the Navy's preferred alternative for construction of the 1982 increment, and subsequent required units, was at the former U.S. Naval Retraining Command, Camp Elliott, San Diego. The Navy, however, in consideration of the controversy surrounding the Camp Elliott site, did subsequently note in the final statement (July 1982) that the sites selected for the initial 290 units would be constructed at Naval Air Station (NAS) Miramar and at the Carroll Canyon Navy Fire Fighting School. Also, as the result of the circulation of the DEIS, the alternative of purchasing existing housing in San Diego; was recommended.

As a result of the above review process and recommendations received, and to satisfy initial housing needs, the Navy now will purchase 132 units from existing and available civilian housing, located at three multifamily apartment complexes in San Diego; build approximately 50 units on a 5 plus acre unit site in the city, located on the south side of Home Avenue, between Fairmont and Euclid streets; and construct the remainder of about 108 units at the Carroll Canyon Fire Fighting School. No units will be build at the Camp Elliott site and that alternative is no longer considered prominent in the Navy's plans for future development.

The remaining environmental issue of consequence is that both the Home Avenue site designated for construction and the 47-unit Home Terrace Condominiums to be purchased are located within a 100-year floodplain as determined by the Department of Housing and Urban Development (HUD) and the Federal Emergency Management Agency (FEMA). The condominiums already exist and comply with existing zoning and land use regulations. Additionally, their construction accommodates anticipated flood conditions and culvert protection has been provided. The construction site is designed to be protected from the flooding of a Standard Project Storm by two 96-inch culverts. Structures will be designed and built to minimize damage which might result from failure of the culverts to contain floodflows. Based on consideration of the critical need for housing, the residential zoning designation, and the lack of other significant environmental impacts, it has been determined that occupancy of the existing units and construction of new units is consistent with the requirements of Executive Order 11988 on Floodplain Management.

F. N. Ottie,

Lieutenant Commander, JAGC, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 82-28583 Filed 10-18-82; 8:45 am]

BILLING CODE 3810-AE-M

DEPARTMENT OF EDUCATION

Office for Civil Rights

Proposed Annual Operating Plan for Fiscal Year 1983

AGENCY: Department of Education.

ACTION: Proposed annual operating plan for Fiscal Year 1983.

SUMMARY: The Secretary of Education invites comments on the proposed FY

1983 Annual Operating Plan for the Office for Civil Rights.

DATES: Interested persons are invited to submit comments, suggestions, and objections regarding the proposed plan on or before December 3, 1982.

ADDRESS: Written comments should be addressed to Harry M. Singleton, Assistant Secretary for Civil Rights, Department of Education (Room 5000, Switzer Building), 400 Maryland Avenue, SW., Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Judith Moss Daidy, (202) 426-6917.

SUPPLEMENTARY INFORMATION: The basic purpose of the Office for Civil Rights (OCR) is to ensure that no person is unlawfully discriminatd against by recipients of Federal education funds in the delivery of services or the provision of benefits on the basis of race, national origin, sex, handicap, or age. The jurisdictional authorities under which OCR operates include Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

Covered under these authorities are 50 State education agencies, 16,000 local school systems, 3,200 colleges and universities, 10,000 proprietary institutions, 55 State rehabilitation agencies and their sub-recipients, as well as other institutions such as libraries and museums which receive financial assistance from the Department of Education (ED). The job of protecting the civil rights of 12 million minority group members, 4 million handicapped persons and 26 million women who attend elementary and secondary schools or postsecondary institutions receiving Federal financial assistance, rests almost exclusively with OCR.

OCR's strategy to ensure compliance with Federal civil rights statutes involves two basic types of activities: compliance activities and technical assistance activities. Nearly all of OCR's compliance activities (complaint investigations, compliance reviews, Title VI *Lau* plan monitoring, and monitoring State higher education systems desegregation) are required by various statutes, regulations and court orders. OCR has discretion, however, as to where it will conduct its compliance reivew activities and what issues those reviews will cover. For the most part, OCR concentrates these investigative activities on those recipients, primarily identified by OCR civil rights compliance survey data, which are believed to be in noncompliance with major civil rights requirements.

OCR is unable to investigate the policies and practices of all the recipients which may not be in compliance with the law. Therefore, through the transfer of information, material and skills, OCR encourages recipients to comply voluntarily with the law and instructs beneficiaries of their rights under Federal civil rights statutes. OCR staff, ED program office staff and contracted personnel have been the major components used by OCR to deliver technical assistance.

It should be noted that the activities planned by OCR in FY 1983 which are outlined below are activities consistent with the FY 1983 budget request as it exists at the time this plan is being prepared. Action on the FY 1983 ED budget has not been completed by Congress. If it becomes necessary to revise this plan, the revisions will be shown in OCR's final FY 1983 Annual Operating Plan to be published before December 31, 1982.

The following narrative and tables describe the activities that OCR plans for FY 1983.

I. Compliance and Enforcement Activities

OCR's compliance and enforcement responsibilities are divided into three general categories: complaint investigations, compliance reviews and monitoring activities.

A. COMPLAINT INVESTIGATIONS

The primary enforcement activity is the investigation and resolution of complaints alleging discrimination. Each timely, written complaint must be resolved in accordance with established procedures and time frames.

OCR received 1,446 and closed 1,885 complaints during the first three quarters of fiscal year 1982. Alleged discrimination against handicapped persons was the basis in approximately 47 percent of complaint receipts, with race and sex complaints following in order of frequency. The largest number of complaints was filed against elementary and secondary schools. Almost 69 percent of complaints in the first three quarters of fiscal year 1982 involved issues of service delivery to students; the remaining complaints involved various employment issues.

Although recent court decisions related to the statutes OCR enforces may have an impact on the number and type of complaints received during fiscal year 1983, it is expected that the complaint workload will not very significantly in type or number from the fiscal year 1982 complaint workload. OCR had a pending caseload of 1,118 complaints as of June 30, 1982.

One initiative to improve OCR's handling of complaints which was implemented during fiscal year 1982 and will be continued in fiscal year 1983, is Early Complaint Resolution (ECR). ECR is a method for the parties in a complaint to resolve themselves the issues raised in the complaint prior to the initiation of an OCR investigation. During the first three months of implementing ECR, 95 percent of the complaints in which the parties agreed to mediation prior to an OCR investigation were resolved. The average duration for this process was 22 days.

Another initiative implemented in fiscal year 1982 to improve OCR's case handling was the pre-determination settlement. This initiative, which is applicable to complaints and to compliance reviews, also will be continued in fiscal year 1983. In the pre-determination settlement, OCR and the recipients of Federal assistance attempt to reach settlements in the early stages rather than waiting for the issuance of the findings. All settlement agreements resulting from this approach are confirmed in writing by the issuance of a letter to the recipients which satisfies the applicable statutory requirements and which includes all the remedies that will be implemented by the recipients. OCR then monitors the implementation of the remedies by the recipient.

B. COMPLIANCE REVIEWS

Compliance reviews differ from complaint investigations in that OCR has some discretion in selecting the issues and institutions for review. In the first three quarters of fiscal year 1982, OCR initiated compliance reviews of 168 recipients and closed 173 reviews. Table 1 shows the compliance review starts in the first three quarters of fiscal year 1982 by issue. The number of compliance reviews initiated in fiscal year 1982 greatly exceeded the projections in the fiscal year 1982 annual operating plan (AOP). The fiscal year 1982 AOP assumed there would be 72 compliance review starts during fiscal year 1982. As of June 30, 1982 (after three quarters of the fiscal year), 168 compliance reviews had been initiated. It is projected that 160 compliance reviews will be in progress at the end of fiscal year 1982 and will carry over into fiscal year 1983.

For fiscal year 1983, OCR will broaden its listing of compliance review issues to assure that the widest coverage against the various types of discrimination will be provided. Table 2 shows the general issues to be included in the fisal year 1983 compliance review program and

provides a brief description of the issues. OCR relies on survey data and other available information in selecting the sites for compliance reviews. The ability to select the issues and the sites for compliance reviews enables OCR to balance the compliance program by jurisdiction and geographically, and to identify and then remedy discrimination that may not be addressed through complaints.

Because of the varied civil rights needs throughout the country, each of the 10 regional offices will develop and implement its own compliance program in fiscal year 1983. Table 3 provides the location of the 10 regional offices and the States assigned to each office.

C. MONITORING ACTIVITIES

In fiscal year 1983, OCR will increase its monitoring of remedies or corrective actions being taken by recipients. As explained above, OCR monitors the implementation of pre-determination settlements and evaluates the results.

OCR will pursue other monitoring activities in fiscal year 1983 which include reviewing the compliance activities of 56 States and territories concerning the civil rights compliance of their vocational education sub-recipients.

OCR also monitors the implementation of remedial plans by recipients found in violation of the civil rights laws. This type of monitoring includes *Adams* higher education desegregation and *Lau* plan monitoring.

• *Adams* Higher Education Desegregation Plan Monitoring—in fiscal year 1983 OCR will be monitoring implementation of 11 statewide higher education desegregation plans covering approximately 260 institutions of higher education.

• Title VI *Lau* Plan Monitoring—OCR is required to monitor the implementation of Title VI *Lau* plans by recipients. In FY 1983, OCR will be monitoring implementation of approximately 50 Title VI *Lau* plans.

II. Technical Assistance Activities

Over 20,000 education institutions which receive Federal financial assistance must comply with a number of complex civil rights requirements. Because of the number of recipient institutions involved, OCR is unable to investigate the policies or practices of each recipient.

The role of the Federal government is enforcing civil rights can be greatly enhanced through efforts to assist and support State and local governments and other ED recipients in achieving compliance. Technical assistance is central, therefore, to the success of OCR's overall program.

This approach allows OCR not only to reach those recipients that may be subject to a complaint investigation or a compliance review but also allows OCR to address specific problem areas that may be of concern to a number of institutions and assist them in a very positive way to comply with the law.

OCR has developed a number of programs to increase the amount and impact of technical assistance provided. The major portion of these technical assistance activities will address the same issues covered by compliance reviews.

In FY 1983 OCR will explore ways to increase the involvement of States in civil rights compliance activities. To this end, OCR will consider the following options:

• Identify States with laws substantially equivalent to the Federal civil rights laws, and with the capacity to undertake civil rights compliance activities.

• Work with State education and human rights agencies to explore cooperative activities that will reduce duplicative efforts and improve OCR's efficiency.

• Promote cost-effective voluntary compliance by close coordination of OCR's technical assistance activities with those of ED.

OCR's technical assistance contract program also assists voluntary compliance by training and informing ED recipients and beneficiaries on how to comply with civil rights laws in a cost-effective manner. During FY 1983 OCR's contract program will be designed to continue to increase the States' and local education agencies' (LEAs) capacity to undertake civil rights activities.

Technical assistance contract topics are identified through analyses of OCR and other data and through consultations with staff of other ED program offices. ED recipient and beneficiary groups are also consulted. To date, OCR has provided technical assistance primarily through workshops and through the development and distribution of technical assistance materials. During FY 1983, OCR will increase its outreach activities to ED recipient and beneficiary groups, both to identify technical assistance needs and to identify new techniques for providing technical assistance. OCR's regional staff will continue to provide technical assistance initiatives that reflect unique regional characteristics, priorities and resources. In providing this assistance each Regional Technical Assistance Staff (RTAS) combines workshops and on-site consultations with telephone and written responses to address recipient and beneficiary needs for assistance.

Other OCR technical assistance outreach activities will include: collecting and disseminating published information about model solutions to civil rights problems; and working closely with ED program offices that deliver civil rights related technical assistance.

III. Program Management Activities

In order to carry out effectively its compliance, enforcement and technical assistance activities, OCR conducts a comprehensive legal, management and evaluation program that includes:

—Formulating regulations, policies and investigation manuals;
—Providing technical guidance on complaints and compliance reviews referred from regional offices;
—Conducting hearings before Administrative Law Judges on the compliance of Federal financial recipients with civil rights requirements;
—Meeting with school district representatives, college and university officials, complainants and civil rights groups to discuss OCR activities;
—Conducting OCR surveys and data collection projects to obtain information on recipients and beneficiary populations;
—Operating a data base management system to assure that complaint and compliance review processing time frames are met;
—Providing training to investigators and legal staff;
—Conducting systematic on-site reviews of technical assistance contractors' activities;
—Directing and monitoring the implementation of Regional Technical Assistance workplans; and
—Developing Requests for Proposals and participating in the selection of contractors for technical assistance activies.

IV. Summary

The planning for OCR's FY 1983 compliance, enforcement and technical assistance program will become more regionally focused than in FY 1982. As in previous years, each regional OCR director will be responsible for timely fulfillment of OCR's obligations in complaint investigations and compliance reviews. In addition, in FY 1983 the OCR regional director will have an expanded role in planning the region's overall program. This program,

primarily through the selection of compliance review sites and the provision of technical assistance, will reflect a balance in the commitment of OCR resources to each of the civil rights jurisdictions and in the geographic area serviced by the regional office. The program will reflect the region's characteristics and civil right priorities. The scope of a regional office's program, beyond the required activities, will be determined by available resources within the office.

Table 4 presents a national profile of OCR's 10 regional offices, by general functions and the approximate percentage of full-time equivalency (FTE) staff assigned to the functions. Regional variation from the national profile will be influenced by such considerations as the number of complaints involving elementary/secondary institutions as contrasted to complaints involving postsecondary institutions or the number of requests for technical assistance by recipients. It may be, therefore, that no two regional compliance programs will be identical or will replicate OCR's national profile.

In FY 1983, OCR will monitor each region's compliance program to ensure its efficiency and effectiveness in implementing OCR's national program.

TABLE 1.—COMPLIANCE REVIEW STARTS BY ISSUE OCTOBER 1, 1981 TO JUNE 30, 1982

Elementary and secondary	Review starts
Issues	
Within school discrimination	49
Vocational education	20
Special purpose schools	6
Unserved special education	20
School segregation	1
Services to LEP children	11
Joint issue:	
Vocational education and unserved	
Special education	2
Postsecondary issues	
Program accessibility	12
Graduate admissions	20
Vocational education	18
Student services	9

TABLE 2.—FISCAL YEAR 1983 COMPLIANCE REVIEW ISSUES

[Elementary and secondary education]

Issue	Issue description
Within School Discrimination: Classroom Assignments, Tracking and Ability Grouping, Special and Physical Education	Discriminatory assignment of students on the basis of race, national origin, sex and/or handicap to courses (including industrial arts and

TABLE 2.—FISCAL YEAR 1983 COMPLIANCE REVIEW ISSUES—Continued

[Elementary and secondary education]

Issue	Issue description
and Secondary School Athletics.	home economics), classrooms, special programs, ability groups, and physical education programs. (Special programs would include those for the educable mentally retarded as well as those for the gifted or talented, e.g., advanced mathematics or science.) This issue also would cover biased counseling and appraisals of students as well as unequal opportunities involving athletics.
Vocational Education: Access, Admissions and Job Placement.	Discrimination on the basis of race, national origin, sex and/or handicap in vocational and education programs, courses and apprentice training. Review of State agency compliance with Methods of Administration agreements.
Special Purpose Schools: Placement, Referral, Program Availability and Least Restrictive Environment.	Discrimination in admissions, accessibility, programs and services, treatment or employment in State administered special purpose schools on the basis of race, national origin, sex and/or handicap.
Unserved Special Education.	Discrimination in the provision of free and appropriate education on the basis of handicap.
Identification of and Services to Limited-English-Proficient (LEP) Children.	Discrimination in the provision of education services to non-English-speaking (NES) or limited-English-proficient (LEP) children.
School Discipline: Expulsions and Suspensions.	Discriminatory disciplinary treatment of students on the basis of race, national origin, sex and/or handicap.
Employment	Discrimination on the basis of sex in matters related to employment such as selection, promotion, compensation and termination.
Within district comparability—Discriminatory delivery of services.	In districts having schools that are disproportionately minority, discrimination on the basis of race and national origin in the provision of educational services and benefits among schools (e.g., limited course offerings, less qualified staff).
Postsecondary education	
Program accessibility for the handicapped.	Lack of program accessibility and accommodation for handicapped students in postsecondary institution programs.
Admissions	Discrimination on the basis of sex, race and/or national origin in admissions to undergraduate, graduate and professional schools.
Intercollegiate athletics	Discrimination on the basis of sex in athletic financial assistance or athletic financial assistance and overall program comparability.
Vocational education: Access, admissions and job placement.	Discrimination on the basis of race, national origin, sex and/or handicap in vocational education programs and courses.
Student services	Discrimination on the basis of race, national origin, sex and/or handicap as applica-

TABLE 2.—FISCAL YEAR 1983 COMPLIANCE REVIEW ISSUES—Continued

[Elementary and secondary education]

Issue	Issue description
	ble in the provision of services such as financial aid, housing, special programs for minorities, counseling and tutorial services, auxiliary aids and/or student employment and placement services.
Vocational rehabilitation services.	Discrimination in the provision of services and benefits to individuals on the basis of handicap, race and/or national origin.
Employment	Discrimination on the basis of sex in matters related to employment such as selection, promotion, compensation and termination.

Table Three—Department of Education

Regional Civil Rights Directors

Region I—Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Dr. Richard McCann, Regional Director, Office for Civil Rights, Education Dept., 140 Federal Street, 14th Floor, Boston, MA 02110

Region II—New Jersey, New York, Puerto Rico, Virgin Islands

Mr. Charles J. Tejada, Regional Director, Office for Civil Rights, Education Dept., 26 Federal Plaza—33rd Floor, New York, NY 10027

Region III—Delaware, District of Columbia, Maryland, Virginia, Pennsylvania, W. Virginia

Mr. Dewey E. Dodds, Regional Director, Office for Civil Rights, Education Dept., Gateway Building, 3535 Market Street, Post Office Box 13716, Philadelphia, PA 19101

Region IV—Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee

Mr. William H. Thomas, Regional Director, Office for Civil Rights, Education Dept., 101 Marietta Street—27th Floor, Atlanta, GA 30323

Region V—Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

Mr. Kenneth A. Mines, Regional Director, Office for Civil Rights, Education Dept., 300 South Wacker Drive, Chicago, IL 60606

Region VI—Arkansas, Louisiana, New Mexico, Oklahoma, Texas

Mr. Taylor August, Regional Director, Office for Civil Rights, Education

Dept., 1200 Main Tower Building—Room 1930, Dallas, TX 75202

Region VII—Iowa, Kansas, Missouri, Nebraska

Mr. Jesse L. High, Regional Director, Office for Civil Rights, Education Dept., 324 East 11th Street—24th Floor, Kansas City, MO 64106

Region VIII—Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming

5Dr. Gilbert Roman, Regional Director, Office for Civil Rights, Education Dept., Federal Office Building, 1961 Stout Street—Room 1185, Denver, CO 80294

Region IX—Arizona, California, Nevada, Hawaii, Guam, American Samoa, Trust Territory of Pacific Islands

Mr. Robert Brown, Regional Director, Office for Civil Rights, Education Dept., 1275 Market Street—14th floor, San Francisco, CA 94103

Region X—Alaska, Idaho, Oregon, Washington

Mr. Gary Jackson, Regional Director, Office for Civil Rights, Education Dept., 1321 Second Avenue—MS/523, Seattle, WA 98101

TABLE FOUR—NATIONAL PROFILE OF OCR REGIONAL OFFICES

Function	Approximate percentage FTE staff
Compliance and Enforcement:	
● Elementary & Secondary Education	43
● Postsecondary Education	27
Technical Assistance	7
Compliance Support:	
● Management	4
● Adminstrative	7
● Legal	12

V. Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding the proposed plan. Written comments and recommendations may be sent to the address given at the beginning of this document. All comments received on or before the end of the comment period will be considered in the development of the final plan.

All comments submitted in response to the proposed plan will be available for public inspection, during and after the comment period, at the Department of Education, Room 4094, Switzer Building, 330 C Street, S.W., Washington, D.C. between the hours of 9:00 a.m. and 5:00 p.m., Monday through Friday of each week except Federal holidays.

Dated: October 13, 1982.

T. H. Bell,

Secretary of Education.

[FR Doc. 82-28640 Filed 10-18-82; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

[ERA Docket No. 82-CERT-015]

Atlas Power Co.; Application for Recertification of the Use of Natural Gas to Displace Fuel Oil

On November 20, 1981, Atlas Powder Company (Atlas), Park Central Ill. 12700 Park Central Place, Dallas, Texas 75251, was granted a recertification of eligible use of natural gas to displace fuel oil by the Administrator of the Economic Regulatory Administration (ERA) (Docket No. 81-CERT-020). The recertification involved the purchase and transportation of natural gas from Cities Service Gas Company (Cities Service), Oklahoma City, Oklahoma 73125, for use by Atlas at its plant in Joplin, Missouri. The ERA certificate expires on November 19, 1982.

On August 25, 1982, Atlas filed an application for recertification of an eligible use of natural gas to displace fuel oil at its plant located in Joplin, Missouri, pursuant to 10 CFR Part 595 (44 FR 47920, August 16, 1979).

More detailed information is contained in the application on file with the ERA and available for public inspection at the ERA, Natural Gas Branch Docket Room, Room 6144, 12th and Pennsylvania Avenue, N.W., Washington, D.C. 20461, from 8:00 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

In its application, Atlas states that the volume of natural gas for which it requests recertification is an amount not to exceed 292,600 Mcf per year. This volume is estimated to displace the use of approximately 2,400,000 gallons (57,143 barrels of No. 2 diesel fuel oil (0.34 to 1.0 percent sulfur)) per year at the Joplin, Missouri, facilities. Atlas requests recertification for an additional year. The eligible seller and transporter of the natural gas is Cities Service.

In order to provide the public with as much opportunity to participate in this proceeding as is practicable under the circumstances, we are inviting any person wishing to comment concerning this application to submit comments in writing to the Economic Regulatory Administration, Room 6144, 12th and Pennsylvania Avenue, N.W., Washington, D.C., Attention: Paula A. Daingneault, within ten (10) calendar days of the date of publication of this notice in the **Federal Register**.

An opportunity to make an oral presentation of data, views, and arguments either against or in support of this application may be requested by any interested person in writing within the ten (10) day comment period. The request should state the person's interest, and if appropriate, why the person is a proper representative of a group or class of persons that has such an interest. The request should include a summary of the proposed oral presentation and a statement as to why an oral presentation is necessary. If ERA determines that an oral presentation is necessary, further notice will be given to Atlas and any persons filing comments and will be published in the **Federal Register**.

Issued in Washington, D.C., on October 13, 1982.

F. Scott Bush,

Director, Oil and Gas Imports Division, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 82-28635 Filed 10-18-82; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. ERA-R-81-05]

Applicable Administrative Procedures for Natural Gas Import and Export Proceedings

AGENCY: Economic Regulatory Administration, Energy.

ACTION: Notice of the Applicable Administrative Procedures used by ERA for Import and Export Proceedings.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives notices to the public that the final rule issued by the Federal Energy Regulatory Commission (FERC) on April 28, 1982 (47 FR 19014, May 3, 1982) which modified the FERC's general rules of practice and procedure in 18 CFR Part I and which became effective on August 26, 1982, does not change the procedures applicable to ERA natural gas import and export proceedings. As announced by ERA on November 30, 1977 (42 FR 61856, December 7, 1977), ERA will continue to conduct the natural gas import and export proceedings in accordance with the procedural rules of the former Federal Power Commission (FPC) in effect at the time of the establishment of DOE on October 1, 1977, until such time as ERA finalizes its own procedural regulations.

FOR FURTHER INFORMATION CONTACT: Stanley C. Vass (Natural Gas Branch, Oil and Gas Imports Division),

Economic Regulatory Administration, 12th & Pennsylvania Avenue, N.W., Room 6144, RG-631, Washington, D.C. 20461, (202) 633-9296

Michael T. Skinker (Office of General Counsel, Natural Gas and Mineral Leasing), 1000 Independence Avenue, S.W., Forrestal Building, Room 6E-042, GC-15, Washington, D.C. 20585, (202) 252-6667

SUPPLEMENTARY INFORMATION: Section 301(b) and 402(f) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 *et seq.*) transferred the authority of Section 3 of the Natural Gas Act (NGA) (Act of June 21, 1938, c. 556, 52 Stat. 821-833, 15 U.S.C. 717-717W) to regulate imports and exports of natural gas from the former FPC to the Secretary of Energy who further delegated it to the Administrator of the ERA by DOE Delegation Order 0204-4. Areas of responsibility between the ERA and the FERC have been further delineated by DOE Delegation Orders No. 0204-54 (to ERA) and 0204-55 (to FERC) (44 FR 56765, October 2, 1979).

The ERA Administrator gave notice on November 30, 1977 (42 FR 61856, December 7, 1977), that the procedural regulations of the former FPC contained in 18 CFR, Parts 1 and 153, would be followed until ERA issued its own administrative rules and regulations regarding natural gas import and export cases. On August 24, 1978 (43 FR 39080, September 1, 1978), the ERA issued a final rule in 10 CFR Part 205, Subpart U, governing off-the-record communications in natural gas import and export cases and electricity export cases and gave further notice that other import and export matters would continue to be covered by the regulations in 18 CFR Parts 1 and 153.

On August 26, 1981 (46 FR 44696, September 4, 1981), the ERA proposed new administrative procedures to govern applications to import or export natural gas which would replace both the old FPC procedures and ERA's procedures regarding off-the-record communications.

On April 28, 1982 (47 FR 19014, May 3, 1982), the FERC adopted a final rule, effective August 26, 1982, modifying the general rules of practice and procedure in 18 CFR Part 1. In view of these changes, this notice is being issued to inform the public that the procedures applicable to ERA's natural gas import and export proceedings remain unaffected by FERC's new rules. The ERA will continue to follow those procedural rules that were in effect on October 1, 1977, in 18 CFR Parts 1 and 153, and the ERA's procedures regarding off-the-record communications in 10 CFR Part 205, Subpart U, until such time as ERA finalizes its proposed new administrative procedures.

Issued in Washington, D.C., on October 12, 1982.

James W. Workman,

Director, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 82-28636 Filed 10-18-82; 8:45 am]

BILLING CODE 6450-01-M

[ERA Docket No. 82-CERT-017]

Public Service Electric and Gas Co.; Certification of Eligible Use of Natural Gas To Displace Fuel Oil

On September 23, 1982, Public Service Electric and Gas Company (Public Service), 80 Park Plaza, T5E, Newark, New Jersey 07101, filed with the Administrator of the Economic Regulatory Administration (ERA) pursuant to 10 CFR Part 595 an application for certification of an eligible use of approximately 6.0 billion cubic feet of natural gas which is expected to displace the use of approximately 922,000 barrels of No. 6 fuel oil (0.3 percent sulfur) and approximately 38,000 barrels of No. 2 fuel oil (0.2 percent sulfur) or kerosene (0.1 percent sulfur) per year at eight of its electric generating stations located in New Jersey. The eight stations are: Bergen in Ridgefield; Essex in Newark; Hudson in Jersey City; Kearny in Kearny; Linden in Linden; Sewaren in Sewaren; Edison in Edison; and Mercer in Trenton.

The quantities at each location are subject to considerable variation with changes in demand and availability of the various generating units, but estimated gas usage and resulting oil displacement volumes are listed below:

Location	Estimated Volume (MMCF) [1]	Estimated oil displacement (000 barrels)	
		0.3% sulfur [2]	0.2% sulfur [3]
1. Bergen Generating Station, Ridgefield, New Jersey	2,600	422	.....
2. Essex Generating Station, Newark, New Jersey	100	.....	19
3. Hudson Generating Station, Jersey City, New Jersey	2,300	366	.....
4. Kearny Generating Station, Kearny, New Jersey	.....	.....	.....
5. Linden Generating Station, Linden, New Jersey	.....	.....	.....
6. Sewaren Generating Station, Sewaren, New Jersey	900	134	.....
7. Edison Generating Station, Edison, New Jersey	100	.....	19
8. Mercer Generating Station, Trenton, New Jersey	.....	.....	.....
Total	6,000	922	38

[1] MMCF is million cubic feet.
[2] No. 6 oil
[3] No. 2 oil or 0.1 percent sulfur kerosene.

The eligible seller of the natural gas is North Penn Gas Company, 76-80 Mill Street, Port Allegany, Pennsylvania 16743. The gas will be transported by the Transcontinental Gas Pipeline Corporation, 2700 South Post Oak Road, P.O. Box 1396, Houston, Texas 77001; and Consolidated Gas Supply Corporation, 445 W. Main Street, Clarksburg, West Virginia 26301.

Public Service has in effect certifications by the ERA which authorize purchases of 24.8 billion cubic feet of natural gas from various eligible sellers for use at the electric generating stations named in this certification as follows:

ERA Docket No.	Amount	Remarks
82-CERT-008	3.0 Bcf/yr	Expires May 23, 1983.
82-CERT-009	7.3 Bcf/yr	Expires June 24, 1983.
82-CERT-010	7.5 Bcf/yr	Expires June 24, 1983.
82-CERT-012	7.0 Bcf/yr	Expires July 24, 1983.

Because the natural gas involved in this application will only be available for a limited period of time, Public Service has requested that the certification be issued expeditiously in order that Public Service may be in a position to purchase all of the natural gas and to displace the full volumes of fuel oil.

The ERA has carefully reviewed Public Service's application for certification in accordance with 10 CFR Part 595 and the policy considerations expressed in the Final Rulemaking Regarding Procedures for Certification of the Use of Natural Gas to Displace Fuel Oil (44 FR 47920, August 16, 1979). The ERA has determined that Public Service's application satisfies the criteria enumerated in 10 CFR Part 595. We are, therefore, granting the certification and transmitting that certification to the Federal Energy Regulatory Commission. More detailed information, including a copy of the application, transmittal letter, and the actual certification, is available for

public inspection at the ERA, Natural Gas Branch Docket Room, Room 6144, RG-631, 12th & Pennsylvania Avenue, NW., Washington, D. C. 20461, from 8:00 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

The requested certification is being issued prior to the 10-day public comment period because it involves the displacement of large volumes of fuel oil, and it is in the public interest to maximize the displacement of fuel oil. The application also states that the use of this natural gas will be available to displace fuel oil only for a limited five-month period, commencing November 1, 1982 and ending March 31, 1983.

Given the limited availability of the gas and the authority of the Administrator to terminate a certification for good cause (10 CFR 595.08), it is not in the public interest to permanently lose this opportunity to displace large volumes of fuel oil while public comments are being solicited.

In order to provide the public with as much opportunity to participate in this proceeding as is practicable under the circumstances, we are inviting any person wishing to comment concerning this application to submit comments in writing to the Economic Regulatory Administration, Natural Gas Branch, Room 6144, RG-631, 12th & Pennsylvania Avenue, N. W., Washington, D. C. 20461, Attention: Paula Daigneault, within ten (10) calendar days of the date of publication of this notice in the **Federal Register.**

An opportunity to make an oral presentation of data, views, and arguments either against or in support of this application may be requested by any interested person in writing within the ten (10) day comment period. The request should state the pearson's interest, and, if appropriate, why the person is a proper representative of a group of calss of persons that has such an interest. The request should include a summary of the proposed oral presentation and a statement as to why an oral presentation is necessary. If ERA determines that an oral presentation is necessary, further notice will be given to Public Service and any persons filing comments and will be published in the **Federal Register.**

Issued in Washington, D. C., October 13, 1982.

James W. Workman,

Director, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 82-28657 Filed 10-18-82; 8:45 am]

BILLING CODE 6450-01-M

Office of Assistant Secretary for International Affairs

Proposed Subsequent Arrangement

Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160) notice is hereby given of a proposed "subsequent arrangement" under the Agreement for Cooperation Between the Government of the United States of America and the International Atomic Energy Agency (IAEA) Concerning Peaceful Uses of Atomic Energy, as amended.

The subsequent arrangement to be carried out under the above mentioned agreement involves approval for supply of the following materials:

Contract Number WC-IA-128, to the Central Control Laboratory, Nuclear Research Institute, Czechoslovak Socialist Republic, 105.7 grams of uranium enriched to 4.30% in U-235, and 23.6 grams of uranium enriched to 2.84% in U-235.

These materials are to be utilized in the Safeguards Analytical Laboratory Evaluation (SALE) Program. This program is designed to evaluate the capability of participating laboratories to analyse materials to be safeguarded in the nuclear fuel cycle, and to provide means by which measurement capability may be improved through the interchange of measurement technology.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that the furnishing of these nuclear materials will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

Dated: October 13, 1982.

For the Department of Energy.

George Bradley,

Principal Deputy Assistant Secretary for International Affairs.

[FR Doc. 82-28587 Filed 10-18-82; 8:45 am]

BILLING CODE 6450-01-M

Voluntary Agreement and Plan of Action To Implement the International Energy Program; Meeting

In accordance with section 252(c)(1)(A)(i) of the Energy Policy and Conservation Act (42 U.S.C. 6272), the following meeting notice is provided.

A meeting of the Industry Advisory Board (IAB) of the International Energy Agency (IEA) will be held on October 25, 1982, at the offices of the IEA , 2 Rue Andre Pascal, Paris 16, France, beginning at 3:00 p.m. The purpose of this meeting is to permit attendance by representatives of members of the IAB at a meeting of the IEA Standing Group on Emergency Questions (SEQ).

The agenda for the meeting is under the control of the SEQ. It is expected that the following draft agenda will be followed:

1. Adoption of the draft agenda;
2. Record of the 41st meeting and matters arising from it;
3. Preparation of AST-4: Report of the AST-4 Design Group; and Introduction of pricing elements into AST-4;
4. Any other business; and
5. Date of next meeting.

As permitted by 10 CFR 209.32, the usual 7-day notice period has been shortened because unanticipated procedural delays prevented processing in sufficient time to provide such notice.

As provided in section 252(c)(1)(A)(ii) of the Energy Policy and Conservation Act, this meeting will not be open to the public.

Issued in Washington, D.C. October 15, 1982.

Craig S. Bamberger,

Assistant General Counsel, International Trade and Emergency Preparedness.

[FR Doc. 82-28815 Filed 10-18-82; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[AEN-FRL—2231-3]

[Fuels and Fuel Additives; Waiver Application]

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On August 25, 1982, Mr. R. A. Darby, on behalf of E.I. Du Pont de Nemours & Company (Du Pont), submitted an application for a waiver of the section 211(f) prohibition on certain fuels and fuel additives set forth in the Clean Air Act (Act). This application is for a waiver of a blend of unleaded fuel with up to 3% methanol by volume, such that the final fuel composition has an oxygen content of no more than 3.5% by weight. The Administrator of EPA has until February 22, 1983 (180 days from the date of receipt of the application) to grant or deny this application.

DATE: Comments should be submitted on or before December 3, 1982.

ADDRESS: Copies of information relative to this application are available for inspection in public docket A-82-33 at the Central Docket Section (A-130) of the EPA, Gallery I—West Tower, 401 M Street, S.W., Washington, D.C. 20460, (202) 755-0245, between the hours of 8:00 a.m. and 4:00 p.m. Any comments from

interested parties should be addressed to this docket with a copy forwarded to Richard G. Kozlowski, Director, Field Operations and Support Division (EN-397), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. As provided in 40 CFR Part 2, a reasonable fee may be charged for copying services.

FOR FURTHER INFORMATION CONTACT: Alan P. Loeb, Attorney-Advisor, Field Operations and Support Division (EN-397), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, (202) 382-2668.

SUPPLEMENTARY INFORMATION: Section 211(f)(1) of the Act makes it unlawful, effective March 31, 1977, for any manufacturer of a fuel or fuel additive to first introduce into commerce, or to increase the concentration in use of, any fuel or fuel additive for use in light duty motor vehicles manufactured after model year 1974 which is not substantially similar to any fuel or fuel additive utilized in the certification of any model year 1975, or subsequent model year, vehicle or engine under section 206 of the Act.

EPA's definition of "substantially similar," published at 46 Fed. Reg. 38528 (July 28, 1981), allows the blending of certain oxygenated components in unleaded gasoline at up to 2% oxygen by weight in the finished fuel. Du Pont is requesting that up to 3% methanol by volume be added to a fuel which is substantially similar, provided that the oxygen content of the finished fuel does not exceed 3.5% oxygen by weight. Three percent methanol by volume adds approximately 1.6% oxygen by weight to a fuel.

Section 211(f)(4) of the Act provides that upon application by any fuel or fuel additive manufacturer the Administrator of EPA may waive the prohibitions of section 211(f)(1) if the Administrator determines that the applicant has established that such fuel or fuel additive will not cause or contribute to a failure of any emission control device or system (over the useful life of any vehicle in which such device or system is used) to achieve compliance by the vehicle with the emissions standards to which it has been certified pursuant to section 206 of the Act. If the Administrator does not act to grant or deny a waiver within 180 days (by February 22, 1983) or receipt of the application, the waiver shall be treated as granted.

Dated: October 8, 1982.

Kathleen M. Bennett,

Assistant Administrator for Air, Noise and Radiation.

[FR Doc. 82-28644 Filed 10-18-82; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-59099A; TSH-FRL 2231-1]

Polyacrylate Copolymer; Approval of Test Marketing Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA received an application for a test marketing exemption (TM-82-46) under section 5 of the Toxic Substances Control Act (TSCA) on August 31, 1982. Notice of receipt of the application was published in the **Federal Register** of September 10, 1982 (47 FR 39884). EPA has granted the exemption.

EFFECTIVE DATE: This exemption is effective on October 7, 1982.

FOR FURTHER INFORMATION CONTACT: Rose Allison, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-206, 401 M St., SW., Washington, D.C. 20460, (202-382-3738).

SUPPLEMENTARY INFORMATION: Under section 5 of TSCA, anyone who intends to manufacture in, or import into, the United States a new chemical substance for commercial purposes must submit a notice to EPA before manufacture or import begins. A "new" chemical substance is any chemical substance that is not on the Inventory of existing substances compiled by EPA under section 8(b) of TSCA. Section 5(a)(1) requires each premanufacture notice (PMN) to be submitted in accordance with section 5(d) and any applicable requirements of section 5(b). Section 5(d)(1) defines the contents of a PMN and section 5(b) contains additional reporting requirements for certain new chemical substances.

Section 5(h), "Exemptions", contains several provisions for exemptions from some or all of the requirements of section 5. In particular, section 5(h)(1) authorizes EPA, upon application, to exempt persons from any requirements of section 5(a) or section 5(b), and to permit them to manufacture or process chemical substances for test marketing purposes. To grant an exemption, the Agency must find that the test marketing activities will not present any unreasonable risk of injury to health or the environment. EPA must either approve or deny the application within 45 days of its receipt, and under section 5(h)(6) the Agency must publish a notice of this disposition in the **Federal Register**. If EPA grants a test marketing exemption, it may impose restrictions on the test marketing activities.

On August 31, 1982, EPA received an application for an exemption from the requirements of sections 5(a) and 5(b) of TSCA to manufacture a new chemical substance for test marketing purposes. The application was assigned test marketing exemption number TM-82-46. The submission is for polyacrylate copolymer. The substance will be used to treat water. Calgon Corporaton claimed the specific chemical identity, certain specific physical and chemical properties, and the specific use as confidential business information. A maximum of 15,000 pounds (lb) will be manufactured and will be test marketed for a period not to exceed 6 months. The manufacturer states that during manufacture, there could be possible dermal exposure for 8 hours/day for two workers in 3 shifts, and during use there may be a maximum of 30 workers exposed for 2 hours/day.

A notice published in the **Federal Register** of September 10, 1982 (47 FR 39884) announced receipt of this application and requested comment on the appropriateness of granting the exemption. The Agency did not receive any comments concerning the application.

EPA has established that the test marketing of the new substance submitted in TM-82-46 under the conditions set out in the application will not present any unreasonable risk of injury to health or the environment. The Agency identified no significant health or ecological concerns for the substance.

This test marketing exemption is granted based on the facts and information obtained and reviewed, but is subject to all conditions set out in the exemption application and, in particular, those enumerated below.

1. This exemption is granted solely to this manufacturer.

2. The applicant must maintain records of the date(s) of shipment(s) to the customers and the quantities shipped in each shipment, and must make these records available to EPA upon request.

3. Each bill of lading that accompanies a shipment of the substance during the test marketing period must state that the use of the substance is restricted to that described to EPA in the test marketing exemption application.

4. The production volume of the new substance may not exceed the quantity of 15,000 lb described in the test marketing exemption application.

5. The test marketing activity approved in this notice is limited to a 6-month period commencing on the date of signature of this notice by the Director of the Office of Toxic Substances.

6. The number of workers exposed to the new chemical should not exceed that specified in the application and the exposure levels and duration of exposure should not exceed those specified in the application.

The Agency reserves the right to rescind its decision to grant this exemption should any new information come to its attention which casts significant doubt on the Agency's conclusion that the test marketing of this substance under the conditions specified in the application will not present an unreasonable risk of injury to human health or the environment.

Dated: October 7, 1982.

Don R. Clay,

Director, Office of Toxic Substances.

[FR Doc. 82-28642 Filed 10-18-82; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

[BC Docket No. 82-706 and BC Docket No. 82-707, File No. BPCT-820412KE and File No. BPCT-820702IA]

Rappaport Communications, Inc. and Key West Television Partners; Designating Applications for Consolidated Hearing on Stated Issues

Order

Adopted: September 30, 1982.

Released: October 8, 1982.

In re applications of Rappaport Communications, Inc., Key West, Florida, BC Docket No. 82-706, File No. BPCT-820412KE; Key West Television Partners, Key West, Florida, BC Docket No. 82-707, File No. BPCT-820702IA; designating applications for consolidated hearing on stated issues for construction permit for a new television station.

1. The Commission, by the Chief, Broadcast Bureau, acting pursuant to delegated authority, has before it the above-captioned mutually exclusive applications of Rappaport Communications, Inc. and Key West Television Partners for a new commercial television station to operate on Channel 22, Key West, Florida.

2. No determination has been reached that the tower height and location proposed by Key West Television Partners would not constitute a hazard to air navigation. Accordingly, an issue regarding this matter will be specified.

Conclusion and Order

3. The applicants are qualified to construct and operate as proposed. Since the proposals are mutually exclusive, however, they must be designated for hearing in a consolidated proceeding on the issues specified below.

4. Accordingly, it is ordered, that, pursuant to Section 309(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding, to be held before an Administrative Law Judge at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine, with respect to Key West Television Partners, whether there is a reasonable possibility that the tower height and location proposed would constitute a hazard to air navigation.

2. To determine which of the proposals would, on a comparative basis, better serve the public interest.

3. To determine, in light of the evidence adduced pursuant to the foregoing issues, which of the applications should be granted.

5. It is further ordered, That the Federal Aviation Administration is made a party respondent to this proceeding with respect to issue 1.

6. It is further ordered, that, to avail themselves of the opportunity to be heard, the applicants and the party respondent herein shall, pursuant to § 1.221(c) of the Commission's rules, in person or by attorney, within 20 days of the mailing of this Order, file with the Commission, in triplicate, a written appearance stating an intention to appear on the date fixed for hearing and to present evidence on the issues specified in this Order.

7. It is further ordered, that the applicants herein shall, pursuant to Section 311(a)(2) of the Communications Act of 1934, as amended, and § 73.3594 of the Commission's rules, give notice of the hearing within the time and in the manner prescribed in such rule, and shall advise the Commission of the publication of such notice as required by § 73.3594(g) of the rules.

Federal Communications Commission.

Larry D. Eads,

Chief, Broadcast Facilities Division, Broadcast Bureau.

[FR Doc. 82-28581 Filed 10-18-82; 8:45 am]

BILLING CODE 6712-01-M

Study Group A of the U.S. Organization for the International Telegraph and Telephone Consultative Committee (CCITT); Meeting

October 8, 1982.

The Department of State announces that Study Group A of the U.S. Organization for the International Telegraph and Telephone Consultative Committee (CCITT) will meet on October 20, 1982 at 10:00 a.m. in Room 856 of the Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. This Study Group deals with U.S. Government aspects of international telegram and telephone operations and tariffs.

The Study Group will discuss international telecommunications questions relating to telegraph, telex, new record services, data transmission and leased channel services in order to develop U.S. positions to be taken at upcoming international Study Groups I and III meetings.

Members of the general public may attend the meeting subject to the instruction of the Chairman. Admittance of public members will be limited to the seating available. Requests for further information should be directed to Earl S. Barbely, Conference Staff, Federal Communications Commission, Washington, D.C. telephone (202) 632-3214.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 82-28582 Filed 10-18-82; 8:45 am]

BILLING CODE 6712-01-M

[BC Doc. No. 82-701, File No. BP-810309AN, et al.]

Trio Broadcasters, Inc., et al.; Hearings

Adopted: September 23, 1982.

Released: October 6, 1982.

In re applications of Trio Broadcasters, Inc., WMOO, Fairhope, Alabama, Has: 1550 kHz, 50 kW, DA (Mobile, Alabama), Req: 660 kHz, 1 kW, 50 kW-LS, DA-N, U, BC Docket No. 82-701, File No. BP-810309AN, Ed Winton, WWLF, Kenneth City, Florida, Has: 680 kHz, 1 kW, D (St. Petersburg, Florida), Req: 660 kHz, 2.5 kW, 10 kW-LS, DA-2, U, BC Docket No. 82-702, File No. BP-810622AE, Holt-Robinson of Mississippi, Inc., Ridgeland, Mississippi, Req: 660 kHz, 1 kW, 2.5 kW-CH, 50 kW, LS, DA-3, U, BC Docket No. 82-703, File No. BP-810622AB. For construction permit*

*Operation with the facilities specified herein is subject to modification, suspension or termination without right to hearing, if found by the Commission

designating applications for consolidated hearing on stated issues.

1. The Commission, by the Chief, Broadcast Bureau, acting pursuant to delegated authority, has under consideration: (a) the above-captioned application of Trio Broadcasters, Inc. (Trio) to change the facilities of station WMOO; (b) the above-captioned mutually exclusive application of Ed Winton (Winton) to change the facilities of station WWLF; (c) the above-captioned mutually exclusive application of Holt-Robinson of Mississippi, Inc. (Holt-Robinson) for a new AM station at Ridgeland, Mississippi; (d) a petition to dismiss the Winton application filed by Trio; (e) a petition to dismiss or deny the Winton application filed by Harte-Hanks Radio, Inc., licensee of station WRBQ(FM), Tampa, Florida; (f) a petition to dismiss the Holt-Robinson application filed by Trio; and (g) related pleadings.

2. *Ed Winton.* Trio Broadcasters, Inc., filed a petition to dismiss the Winton application. Trio urges dismissal of the Winton application because Ed Winton was not the licensee of WWLF at the time the application was filed only the proposed assignee. In addition, Trio asserts the application is contingent on concurrent grant by the Commission of two assignment applications one of which Trio asserts, is defective. Trio further asserts that action on its mutually exclusive application should not be withheld while the Commission determines whether or not the contingencies involved in other applications will be satisfied. Section 73.3517 of the Rules permits assignees of broadcast licenses to file applications in their own names to make changes in the facilities to be assigned. Further, the assignment applications were granted after Trio filed its petition.[1] Therefore, we will deny Trio's petition to dismiss.

3. Harte-Hanks filed a petition to deny or dismiss the Winton application. Petitioner asserts that its station WRBQ(FM) at Tampa and WWLF compete for listeners and revenue and if the application is granted it will suffer economic injury. We find that Harte-Hanks has standing as a party in interest within the meaning of Section 309(d) of the Communications Act of 1934, as amended, *FCC* v. *Sanders Brothers Radio Station,* 309 U.S. 470 (1940). Petitioner asserts that Winton proposes to change WWLF's city of license from St. Petersburg with a population of 236,893 to Kenneth City, a smaller community near St. Petersburg with a population of 4,344 but the proposed mV/m daytime contour will totally encompass St. Petersburg and also Tampa with a population of 271,523. Harte-Hanks further asserts that under these circumstances it is Commission policy that a presumption arises that WWLF's principal community is Tampa rather then Kenneth City. Harte-Hanks is correct in its assertion that current Commission policy[2] requires that a suburban community issue be specified in circumstances such as are found here. To that extent the Harte-Hanks petition is granted and is denied in all other respects. To accord it the opportunity to appear and present evidence we will make Harte-Hanks a party to these proceedings.

4. Section 1.1303(a)(3) of the Commission's Rules states that AM station directional arrays without regard to height are major Commission actions within the meaning of the National Environmental Policy Act. Section 1.1311 requires the submission of an environmental narrative statement in such cases. As Winton proposes a directional antenna system it must submit the required statement.

5. Winton proposes to operate with nighttime power of 2.5 kilowatts. Section 73.21(a)(ii)(c) of the Rules establishes a one-kilowatt nighttime power ceiling for Class II-B stations on a 1-A clear channels in already well served areas such as St. Petersburg, Florida. Winton has requested a waiver of the rule but has submitted no documentation or information in support of its request. The applicant has a heavy burden to show that the power it proposes is necessary to provide principal city service and will not impede the allocation objectives; it may meet the latter by showing either that the higher power would not preclude other possible co-channel unlimited-time class II assignments or that the improved principal city service entailed by the higher power clearly outweighs any potential service that might be precluded. Since it cannot be determined from the record if waiver of § 73.21 is warranted, an issue will be specified.

6. *Holt-Robinson of Mississippi, Inc.* Trio filed a petition to dismiss the Holt-Robinson application. Petitioner alleges the application, if granted, will violate § 73.35 (a) and (b) of the multiple ownership rules in that principals of Holt-Robinson controll the licensees of stations WHSY(AM) and (FM) at Hattiesburg, Mississippi and WHNY, McComb, Mississippi and primary service contours of these stations and the proposed station will overlap. We will deny Trio's petition to dismiss. The Holt-Robinson application was timely filed and contained a request for waiver of the rules with which it was inconsistent as required by § 73.3566 of the rules; it is, therefore, acceptable for filing.

7. On August 19, 1981, Holt-Robinson timely filed an amendment to its application. The amendment proposed a change in the transmitter location and the directional patterns during daytime and critical hours; these changes eliminated the prohibited overlap between the proposed station and other commonly owned stations. On September 18, 1981, Trio filed a pleading entitled "Further Petition to Dismiss Application." Petitioner asserts that the August 19, 1981 site change amendment should be considered as a major change in the application and pursuant to § 73.3571 of the rules it requires a new file number. Further, petitioner asserts Section 1.227 of the Rules provides that an application which is amended so as to require a new file number may not be consolidated for hearing with a mutually exclusive application which has already been cut-off. The cut-off date for applications mutually exclusive with Trio's application is June 22, 1981. Thus, Trio asserts the application should be dismissed. Trio concedes that § 73.3571 of the rules does not specifically provide that the above combination of changes in an AM application will be considered a major change. However, petitioner asserts that the rule gives the staff discretion to treat any application as a major change and it requests that the staff exercise its discretion and consider the amendment a major change. In support of its position Trio asserts that the amendment involves an 80.6% change in area coverage within the 0.5 mV/m contours (43.2% loss in area previously proposed and 37.4% gain in new area); a 66.23% change in population within that area (36.48% in the loss area and 29.75% in the gain area), and, in addition, 45 communities

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to be necessary in order to conform to the Final Acts of the ITU Administrative Conference on Medium Frequency Broadcasting in Region 2, Rio de Janeiro 1981, and to bilateral and other multilateral agreements between the United States and other countries.

[1] The two contingent assignment applications, WWLF from WWBA, Inc., to Ed Winton (BAL-810622ER) and WWBA(FM) from WWBA, Inc., to Malrite of Ohio, Inc. (BALH-810701HF), were granted September 25, and November 9, 1981, respectively. The transactions were consummated January 1 (AM) and January 4, 1982 (FM). Trio's concern that Commission action on its own application will be delayed as the result of the contingent assignment applications is not warranted since the assignment applications were granted well in advance of the comparative hearing proceedings. Any potential questions regarding possible prejudice to Trio are now moot.

[2] See paragraph 12 below and authority cited therein.

in the gain area have populations greater than Ridgeland, the designated city of license.

8. Clearly, the Holt-Robinson amendment to its application is a minor amendment under the rules and we can find no basis for treating it otherwise. The excercise of the staff's discretion in the manner urged by Trio would result in elimination of a competing application and is counter to well established Commission policy that the public interest is served by having a choice among many qualified applicants who appear together at a hearing. *Azalea Corp.*, 31 FCC 2d 561 (1971). We will therefore deny Trio's further petition to dismiss.

9. Question 13 of Section V-A of the application (FCC Form 301) requires that population figures for areas within the various service contours be submitted. Holt-Robinson states that the information will be supplied when the 1980 census maps become available. The population figures have not been filed. Therefore, Holt-Robinson must submit the required information.

10. *Other matters.* Trio proposes to change its city of license from Mobile, Alabama (population 200,452)[3] to Fairhope, Alabama (population 7,286) but would still provide daytime 5 mV/m service to all of Mobile. Ed Winton proposes to change its city of license from St. Petersburg, Florida (population 238,647) to Kenneth City, Florida (population 4,344) but its 5 mV/m contour will encompass the cities of St. Petersburg and Tampa (population 271,523). Holt-Robinson proposes to construct a new station at Ridgeland, Mississippi (population 5,461) but its 5 mV/m contour will penetrate parts of Jackson, Mississippi (population 202,895). Under a policy announced in *Policy Statement on Section 307(b)*, 2 FCC 2d 190 (1965), and affirmed in *AM Station Assignment Standards*, 54 FCC 2d 1, 21-22 (1975), a presumption arises that the applicants realistically propose to serve the larger communities rather than their designated communities.[4] Appropriate issues will be specified.

11. Except as indicated by the issues specified below, the applicants are qualified to construct and operate as proposed. However, the proposals are mutually exclusive and must be set for hearing in a consolidated proceeding. Although the proposals are for different communities, they would serve substantial areas, in common. Consequently, in addition to an issue to determine pursuant to Section 307(b) of the Communications Act of 1934, as amended, which of them would better provide a fair, efficient, and equitable distribution of radio service, a contingent comparative issue also will be specified.

12. Accordingly, it is ordered, that pursuant to Section 309(e) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding, at a time and place to be specified in a subsequent order, upon the following issues:

1. To determine whether the proposal of Trio Broadcasters, Inc., would realistically provide a local transmission service for Fairhope, Alabama, of for Mobile, Alabama.

2. To determine, in the event it is concluded pursuant to issue 1 that Trio's proposal would not realistically provide a local transmission service for Fairhope, Alabama, whether the proposal meets the technical provisions of the rules for AM broadcast stations assigned to Mobile, Alabama.

3. To determine with respect to Ed Winton's nighttime proposal whether circumstances exist which warrant waiver of § 73.21(a)(2)(ii)(c) of the rules.

4. To determine whether the proposal of Ed Winton would realistically provide a local transmission service for Kenneth City, Florida or for Tampa, Florida.

5. To determine, in the event it is concluded pursuant to issue 4 that the Winton proposal would not realistically provide a local transmission service for Kenneth City, Florida, whether the proposal meets the technical provisions of the rules for AM broadcast stations assigned to Tampa, Florida.

6. To determine whether the proposal of Holt-Robinson of Mississippi, Inc., would realistically provide a local transmission service for Ridgeland, Mississippi or for Jackson, Mississippi.

7. To determine, in the event it is concluded pursuant to issue 6 that the Holt-Robinson proposal would not realistically provide a local transmission service for Ridgeland, Mississippi, whether the proposal meets the technical provisions of the rules for AM broadcast stations assigned to Jackson, Mississippi.

8. To determine the areas and populations which would receive primary service from each proposal, and the availability of other primary aural service to such areas and populations.

9. To determine, in light of Section 307(b) of the Communications Act of 1934, as amended, which of the proposals would better provide, a fair, efficient, and equitable distribution of radio service.

10. To determine, in the event it is concluded that a choice between the applicants should not be based solely on considerations relating to Section 307(b), which of the proposals would, on a comparative basis, best serve the public interest.

11. To determine, in light of the evidence adduced pursuant to the foregoing issues, which application should be granted.

13. It is further ordered, that the petition to dismiss or deny the Ed Winton application filed by Harte-Hanks Radio, Inc. is granted to the extent indicated above and is denied in all other respects.

14. It is further ordered, that the petition to dismiss the Ed Winton application filed by Trio Broadcaster's Inc., is denied.

15. It is further ordered, that Ed Winton shall file the environmental narrative statement required by § 1.1311 of the Rules with the Administrative Law Judge within 30 days after this order is published in the **Federal Register.**

16. It is further ordered, that the petition to dismiss and the further petition to dismiss both filed by Trio Broadcasters, Inc., against the Holt-Robinson of Missisippi, Inc., application are denied.

17. It is further ordered, that Holt-Robinson of Mississipppi, Inc., shall file the population figures within the relevant contours as discussed in paragraph 9, above, with the Administrative Law Judge within 30 days of the publication of this order in the **Federal Register.**

18. It is further ordered, that to avail themselves of the opportunity to be heard and pursuant to § 1.221(c) of the Commission's rules, the applicants shall within 20 days of the mailing of this order, in person or by attorney, file with the Commission, in triplicate, written appearances stating an intention to appear on the date fixed for hearing and to present evidence to the issues specified in this order.

19. It is further ordered, that Harte-Hanks Radio, Inc., is made a party to these proceedings and in order to avail itself of the opportunity to be heard shall within 20 days of the mailing of this order file with the Commission, in person or by attorney, a written appearance in triplicate, stating an intention to appear on the date fixed for hearing and present evidence to the issues specified in this order.

20. It is further ordered, that pursuant to Section 311(a)(2) of the

[3] All census figures are from the 1980 census.

[4] The Suburban community policy is currently under review in BC Docket No. 82-230. The disposition of the issues specified here will, of course, be governed by the policies then in effect as a result of that review.

Communications Act of 1934, as amended, and § 73.3594 of the Commission's rules, the applicants shall give notice of the hearing as prescribed in the rule and shall advise the Commission of the publication of such notice as required by § 73.3594(g) of the rules

Federal Communications Commission.

Larry D. Eads,

Chief, Broadcast Facilities Division Broadcast Bureau.

Appendix

21. The Commission has not yet received Federal Aviation Administration clearance for the antenna tower(s) proposed by the below listed applicant. Accordingly, it is further ordered, that the following issue is specified:

To determine whether there is a reasonable possibility that a hazard to air navigation would occur as a result of the tower height and locations proposed by Holt-Robinson of Mississippi, Inc.

22. It is further ordered, than the Federal Aviation Administration is made a party to the proceeding.

[FR Doc. 82-28580 Filed 10-18-82; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

Agreements Filed

The Federal Maritime Commission hereby gives notice that the following agreements have been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of each of the agreements and the justifications offered therefor at the Washington Office of the Federal Maritime Commission, 1100 L Street, N.W., Room 10327; or may inspect the agreements at the Field Offices located at New York, N.Y.; New Orleans, Louisiana; San Francisco, California; Chicago, Illinois; and San Juan, Puerto Rico. Interested parties may submit comments on each agreement, including requests for hearing, to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, within 20 days after the date of the **Federal Register** in which this notice appears. Comments should include facts and arguments concerning the approval, modification, or disapproval of the proposed agreement. Comments shall discuss with particularity allegations that the agreement is unjustly discriminatory or unfair as between carriers, shippers, exporters, importers, or ports, or between exporters from the United States and their foreign competitors, or operates to the detriment of the commerce of the United States, or is contrary to the public interest, or is in violation of the Act.

A copy of any comments should also be forwarded to the party filing the agreements and the statement should indicate that this has been done.

Agreement No. T-2401-5.

Filing party: Mr. Richard L. Landes, Deputy City Attorney, City of Long Beach, Harbor Administration Building, P.O. Box 570, Long Beach, California 90801.

Summary: Agreement No. T-2401-5 between the City of Long Beach and Sea-Land Service, Inc. (Sea-Land), modifies the basic agreement which provides for the preferential assignment covering the lease to Sea-Land of certain premises on Pier G in the Harbor District, for use as a marine terminal. The purpose of the modification is to provide for the renegotiation of compensation for the 5-year period of the term commencing April 1, 1983, and to revise the language of the Agreement affecting documentation of future renegotiations of rental. Sea-Land shall pay as compensation the monthly amount of $72,938.

Agreement No. T-3945-1.

Filing Party: Mr. John E. Nolan, Assistant Port Attorney, Port of Oakland, 66 Jack London Square, P.O. Box 2064, Oakland, California 94604.

Summary: Agreement No. T-3945-1, between the Port of Oakland (Port) and Maersk Line Pacific, Ltd. (Maersk), modifies the basic agreement between the parties which provides for the nonexclusive preferential assignment by Port to Maersk of 22 acres, including berth area, at the Outer Harbor Terminal Area in the Port of Oakland. The purpose of the modification is to provide for the reimbursement by Port to Maersk of the installation cost of 118 reefer outlets on the assigned premises.

Agreement No. T-4075.

Filing party: Mr John E. Nolan, Assistant Port Attorney, Port of Oakland, 66 Jack London Square, P.O. Box 2064, Oakland, California 94604.

Summary: Agreement No. T-4075, between the Port of Oakland (Port) and Compagnie Generale Maritime, Hapag Lloyd AG and Intercontinental Transport (ICT) BV, constituting Euro-Pacific (EP), is a terminal use agreement which provides that EP shall have nonexclusive right to certain premises at the Port's 7th Street Public Container Terminal for the berthing, loading, discharging and related operations in its European-Pacific Coast Service. EP agrees that the assigned premises shall be its published regularly scheduled San Francisco Bay Area port of call. The authority to manage the premises for the Port is vested in Marine Terminals Corp., as separately provided for under Agreement No. T-4008. The provisions of the Port's Tariff No. 2 shall apply to EP's use of the premises. As a consideration for its regular use of the Port, EP will pay to Port 90 percent of tariff dockage and wharfage revenues, instead of 100 percent of said charges, and if EP generates in excess of 31,000 revenue tons per acre in a year, no further wharfage payments to Port are required. The term of the agreement commences upon Commission approval and runs for five years.

Agreement No. T-4076.

Filing party: Frank Wagner, Deputy City Attorney, City of Los Angeles, Harbor Division, P.O. Box 15, San Pedro, California 90733.

Summary: Agreement No. T-4076, between the City of Los Angeles (City) and Marine Terminals Corporation (MTC) provides for the nonexclusive preferential use of certain premises at Berth 231 in the Port of Los Angeles to be used for the loading/unloading and related activities of vessels owned, operated, serviced or represented by MTC. City and MTC shall share tariff revenue from wharfage and dockage according to a formula outlined in the agreement. The term of the agreement runs from Commission approval through March 31, 1986.

By Order of the Federal Maritime Commission.

Dated: October 14, 1982.

Francis C. Hurney,

Secretary.

[FR Doc. 82-28676 Filed 10-18-82; 8:45 am]

BILLING CODE 6730-01-M

Agreement Filed

Notice is hereby given that the following agreement has been filed with the Commission for review and approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 47 U.S.C. 814).

Interested parties may inspect and obtain a copy of the agreement and the justification offered therefor at the Washington office of the Federal Maritime Commission, 1100 L Street, N.W., Room 10427; or may inspect the agreement at the Field Offices located at New York, N.Y., New Orleans, Louisiana, San Francisco, California, Chicago, Illinois, and San Juan, Puerto Rico. Interested parties may submit comments on the agreement, including

request for hearing, to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, within *10* days after the date of the **Federal Register** in which this notice appears. Comments should include facts and arguments concerning the approval, modification, or disapproval of the proposed agreement. Comments shall discuss with particularity allegations that the agreement is unjustly discriminatory or unfair as between carriers, shippers, exporters, importers, or ports, or between exporters from the United States and their foreign competitors, or operates to the detriment of the commerce of the United States, or is contrary to the public interest, or is in violation of the Act.

A copy of any comments should also be forwarded to the party filing the agreement and the statement should indicate that this has been done.

Agreement No. T–4074.

Filing party: Mr. Sam DeNoms, Special Projects Assistant, Port Everglades Authority, P.O. Box 3136, Port Everglades, Florida 33316.

Summary: Agreement No. T–4074, between Port Everglades Authority (Port) and Sea-Land Service, Inc. (Sea-Land), restates and extends the terms of a previous lease agreement between the parties. Agreement No. T–4074 provides for the one-year lease by Port to Sea-Land of approximately six acres of land for use in the handing and processing of containers and related equipment. As compensation, Sea-Land will pay Port an annual rental of $55,920, as well as applicable taxes. Rental, however, may be offest by dockage and wharfage payments.

By Order of the Federal Maritime Commission.

Dated: October 14, 1982.

Francis C. Hurney,

Secretary.

[FR Doc. 82–28677 Filed 10–18–82; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Acquisition of Bank Shares by a Bank Holding Company

The company listed in this notice has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire voting shares or assets of a bank. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated. With respect to the application, interested persons may express their views in writing to the address indicated. Any comment on the application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

A. **Board of Governors of the Federal Reserve System** (William W. Wiles, Secretary) Washington, D.C. 20551:

1. *Texas American Bancshares Inc.*, Fort Worth, Texas; to acquire 100 percent of the voting shares or assets of Forum Bank, Arlington, Texas. This application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Comments on this application must be received not later than November 12, 1982.

Board of Governors of the Federal Reserve System, October 13, 1982.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 82–28594 Filed 10–18–82; 8:45 am]

BILLING CODE 6210–01–M

Formation of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become bank holding companies by acquiring voting shares and/or assets of a bank. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated for that application. With respect to each application, interested persons may express their views in writing to the address indicated for that application. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

A. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *American Commerce Banshares Inc.*, Oklahoma City, Oklahoma; to become a bank holding company by acquiring 80 percent or more of the voting shares of American Bank of Commerce, Oklahoma City, Oklahoma. Comments on this application must be received not later than November 12, 1982.

2. *Blair Bancshares, Inc.*, Blair, Oklahoma; to become a bank holding company by acquiring at least 80 percent of the voting shares of Peoples State Bank, Blair, Oklahoma. Comments on this application must be recieved not later than November 12, 1982.

B. **Federal Reserve Bank of San Francisco** (Harry W. Green, Vice President) 400 Sansome Street, San Francisco, California 94120:

1. *Combancorp*, City of Commerce, California; to become a bank holding company by acquiring at least 100 percent of the voting shares of Commerce National Bank (in organization), City of Commerce, California. Comments on this application must be received not later than November 12, 1982.

Board of Governors of the Federal Reserve System, October 13, 1982.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 82–28592 Filed 10–18–82; 8:45 am]

BILLING CODE 6210–01–M

Schroders Public Limited Company; Proposed Acquisition of Wainwright Econometrics, Inc.

Schroders Public Limited Company, London, England, has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission to acquire voting shares of Wainwright Econometrics, Inc., Boston, Massachusetts.

Applicant states that the proposed subsidiary would engage in providing general economic information and statistical forecasting services in the United States and Canada. These activities would be performed from offices of Applicant's subsidiary in Boston, Massachusetts, and the geographic areas to be served are the entire United States and Canada. Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue

concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of New York.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than November 12, 1982.

Board of Governors of the Federal Reserve System, October 12, 1982.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 82-28593 Filed 10-18-82; 8:45 am]

BILLING CODE 6210-01-M

GENERAL SERVICES ADMINISTRATION

Public Buildings Service

[E-82-26]

Delegation of Authority to the Secretary of Energy

1. *Purpose.* This delegation authorizes the Secretary of Energy to represent the consumer interests of the executive agencies of the Federal Government in proceedings before the Federal Energy Regulatory Commission involving transmission rates, Docket No. ER 82-729.

2. *Effective date.* This delegation is effective immediately.

3. *Delegation.*

a. Pursuant to the authority vested in the Administrator of General Services by the Federal Property and Administrative Services Act of 1949, 63 Stat. 377, as amended, particularly sections 201(a)(4) and 205(d) 40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Energy to represent the consumer interests of the executive agencies of the Federal Government in proceedings before the Federal Energy Regulatory Commission involving the application of the Pacific Gas and Electric Company for an increase in its transmission rates in Docket No. ER 82-729.

b. The Secretary of Energy may redelegate this authority to any officer, official, or employee of the Department of Energy.

c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration (GSA), and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

d. The Department of Energy shall add GSA to its service list in this case so that GSA will receive copies of testimony, briefs, and other Department of Energy filings.

Richard O. Haase,

Commissioner, Public Buildings Service.

[FR Doc. 82-28628 Filed 10-18-82; 8:45 am]

BILLING CODE 6820-23-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open pubic hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA regulations (21 CFR Part 14) relating to advisory committees. The following advisory committee meetings are announced:

Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. November 4 and 5, 9 a.m., Wilson Hall, Bldg. 1, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. Open public hearing, November 4, 9:30 a.m. to 10:30 a.m.; open committee discussion, November 4, 10:30 a.m. to 4 p.m., November 5, 9 a.m. to 10 a.m.; closed committee deliberations, November 5, 10 a.m. to 12 noon; Conrad J. Ledet, National Center for Drugs and Biologics (HFD-160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3500. If any special arrangements or accommodations are needed, contact Mr. Ledet by October 29.

General function of the committee. The committee reviews and evaluates available data on the safety and efficacy of marketed and investigational prescription drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechnisms.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Open committee discussion. The committee will discuss the concomitant use of $Beta_2$ agonists and methyl xanthines; theophylline/ephedrine fixed combinations; synthetic peptides and aspects of their use in the treatment of allergic disease (R. Hamburger, M.D. IND 12,291); the use of leukotrienes in the evaluation of the mechanisms operative in allergic disease (R. Patterson, M.D., IND 19,863); and combinations of theophylline and iodides as expectorant bronchodilators.

Closed committee deliberations. The committee will discuss trade secret or confidential commercial information regarding IND 19,280 and IND 17,431. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel

Date, time, and place. November 15 and 16, 9 a.m., Auditorium, 200 Independence Ave. SW., Washington, DC.

Type of meeting and executive secretary. Open public hearing, November 15, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. to 1 p.m.; closed committee deliberations, 2 p.m. to 5 p.m.; open public hearing, November 16, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. to 1 p.m.; closed committee deliberations, 2 p.m. to 3 p.m.; open committee discussion, 3 p.m. to 5 p.m.; George C. Murray, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7940.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation. The committee also reviews data on new devices and makes recommendations regarding their safety and effectiveness and their suitability for marketing.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in

writing, on issues pending before the committee. Those desiring to make formal presentations should notify the executive secretary before November 1, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On November 15, the committee will discuss premarket approval applications (PMA's) for intraocular lenses (IOL's) and may discuss PMA's for other ophthalmic products. If discussion of all pertinent IOL issues is not completed, discussion will be continued the following day. On November 16, the committee may discuss PMA's or general issues relating to contact lenses or other ophthalmic products.

Closed committee deliberations. On November 15 and 16, the committee will conduct reviews of PMA's for IOL applications. On November 15 and 16, the committee may also discuss trade secret or confidential commercial information relevant to PMA's for contact lens products. These portions of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Immunology Device Section of the Immunology and Microbiology Devices Panel

Date, time, and place. November 22, 9 a.m., 8757 Georgia Ave., Silver Spring, MD.

Type of meeting and panel section leader. Open public hearing, 9 a.m. to 10 a.m.; closed presentation of data, 10 a.m. to 12 p.m.; closed committee deliberations, 1 p.m. to 3 p.m.; open committee discussion, 3 p.m. to 5 p.m.; Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the panel section leader before November 1, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss premarket approval application (PMA) #P820060: Abbott AFP-EIA Diagnostic Kit, Abbott Laboratories.

Closed presentation of data. Representatives of Abbott Laboratories will present trade secret or confidential commercial information regarding PMA #P820060 for committee review. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Closed committee deliberations. The committee will discuss trade secret or confidential commercial information regarding PMA #P820060, Abbott Laboratories. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairman determines will facilitate the committee's work.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be requested from the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA), as amended by the Government in the Sunshine Act (Pub. L. 94-409), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files complied for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general

preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant ot the FACA, as amended; and, notably deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

Dated: October 13, 1982.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 82-28597 Filed 10-18-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82F-0309]

Monsanto Industrial Chemicals Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Monsanto Industrial Chemicals Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a mixture of partially hydrogenated terphenyl and quaterphenyl as a component of adhesives for food-contact use.

FOR FURTHER INFORMATION CONTACT: James H. Maryanski, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B3655) has been filed by Monsanto Industrial Chemicals Co., 800 N. Lindbergh Blvd., St. Louis, MO 63167, proposing that § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of a mixture of partially hydrogenated terphenyl and quaterphenyl as a component of adhesives for food-contact use.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: October 8, 1982.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 82-28559 Filed 10-16-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82M-0317]

National Patent Development Corp.; Premarket Approval of Hydron ® Lens Care Unit (Thermal Disinfector)

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application for premarket approval under the Medical Device Amendments of 1976 of the Hydron ® Lens Care Unit (Thermal Disinfector) sponsored by National Patent Development Corp., New Brunswick, NJ. After reviewing the recommendation of the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, FDA notified the sponsor that the application was approved because the device had been shown to be safe and effective for use as recommended in the submitted labeling.

DATE: Petitions for administrative review by November 18, 1982.

ADDRESS: Requests for copies of the summary of safety and effectiveness data and petitions for administrative review may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Charles Kyper, Bureau of Medical Devices (HFK-402), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7445.

SUPPLEMENTARY INFORMATION: On January 21, 1982, National Patent Development Corp., New Brunswick, NJ, submitted to FDA an application for premarket approval of the Hydron ® Lens Care Unit (Thermal Disinfector) for use with all heat (thermal) disinfected soft (hydrophilic) contact lenses. The application was reviewed by the Ophthalmic Device Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel, an FDA advisory committee, which recommended approval of the application. On September 29, 1982, FDA approved the application by a letter to the sponsor from the Acting Associate Director for Device Evalution, Bureau of Medical Devices.

Before enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295, 90 Stat. 539-583), soft contact lens accesories were regulated as new drugs. Because the amendments broadened the definition of the term "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(h)), soft contact lens accessories are now regulated as class III devices (premarket approval). As FDA explained in a notice published in the **Federal Register** of December 16, 1977 (42 FR 63472), the amendments provide transitional provisions to ensure continued premarket approval requirements for class III devices formerly regulated as new drugs. Furthermore, as a condition to approval, FDA requires that sponsors of applications for premarket approval of soft contact lenses or accessories comply with the records and reports provisions of Part 310 (21 CFR Part 310), Subpart D, until these provisions are replaced by similar requirements under the amendments.

A summary of the safety and effectiveness data on which FDA's approval is based is on file with the Dockets Management Branch (address above) and is available upon request from that office. A copy of all approved final labeling is available for public inspection at the Bureau of Medical Devices—contact Charles Kyper, address above. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of FDA's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and FDA's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration of FDA action under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will

publish a notice of its decision in the **Federal Register.** If FDA grants the petition, the notice will state the issues to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before November 18, 1982, file with the Dockets Management Branch (address above) four copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 13, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-28598 Filed 10-19-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 79N-0340; DESI No.10210]

Prednisolone Acetate and Sodium Sulfacetamide for Ophthalmic Use; Drugs for Human Use; Drug Efficacy Study Implementation; Postponement of Effective Date for Amendment

AGENCY: Food and Drug Administration (FDA).

ACTION: Notice.

SUMMARY: This notice postpones the requirement, announced in the **Federal Register** of May 18, 1982, that a revised Indication section of the labeling for ophthalmic drug products containing prednisolone acetate and sodium sulfacetamide be put into use by November 15, 1982. This postponement is necessary to allow review and, if necessary, correction of certain information in the revised section.

DATES: Information concerning the susceptibility of common eye pathogens to the sodium sulfacetamide component of the combination drug due on or before December 20, 1982.

ADDRESSES: Communications in response to this notice should be directed to the attention of the appropriate office named below and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Information concerning the susceptibility of common eye pathogens to the sodium sulfacetamide component of the combination drug (identify as "Susceptibility Data-DESI 10210"): Division of Anti-Infective Drug Products (HFD-140), Rm. 12B-45, National Center for Drugs and Biologics.

Other communications regarding this notice (identify with DESI 10210): Drug Efficacy Study Implementation Project Manager (HFD-501), National Center for Drugs and Biologics.

FOR FURTHER INFORMATION CONTACT: Douglas I. Ellsworth, National Center for Drugs and Biologics (HFD/32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 29, 1980 (45 Fr 57780), FDA announced its conclusion that the combination of 5 mg of prednisolone acetate and 100 mg of sodium sulfacetamide for ophthalmic use (NDA 10-210; Metimyd Ophthalmic Suspension; Schering Corp., Galloping Hill Rd., Kenilworth, NJ 07033), is effective. The notice set forth the conditions for marketing and approval of such drug products. In the **Federal Register** of May 18, 1982 (47 FR 21296), FDA amended these conditions to require that a revised Indication section be put into use by November 15, 1982.

After the 1982 notice was published, the National Center for Drugs and Biologics determined that certain statements in the labeling revisions for ophthalmic products containing prednisolone acetate and sodium sulfacetamide need to be corrected. These statements concern common eye pathogens that are generally susceptible to the sodium sulfacetamide component of the combination drug and those that are not.

To allow time to review the changes needed and to minimize the impact of requiring repeated labeling revisions in a short period of time, the Director of the National Center for Drugs and Biologics hereby postpones the November 15, 1982 effective date announced in the May 18, 1982 notice as it pertains to the combination of prednisolone acetate and sodium sulfacetamide for ophthalmic use. Such drug products which are the subject of approved applications may continue to be marketed labeled in accordance with the conditions announced in either the August 29, 1980 notice or the May 18, 1982 notice. Abbreviated new drug applications remain acceptable for this type of combination drug and will be approvable in the interim under the conditions announced in either the August 29 or May 18 notice. Further labeling revisions in the conditions for continued marketing of approved drug products and in the conditions for approval of new products will be announced in a future **Federal Register** notice.

In addition, to facilitate the National Center's review of the labeling for these products, the Director invites interested persons to submit susceptibility data pertinent to an evaluation of which common eye pathogens are susceptible to the sodium sulfacetamide component of the combination drug on or before December 20, 1982. This information should be submitted to the Division of Anti-Infective Drug Products (address given above).

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053, as amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the National Center for Drugs and Biologics (see 21 CFR 5.70 and 47 FR 26913 published in the **Federal Register** of June 22, 1982.

Dated: October 8, 1982.

Harry M. Meyer, Jr.,

Director, National Center for Drugs and Biologics.

[FR Doc. 82-28596 Filed 10-18-82; 8:45 am]

BILLING CODE 4160-01-M

Peripheral and Central Nervous System Drugs Advisory Committee; Clarification of Meeting Agenda

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is republishing the agenda portion of the notice announcing a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee scheduled for October 28 and 29, 1982. The meeting was announced in the **Federal Register** of September 28, 1982 (47 FR 42633).

FOR FURTHER INFORMATION CONTACT: Frederick J. Abramek, National Center for Drugs and Biologics (HFD-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3800.

SUPPLEMENTARY INFORMATION: The revised agenda paragraph should read as follows:

Open committee discussion. The committee will discuss orphan products development, phenytoin use in myotonic disorders and continuous muscle fiber activity syndrome, Office of Drugs advisory committee system (film), skeletal muscle relaxants (over-the-counter considerations), and clinical trial design for status epilepticus.

Dated: October 14, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-26725 Filed 10-15-82; 11:32 am]

BILLING CODE 4160-01-M

National Institutes of Health

Filing of Annual Reports

Pursuant to Sections 10(d) and 13 of the Federal Advisory Committee Act, Pub. L. 92-463, notice is hereby given that the annual reports for the committees listed below have been filed with the Library of Congress. Copies are available to the public for inspection at the Library of Congress, Special Forms Reading Room, Main Building, or on weekdays, at the Department Library, North Building, Room 1436, Washington, D.C. 20201, between 9:00 a.m. and 4:30 p.m.

Advisory Committee to the Director, NIH
Aging Review Committee
Allergy, Immunology, and Transplantation Research Committee
Allergy and Immunology Study Section
Animal Resources Review Committee
Arteriosclerosis, Hypertension and Lipid Metabolism Advisory Committee
Arthritis, Metabolism, and Digestive Diseases Special Projects Review Committee
Bacteriology and Mycology Study Section
Behavioral and Neurosciences Study Section
Behavioral Medicine Study Section
Bio-Organic and Natural Products Chemistry Study Section
Biochemical Endocrinology Study Section
Biochemistry Study Section
Biomedical Library Review Committee
Biomedical Sciences Study Section
Biometry and Epidemiology Contract Review Committee
Biophysical Chemistry Study Section
Biopsychology Study Section
Biotechnology Resources Review Committee
Bladder and Prostatic Cancer Review Committee
Blood Diseases and Resources Advisory Committee
Board of Regents of the National Library of Medicine
Board of Scientific Counselors, Division of Cancer Biology and Diagnosis
Board of Scientific Counselors, Division of Cancer Cause and Prevention
Board of Scientific Counselors, Division of Cancer Treatment
Board of Scientific Counselors, Division of Resources, Centers and Community Activities
Board of Scientific Counselors, National Library of Medicine
Board of Scientific Counselors, National Eye Institute
Board of Scientific Counselors, National Heart, Lung, and Blood Institute
Board of Scientific Counselors, National Institute on Aging
Board of Scientific Counselors, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases
Board of Scientific Counselors, National Institute of Allergy and Infectious Diseases
Board of Scientific Counselors, National Institute of Child Health and Human Development
Board of Scientific Counselors, National Institute of Dental Research
Board of Scientific Counselors, National Institute of Environmental Health Sciences
Board of Scientific Counselors, National Institute of Neurological and Communicative Disorders and Stroke
Breast Cancer Task Force Committee
Cancer Center Support Review Committee
Cancer Clinical Investigation Review Committee
Cancer Control Grant Review Committee
Cancer Control Intervention Programs Review Committee
Cancer Regional Studies Review Committee
Cancer Resources and Repositories Contracts Review Committee
Cancer Research Manpower Review Committee
Cancer Special Program Advisory Committee
Cardiology Advisory Committee
Cardiovascular and Pulmonary Study Section
Cardiovascular and Renal Study Section
Cell Biology Study Section
Cellular and Molecular Basis of Disease Review Committee
Clinical Pathology Study Section
Clinical Applications and Prevention Advisory Committee
Clinical Cancer Education Committee
Clinical Cancer Program Project Review Committee
Clinical Sciences Study Section
Clinical Trials Committee
Clinical Trials Review Committee
Communicative Disorders Review Committee
Communicative Sciences Study Section
Developmental Therapeutics Contracts Review Committee, NCI
Diagnostic Radiology Study Section
Endocrinology Study Section
Environmental Health Sciences Review Committee
Epidemiology and Disease Control Study Section
Epilepsy Advisory Committee
Experimental Cardiovascular Sciences Study Section
Experimental Immunology Study Section
Experimental Therapeutics Study Section
Experimental Virology Study Section
Frederick Cancer Research Facility Advisory Committee
General Clinical Research Centers Committee
General Medicine A Study Section
General Medicine B Study Section
General Research Support Review Committee
Genetic Basis of Disease Review Committee
Genetics Study Section
Heart, Lung, and Blood Research Review Committee A
Heart, Lung, and Blood Research Review Committee B
Hematology Study Section
Human Development and Aging Study Section
Human Embryology and Development Study Section
Immunobiology Study Section
Immunological Sciences Study Section
Large Bowel and Pancreatic Cancer Review Committee
Mammalian Genetics Study Section
Maternal and Child Health Research Committee
Medicinal Chemistry Study Section
Mental Retardation Research Committee
Metabolism Study Section
Metallobiochemistry Study Section
Microbial Physiology and Genetics Study Section
Microbiology and Infectious Diseases Advisory Committee
Minority Access to Research Careers (MARC) Review Committee
Molecular and Cellular Biophysics Study Section
Molecular Biology Study Section
Molecular Cytology Study Section
National Advisory Allergy and Infectious Diseases Council
National Advisory Child Health and Human Development Council
National Advisory Council on Aging
National Advisory Dental Research Council
National Advisory Environmental Health Sciences Council
National Advisory Eye Council
National Advisory General Medical Sciences Council
National Advisory Neurological and Communicative Disorders and Stroke Council
National Advisory Research Resources Council
National Arthritis Advisory Board

National Arthritis, Diabetes, and Digestive and Kidney Diseases Advisory Council
National Cancer Advisory Board
National Diabetes Advisory Board
National Digestive Diseases Advisory Board
National Heart, Lung and Blood Advisory Council
National Institute of Dental Research Programs Advisory Committee
National Institute of Dental Research Special Grants Review Committee
Neurological Disorders Program—Project Review A Committee
Neurological Disorders Program—Project Review B Committee
Neurological Sciences Study Section
Neurology A Study Section
Neurology B Study Section
Nutrition Study Section
Oral Biology and Medicine Study Section
Orthopedics and Musculoskeletal Study Section
Pathobiochemistry Study Section
Pathology A Study Section
Pathology B Study Section
Pharmacological Sciences Review Committee
Pharmacology Study Section
Physical Biochemistry Study Section
Physiological Chemistry Study Section
Physiology Study Section
Population Research Committee
President's Cancer Panel
Pulmonary Diseases Advisory Committee
Radiation Study Section
Recombinant DNA Advisory Committee
Reproductive Biology Study Section
Research Manpower Review Committee
Scientific Programs Advisory Committee, NINCDS
Sickle Cell Disease Advisory Committee
Social Sciences and Population Study Section
Surgery and Bioengineering Study Section
Surgery, Anesthesiology and Trauma Study Section
Toxicology Study Section
Tropical Medicine and Parasitology Study Section
Virology Study Section
Vision Research Program Committee
Visual Sciences A Study Section
Visual Sciences B Study Section

Dated: October 6, 1982.

James B. Wyngaarden,

Director, National Institutes of Health.

[FR Doc. 82-28588 Filed 10-18-82; 8:45 am]

BILLING CODE 4140-01-M

National Arthritis Advisory Board; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Arthritis Advisory Board on November 23, 1982, 9:00 a.m. to 5:00 p.m., at the Linden Hill Hotel, 5400 Pooks Hill Road, Bethesda, Maryland 20814. The meeting, which will be open to the public, is being held to discuss the Board's activities and to continue the evaluation of the implementation of the long-range plan to combat arthritis. Attendance by the public will be limited to space available. Notice of the meeting room will be posted in the Hotel lobby.

Certain subcommittees of the Board will meet the day before, November 22. Further information, times and meeting locations of the subcommittees may be obtained by contacting Mr. William Plunkett, Exective Director, National Arthritis Advisory Board, P.O. Box 30286, Bethesda, Maryland 20205, (301) 496-1991. The agenda and rosters of the members can also be obtained from his office. Summaries of the meeting may be obtained by contacting Carole A. Peters, Committee Management Office, NIADDK, National Institutes of Health, Room 9A46, Building 31A, Bethesda, Maryland 20205, (303) 496-5765.

Dated: October 7, 1982.

Betty J. Beveridge,

NIH, Committee Management Officer.

[FR Doc. 82-28589 Filed 10-18-82; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF THE INTERIOR

National Park Service

Intention to Extend Concession Contract

Pursuant to the provisions of Section 5 of the Act of October 9, 1965 (79 Stat. 969; 16 U.S.C. 20), public notice is hereby given that sixty (60) days after the date of publication of this notice, the Department of the Interior, through the Director of the National Park Service, proposes to extend a concession contract with Parkway Inn, Inc., authorizing it to continue to provide accommodations, facilities and services for the public within that section of the Blue Ridge Parkway between Milepost 340 and Milepost 456 for a period of one (1) year from January 1, 1983, through December 31, 1983.

This contract extension has been determined to be categorically excluded from the procedural provisions of the National Environmental Policy Act and no environmental document will be prepared.

The foregoing concessioner has performed its obligations to the satisfaction of the Secretary under an existing contract which expires by limitation of time on December 31, 1982, and therefore, pursuant to the Act of October 9, 1965, as cited above, is entitled to be given preference in the renewal of the contract and in the negotiation of a new contract. This provision in effect, grants Parkway Inn Inc., the opportunity to meet the terms and conditions of any other proposal submitted in response to this Notice which the Secretary may consider better than the proposal submitted by Parkway Inn, Inc.

If Parkway Inn Inc., amends its proposal and the amended proposal is substantially equal to the better offer, then the proposed new contract will be negotiated with Parkway Inn, Inc.

The Secretary will consider and evaluate all proposals received as a result of this notice. Any proposal, including that of the existing concessioner, must be postmarked or hand delivered on or before the sixtieth (60th) day following publication of this notice to be considered and evaluated.

Interested parties should contact the Regional Director, Southeast Region, for information as to the requirements of the proposed contract.

Dated: October 6, 1982.

Robert M. Baker,

Regional Director, Southeast Region.

[FR Doc. 82-28703 Filed 10-18-82; 8:45 am]

BILLING CODE 4310-70-M

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before October 8, 1982. Pursuant to section 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, U.S. Department of the Interior, Washington, DC 20243. Written comments should be submitted by November 3, 1982.

Carol D. Shull,

Chief of Registration, National Register.

ALABAMA

Mobil County

Mobile, *Murphy High School*, 100 S. Carlen St.

Hempstead County

Columbus, *Columbus Presbyterian Church*, AR 73

Ozan, *Ozan Methodist Church*, Mulberry St.

Howard County

Nashville, *First Christian Church*, N. Main St.

Washington County

Canehill, *Blackburn House (Canehill MRA)*, Main and College Sts.
Canehill, *Canehill Cemetery (Canehill MRA)*, SR 13
Canehill, *Canehill College Building (Canehill MRA)*, McClellan and College Sts.
Canehill, *Carroll, A. R., Building (Canehill MRA)*, Main St.
Canehill, *Earle House (Canehill MRA)*, AR 45
Canehill, *Edmiston, D. N., House (Canehill MRA)*, Main St.
Canehill, *Edmiston, John, House (Canehill MRA)*, OffAR 45
Canehill, *Edmiston, Zeb, House (Canehill MRA)*, Main St.
Canehill, *McClellan, E. W., House (Canehill MRA)*, SW of Canehill off AR 45
Canehill, *Methodist Manse (Canehill MRA)*, Main and Spring Sts.
Canehill, *Moore House (Canehill MRA)*, NW of Canehill on SR 13
Canehill, *Pyeatte Mill Site (Canehill MRA)*, S of Canehill on AR 45
Canehill, *Pyeatte, Henry, House (Canehill MRA)*, N of Canehill on AR 45
Canehill, *United Presbyterian Church of Canehill (Canehill MRA)*, Main St.
Canehill, *Welch, William, House (Canehill MRA)*, Main St.

FLORIDA

Duval County

Jacksonville, *Florida Theater*, 128–134 E. Forsyth St.

Orange County

Maitland, *Maitland Art Center*, 231 W. Packwood Ave.

Pinellas County

St. Petersburg, *Snell Arcade*, 405 Central Ave.

St. Johns County

St. Augustine, *Bridge of Lions*, King St.

HAWAII

Hawaii County

Napoopoo vicinity, *Kahikolu Church*, SE of Napoopoo

Honolulu County

Honolulu, *USS Bowfin*, 11 Arizona Memorial Dr.

Maui County

Kawela vicinity, *Archeological Site (T-10) 50-60-04-702*, NE of Kawela
Kawela vicinity, *Archeological Site (T-108) 50-60-03-713*, N of Kawela
Kawela vicinity, *Archeological Site (T-111-116; T-182) 50-60-04-710*, Onioni Dr.
Kawela vicinity, *Archeological Site (T-124) 50-60-04-711*, Off Kupaia Pl
Kawela vicinity, *Archeological Site (T-125-6;T-181) 50-60-03-714*, N of Kawela
Kawela vicinity, *Archeological Site (T-13) 50-60-04-703*, NE of Kawela
Kawela vicinity, *Archeological Site (T-134) 50-60-03-718*, E of Kawela
Kawela vicinity, *Archeological Site (T-135-6) 50-60-03-719*, W of Kawela
Kawela vicinity, *Archeological Site (T-144) 50-60-030-716*, NE of Kawela
Kawela vicinity, *Archeological Site (T-145) 50-60-03-715*, N of Kawela
Kawela vicinity, *Archeological Site (T-155, T-158) 50-60-03-721*, W of Kawela
Kawela vicinity, *Archeological Site (T-165-6) 50-60-03-727*, W of Kawela
Kawela vicinity, *Archeological Site (T-167) 50-60-03-728*, W of Kawela
Kawela vicinity, *Archeological Site (T-171) 50-60-03-729*, W of Kawela
Kawela vicinity, *Archeological Site (T-180) 50-60-04-712*, W of Kawela
Kawela vicinity, *Archeological Site (T-19) 50-60-04-705*, NE of Kawela
Kawela vicinity, *Archeological Site (T-22-4, T-90 AFB) 50-60-04-709*, NE of Kawela
Kawela vicinity, *Archeological Site (T-28) 50-60-04-701*, W of Kawela
Kawela vicinity, *Archeological Site (T-5, T-122, T-178) 50-60-04-142*, Kupaia Pl.
Kawela vicinity, *Archeological Site (T-57) 50-60-03-720*, W of Kawela
Kawela vicinity, *Archeological Site (T-6 complex) 50-60-04-700*, Onioni Dr. and Kupaia Pl.
Kawela vicinity, *Archeological Site (T-70B) 50-60-03-722*, W of Kawela
Kawela vicinity, *Archeological Site (T-75) 50-60-03-725*, W of Kawela
Kawela vicinity, *Archeological Site (T-76) 50-60-03-724*, W of Kawela
Kawela vicinity, *Archeological Site (T-78) 50-60-03-723*, W of Kawela
Kawela vicinity, *Archeological Site (T-79) 50-60-03-726*, W of Kawela
Kawela vicinity, *Archeological Site (T-88) 50-60-04-707*, N of Kawela
Kawela vicinity, *Archeological Site (T-92) 50-60-04-708*, W of Kawela
Kawela vicinity, *Archeological Site (T-12) 50-60-04-704*, E of Kawela
Kawela vicinity, *Archeological Site (T-81, -100, -101, -105, -142) 50-60-03-717*, N of Kawela
Kawela vicinity, *Archeological Site 50-60-04-140*, N of Kawela
Kawela vicinity, *Archeological Site 50-60-04-144*, Kamehameha Hwy and Onioni Dr.
Kawela vicinity, *Archeological Site (T-20 Kamehameha V Wall, and T-42-3) 50-60-04-706*, W of Kawela
Keokea, *Ket Hing Society Building (Chinese Tong Houses of Maui Island TR)*, Cross Rd.
Lahaina, *Wo Hing Society Building (Chinese Tong Houses of Maui Island TR)*, 848 Front St.
Wailuku, *Chee Kung Kong Society Building (Chinese Tong Houses of Maui Island TR)*, 2151 Vine St.

IDAHO

Ada County

Boise, *Abbs, Walter, House (Tourtellotte and Hummel Architecture TR)*, 915 Fort St.
Boise, *Ada Odd Fellows Temple (Tourtellotte and Hummel Architecture TR)*, 109–115 ½ N. 9th St.
Boise, *Allsup, Marion, House (Tourtellotte and Hummel Architecture TR)*, 1301 N. 10th
Boise, *Beck, Albert, House (Tourtellotte and Hummel Architecture TR)*, 1101 Fort St.
Boise, *Boise High School Campus (Tourtellotte and Hummel Architecture TR)*, Washington St. between 9th and 11th Sts.
Boise, *Boise Junior College Administration Building (Tourtellotte and Hummel Architecture TR)*, Boise State University Campus
Boise, *Boise Junior High School (Tourtellotte and Hummel Architecture TR)*, 1105 N. 13th St.
Boise, *Brunzell House (Tourtellotte and Hummel Architecture TR)*, 916 Franklin St.
Boise, *Bryant, H. H., Garage (Tourtellotte and Hummel Architecture TR)*, 11th and Front Sts.
Boise, *Burnett, H. C., House (Tourtellotte and Hummel Architecture TR)*, 124 W. Bannock St.
Boise, *Cavanah, C. C., House (Tourtellotte and Hummel Architecture TR)*, 107 E. Idaho St.
Boise, *Chinese Odd Fellows Building (Tourtellotte and Hummel Architecture TR)*, 610–612 Front St.
Boise, *Coffin, Henry, House (Tourtellotte and Hummel Architecture TR)*, 1403 Franklin St.
Boise, *Daly, John, House (Tourtellotte and Hummel Architecture TR)*, 1015 W. Hays St.
Boise, *Davies, Dr. James, House (Tourtellotte and Hummel Architecture TR)*, 1107 W. Washington St.
Boise, *Davis, R. K., House (Tourtellotte and Hummel Architecture TR)*, 1016 Franklin St.
Boise, *Dunbar, William, House (Tourtellotte and Hummel Architecture TR)*, 1500 W. Hays St.
Boise, *Dunton, Minnie Priest, House (Tourtellotte and Hummel Architecture TR)*, 906 Hays St.
Boise, *Echevarria, Pedro, House (Tourtellotte and Hummel Architecture TR)*, 5605 State St.
Boise, *Eichelberger Apartments (Tourtellotte and Hummel Architecture TR)*, 612–24 N. 9th St.
Boise, *Fleharty, Alva House (Tourtellotte and Hummel Architecture TR)*, 907 Hays St.
Boise, *Fort Street Historic District*, Roughly bounded by Fort, State, 6th, and 16th Sts.
Boise, *Fritchman, H. K., House (Tourtellotte and Hummel Architecture TR)*, 1207 W. Hays St.
Boise, *Funsten, Bishop, House (Tourtellotte and Hummel Architecture TR)*, 2420 Old Penitentiary Rd.
Boise, *Gakey, J. H., House (Tourtellotte and Hummel Architecture TR)*, 1402 Franklin St.
Boise, *Green, John, Mausoleum (Tourtellotte and Hummel Architecture TR)*, Morris Hill Cemetery
Boise, *Guernsey Dairy Milk Depot (Tourtellotte and Hummel Architecture TR)*, 2419 State St.
Boise, *Haines, John, House (Tourtellotte and Hummel Architecture TR)*, 919 W. Hays St.
Boise, *Hays, Samuel, House (Tourtellotte and Hummel Architecture TR)*, 612 Franklin St.
Boise, *Hottes, Fred, House (Tourtellotte and Hummel Architecture TR)*, 509 W. Hays St.
Boise, *Immanuel Methodist Episcopal Church (Tourtellotte and Hummel Architecture TR)*, 1406 Eastman
Boise, *Jefferson, W. E., House (Tourtellotte and Hummel Architecture TR)*, 1117 N. 8th St.

Boise, *Johnson, J. M., House (Tourtellotte and Hummel Architecture TR)*, 1002 Franklin
Boise, *Jones, T. J., Apartments (Tourtellotte and Hummel Architecture TR)*, 10th St. and Fort
Boise, *Joy, Charles, House (Tourtellotte and Hummel Architecture TR)*, 1102 W. Hays St.
Boise, *Kerr, B. L., House (Tourtellotte and Hummel Architecture TR)*, 1116 W. Hays
Boise, *Kieldson Double House (Tourtellotte and Hummel Architecture TR)*, 413–415 Jefferson St.
Boise, *Kieldson, Louis, House (Tourtellotte and Hummel Architecture TR)*, 409 Jefferson St.
Boise, *Kinney, Joseph, Masoleum (Tourtellotte and Hummel Architecture TR)*, Morris Hill Cemetery
Boise, *Marks, M. J., House (Tourtellotte and Hummel Architecture TR)*, 1001 W. Hays St.
Boise, *McElroy, H. E., House (Tourtellotte and Hummel Architecture TR)*, 924 W. Fort St.
Boise, *Mickle, Willis, House (Tourtellotte and Hummel Architecture TR)*, 1415 N. 8th St.
Boise, *Mitchell Hotel (Tourtellotte and Hummel Architecture TR)*, 10th and Front Sts.
Boise, *Morris Hill Cemetery Mausoleum (Tourtellotte and Hummel Architecture TR)*, Morris Hill Cemetery
Boise, *Neal, W. Scott, House (Tourtellotte and Hummel Architecture TR)*, 215 E. Jefferson
Boise, *Neitzel, H. R., House (Tourtellotte and Hummel Architecture TR)*, 705 N. 9th St.
Boise, *Nixon, Axel, House (Tourtellotte and Hummel Architecture TR)*, 815 W. Hays St.
Boise, *Parker, John, House (Tourtellotte and Hummel Architecture TR)*, 713 Franklin St.
Boise, *Paynton, Charles, House (Tourtellotte and Hummel Architecture TR)*, 1213 N. 8th St.
Boise, *Pierce, Walter, House (Tourtellotte and Hummel Architecture TR)*, 1024 Hays St.
Boise, *Regan, John, American Legion Hall (Tourtellotte and Hummel Architecture TR)*, 401 W. Idaho St.
Boise, *Reiger, Fred, Houses (Tourtellotte and Hummel Architecture TR)*, 214 and 216–18 E. Jefferson St.
Boise, *Rosedale Odd Fellows Temple (Tourtellotte and Hummel Architecture TR)*, 1755 Broadway
Boise, *Rossi, Mrs. A. F., House (Tourtellotte and Hummel Architecture TR)*, 1711 Boise Ave.
Boise, *Schmelzel, H. A., House (Tourtellotte and Hummel Architecture TR)*, 615 W. Hays St.
Boise, *Schreiber, Adolph, House (Tourtellotte and Hummel Architecture TR)*, 524 W. Franklin St.
Boise, *Sidenfaden, William, House (Tourtellotte and Hummel Architecture TR)*, 906 Franklin St.
Boise, *Simpson, W. A., House (Tourtellotte and Hummel Architecture TR)*, 1004 N. 10th St.
Boise, *Smith, Nathan, House (Tourtellotte and Hummel Architecture TR)*, Broadway and Targhee
Boise, *South Boise Fire Station (Tourtellotte and Hummel Architecture TR)*, 1011 Williams St.
Boise, *St. Alphonsus' Hospital Nurses' Home and Heating Plant/Laundry (Tourtellotte and Hummel Architecture TR)*, N. 4th St. between Washington and State Sts.
Boise, *St. John's Cathedral Block (Tourtellotte and Hummel Architecture TR)*, 8th and Hays, 9th and Fort Sts.
Boise, *St. Mary's Catholic Church (Tourtellotte and Hummel Architecture TR)*, State and 26th Sts.
Boise, *Stephan, Louis, House (Tourtellotte and Hummel Architecture TR)*, 1709 N. 18th St.
Boise, *Tourtellotte, John, Building (Tourtellotte and Hummel Architecture TR)*, 210–222 N. 10th St.
Boise, *Wallace, J. N., House (Tourtellotte and Hummel Architecture TR)*, 1202 Franklin St.
Boise, *Waymire, C. H., Building (Tourtellotte and Hummel Architecture TR)*, 1521 N. 13th St.
Boise, *Welch, Edward, House (Tourtellotte and Hummel Architecture TR)*, 1321 E. Jefferson St.
Boise, *Wellman Apartments (Tourtellotte and Hummel Architecture TR)*, 5th and Franklin Sts.
Boise, *Wolters Double Houses (Tourtellotte and Hummel Architecture TR)*, 712–16, 720–22 N. 8th St.
Boise, *Zurcher Apartments (Tourtellotte and Hummel Architecture TR)*, 102 S. 17th St.
Eagle, *Jackson, Orville, House (Tourtellotte and Hummel Architecture TR)*, 127 S. Eagle Rd.
Garden City vicinity, *Pierce-Borah House (Tourtellotte and Hummel Architecture TR)*, W. of Garden City off US 26
Meridian, *Biddle and Songer Buildings (Tourtellotte and Hummel Architecture TR)*, Idaho and E. 1st Sts.
Meridian, *Hunt, E. F., House (Tourtellotte and Hummel Architecture TR)*, 49 E. State
Meridian, *Meridian Exchange Bank (Tourtellotte and Hummel Architecture TR)*, 109 E. 2nd St.
Weiser, *Anderson-Elwell House (Tourtellotte and Hummel Architecture TR)*, 547 W. 1st ST.

Bear Lake County

Paris, *Allred, Ezra, Bungalow (Paris MRA)*, 93 Center St.
Paris, *Allred, Ezra, Cottage (Paris MRA)*, 159 Main St.
Paris, *Ashley, Dr. George, House (Paris MRA)*, 40 W. 2nd North
Paris, *Ashley, George, Sr., House (Paris MRA)*, W. 2nd North
Paris, *Athay, Sam, House (Paris MRA)*, 20 W. 2nd North
Paris, *Bear Lake Market (Paris MRA)*, N. Main St.
Paris, *Beck Barns and Automobile Storage (Paris MRA)*, Center St.
Paris, *Bishop West Barn (Paris MRA)*, W. 2nd St.
Paris, *Browning Block (Paris MRA)*, Main and Center Sts.
Paris, *Budge Cottage (Paris MRA)*, Center St.
Paris, *Budge, Alfred, House (Paris MRA)*, N. 1st W. at W. 1st North
Paris, *Budge, Julia, House (Paris MRA)*, 57 W. 1st North
Paris, *Budge, Taft, Bungalow (Paris MRA)*, 86 Center St.
Paris, *Clayton, Russell, Bungalow (Paris MRA)*, 147 E. Center St.
Paris, *Cole House (Paris MRA)*, SW of Paris
Paris, *Collings, James, Jr., House (Paris MRA)*, S of Paris on US 89
Paris, *Cook, Joseph, House (Paris MRA)*, 63 W. 2nd South
Paris, *Davis, E. F., House (Paris MRA)*, 10 W. 2nd North
Paris, *Fielding Academy Site (Paris MRA)*, Center St.
Paris, *Grimmett, John, Jr., House and Outbuildings (Paris MRA)*, 135 W. 2nd North
Paris, *Grimmett, Orson, Bungalow (Paris MRA)*, 28 W. 2nd North
Paris, *Grunder Cabin and Outbuildings (Paris MRA)*, E. 1st North
Paris, *Hoffman Barn (Paris MRA)*, N. 2nd East
Paris, *Hoge, Walter, House (Paris MRA)*, Center and N. 1st East
Paris, *Hotel Paris (Paris MRA)*, 7 Main St.
Paris, *Hulme, Amos, Barn (Paris MRA)*, N. 1st East
Paris, *Innes, Kate, House (Paris MRA)*, 100 E. 2nd South
Paris, *Innes, Thomas, House (Paris MRA)*, 42 W. 1st St. South
Paris, *Jaussi Bungalow (Paris MRA)*, 170 E. 2nd North
Paris, *Keller House and Derick (Paris MRA)*, E. 1st North
Paris, *Kelsey, Robert, Bungalow (Paris MRA)*, 24 E. 2nd South
Paris, *LDS Seminary (Paris MRA)*, Tabernacle Block
Paris, *LDS Stake Office Building (Paris MRA)*, S. Main St.
Paris, *Latham Bungalow (Paris MRA)*, 152 S. 1st East
Paris, *Law, Oren, House and Outbuildings (Paris MRA)*, 592 Main St.
Paris, *Lewis Barn (Paris MRA)*, W. 2nd North
Paris, *Lewis, Bungalow (Paris MRA)*, W. 2nd North
Paris, *Lewis, Fred, Cottage (Paris MRA)*, W. 2nd North
Paris, *Linvall, J. L., House and Outbuilding (Paris MRA)*, E. 2nd South
Paris, *Linvall, Robb, House (Paris MRA)*, Paris Canyon Rd.
Paris, *Low, Morris, Bungalow (Paris MRA)*, 48 W. Center St.
Paris, *Michel House and Barn (Paris MRA)*, E. 1st North
Paris, *Novelty Theatre (Paris MRA)* 36 S. Main St.
Paris, *Nye, James, House (Paris MRA)*, E. 1st South
Paris, *Old LDS Tithing Office/Paris Post Building (Paris MRA)*, Main St.
Paris, *Paris Cemetery (Paris MRA)*, Off US 89
Paris, *Paris Grist Mill Site (Paris MRA)*, Paris Canyon Rd.
Paris, *Paris Lumber Company Building (Paris MRA)*, Main St.
Paris, *Paris Lumberyard Office (Paris MRA)*, Paris Canyon Rd.
Paris, *Paris Photo Studio (Paris MRA)*, W. Center St.

Paris, *Paris Public School (Paris MRA)*, Main and 1st Sts. North
Paris, *Pendrey Drug Store Building (Paris MRA)*, Main and Center Sts.
Paris, *Pendrey, Arthur, Cottage (Paris MRA)*, 193 Main St.
Paris, *Pendrey, Joe and Zina, Bungalow (Paris MRA)*, N. Main St.
Paris, *Poulsen, Jim, House (Paris MRA)*, 146 E. 1st North
Paris, *Preston Bungalow (Paris MRA)*, W. Center St.
Paris, *Price, Dan, House (Paris MRA)*, W. 1st North and N. 1st West
Paris, *Price, Fred, Bungalow (Paris MRA)*, N. 1st West
Paris, *Price, Heber, Bungalow (Paris MRA)*, 60 W. 1st North
Paris, *Price, Joe, House (Paris MRA)*, W. 1st North
Paris, *Price, Robert, House (Paris MRA)*, N. 1st W. at W. 1st North
Paris, *Rich, Joseph, Barn (Paris MRA)*, W. 2nd South
Paris, *Rich, Landon, House (Paris MRA)*, W. 1st South
Paris, *Rich, William L., House (Paris MRA)*, 34 W. 2nd South
Paris, *Rich-Grandy Cabin (Paris MRA)*, E. 2nd South
Paris, *Rogers, Franklin, Bungalow (Paris MRA)*, 55 E. Center St.
Paris, *Rogers, Frederick, House (Paris MRA)*, W. 2nd North
Paris, *Sheidigger, John, House and Outbuildings (Paris MRA)*, S of Paris on US 89
Paris, *Shepherd Bungalow (Paris MRA)*, 55 W. 1st North
Paris, *Shepherd Hardware (Paris MRA)*, Main St.
Paris, *Shepherd, Earl, Bungalow (Paris MRA)*, 104 Center St.
Paris, *Shepherd, J. R., House (Paris MRA)*, 58 W. Center St.
Paris, *Shepherd, Les and Hazel, Bungalow (Paris MRA)*, 185 Main St.
Paris, *Shepherd, Ted, Cottage (Paris MRA)*, N. 1st West
Paris, *Sleight, Thomas, Cabin (Paris MRA)*, Main St.
Paris, *Smedley, Thomas House (Paris MRA)*, E. 1st St. North
Paris, *Spencer, George, House (Paris MRA)*, Center St. and N. 1st East
Paris, *Stoker, Henry, House and Outbuildings (Paris MRA)*, 192 S. 2nd East
Paris, *Stucki, J. U., Barn and Granary (Paris MRA)*, S. 1st West
Paris, *Stucki, J. U., House (Paris MRA)*, S. 1st W. and W. 1st South
Paris, *Stucki, Jane, Barn (Paris MRA)*, W. 1st South
Paris, *Sutton, John, House (Paris MRA)*, 140 Main St.
Paris, *Taylor's Candy Factory (Paris MRA)*, Main St.
Paris, *Taylor, Arthur, House (Paris MRA)*, W. 2nd North
Paris, *Telephone Company Bungalow (Paris MRA)*, Center St.
Paris, *Tueller, Jacob, Jr., House (Paris MRA)*, 75 S. 1st East
Paris, *Tueller, John, Sr., House (Paris MRA)*, 165 E. 1st South
Paris, *Wallentine Farmstead (Paris MRA)*, NW of Paris
Paris, *Weilermann, Gus, House (Paris MRA)*, SW of Paris
Paris, *Wives of Charles C. Rich Historic District (Paris MRA)*, S. 1st West

Bingham County

Blackfoot, *Dubois Historic District*, 211 S. Shilling, 20 Court, 252–320 E. Main Sts.
Blackfoot, *Jones, J. W., Building (Iourtellotte and Hummel Architecture TR)*, 104 NE Main St.
Fort Hall, *Ross Fork Episcopal Church (Tourtellotte and Hummel Architecture TR)*, Mission Rd.

Blaine County

Hailey, *St. Charles of the Valley Catholic Church and Rectory (Tourtellotte and Hummel Architecture TR)*, Pine and S. 1st Sts.
Ketchum, *Bald Mountain Hot Springs (Tourtellotte and Hummel Architecture TR)*, Main and 1st St.

Canyon County

Caldwell, *Caldwell Odd Fellow Home for the Aged (Tourtellotte and Hummel Architecture TR)*, N. 14th Ave.
Caldwell, *St. Mary's Catholic Church (Tourtellotte and Hummel Architecture TR)*, 616 Dearborn
Caldwell, *Steunenberg, A. K., House (Tourtellotte and Hummel Architecture TR)*, 409 N. Kimball
Nampa vicinity, *Idaho State Sanitarium Administration Building (Tourtellotte and Hummel Architecture TR)*, 11th Ave. N.
Nampa, *Dewey, E. H., Stores (Tourtellotte and Hummel Architecture TR)*, 1013–15 1st. St. S.
Nampa, *Nampa American Legion Chateau (Tourtellotte and Hummel Architecture TR)*, 1508 2nd St.
Nampa, *Nampa Department Store (Tourtellotte and Hummel Architecture TR)*, 1st S., and 13th Ave.
Nampa, *Nampa First Methodist Episcopal Church (Tourtellotte and Hummel Architecture TR)*, 12th Ave. S. and 4th St.
Nampa, *Nampa Presbyterian Church (Tourtellotte and Hummel Architecture TR)*, 2nd St. and 15th Ave.
Nampa, *Nampa and Meridian Irrigation District Office (Tourtellotte and Hummel Architecture TR)*, 1503 1st St.
Nampa, *St. Paul's Rectory and Sisters' House (Tourtellottee and Hummel Architecture TR)*, 810 15th Ave.
Parma, *Sacred Hearts of Jesus and Mary Church (Tourtellotte and Hummel Architecture TR)*, 608 7th St.
Roswell, *Roswell Grade School (Tourtellotte and Hummel Architecture TR)*, ID 18 and Stephan Lane

Custer County

Mackay, *Mackay Episcopal Church (Tourtellotte and Hummel Architecture TR)*, Park Ave. and College
Stanley vicinity, *Stanley Ranger Station*, S of Stanley on US 93

Elmore County

Glenns Ferry, *Gorby Opera Theater (Tourtellotte and Hummel Architecture TR)*, Idaho St.
Glenns Ferry, *McGinnis, J. S., Building (Tourtellotte and Hummel Architecture TR)*, 1st and Commercial Sts.
Glenns Ferry, *O'neill Brothers Building (Tourtellotte and Hummel Architecture TR)*, Idaho St.
Glenns Ferry, *Our Lady of Limerick Catholic Church (Tourtellotte and Hummel Architecture TR)*, 113 W. Arthur
Mountain Home, *Ake, F. P. Building (Tourtellotte and Hummel Architecture TR)*, 160–72 Main St.
Mountain Home, *Father Lobell House (Tourtellotte and Hummel Architecture TR)*, 125 4th St.
Mountain Home, *Mountain Home Baptist Church (Tourtellotte and Hummel Architecture TR)*, 265 N. 4th East
St. Anthony vicinity, *Idaho State Industrial School Women's Dormitory (Tourtellotte and Hummel Architecture TR)*, W of St. Anthony on N. Parker Hwy.

Gem County

Emmett, *Bliss, F. T., House (Tourtellotte and Hummel Architecture TR)*, E. 2nd and McKinley Sts.
Emmett, *Fletcher Oil Company (Tourtellotte and Hummel Architecture TR)*, Main St. and Boise Ave.
Emmett, *Gem County Courthouse (Tourtellotte and Hummel Architecture TR)*, Main St. and McKinley Ave.

Gooding County

Gooding, *Gooding College Campus (Tourtellotte and Hummel Architecture TR)*, ID 26
Gooding, *Thompson Mortuary Chapel (Tourtellotte and Hummel Architecture TR)*, 737 Main St.
Gooding, *Trinity Episcopal Church (Tourtellotte and Hummel Architecture TR)*, 7th and Idaho Sts.
Wendell vicinity, *West Point Grade School (Tourtellotte and Hummel Architecture TR)*, Off I–86

Latah County

Bovill, *St. Joseph's Catholic Church (Tourtellotte and Hummel Architecture TR)*, 1st and Cedar
Moscow, *University of Idaho Gymnasium and Armory (Tourtellotte and Hummel Architecture TR)*, University of Idaho Campus

Lemhi County

Salmon, *Salmon City Hall and Library (Tourtellotte and Hummel Architecture TR)*, 200 Main St.

Nez Perce County

Lewiston vicinity, *Hatwai Village Site*, E of Lewiston on US 95
Lewiston, *Idaho Grocery Warehouse and Annex (Tourtellotte and Hummel Architecture TR)*, 1209 Main St.
Lewiston, *Lewiston City Hall (Tourtellotte and Hummel Architecture TR)*, 207 3rd St.
Lewiston, *Lewiston Vineyards Gates (Tourtellotte and Hummel Architecture TR)*, 18th Ave. and 10th

Owyhee County

Bruneau, *Bruneau Episcopal Church (Tourtellotte and Hummel Architecture TR)*, Off ID 51

Murphy, *Owyhee County Courthouse (Tourtellotte and Hummel Architecture TR)*, ID 45

Payette County

New Plymouth, *New Plymouth Congregational Church (Tourtellotte and Hummel Architecture TR)*, Southwest Ave. between West Park and Plymouth

Payette, *Jacobsen, N.A., Building (Tourtellotte and Hummel Architecture TR)*, N. 8th St. and 1st Ave.

Payette, *Palumbo, J.C., Fruit Company Packing Warehouse Building (Tourtellotte and Hummel Architecture TR)*, 2nd Ave. and 6th St.

Shoshone County

Pinehurst, *Pine Creek Baptist Church (Tourtellotte and Hummel Architecture TR)*, Main and S. 3rd Sts.

Twin Falls County

Twin Falls, *Continental Oil Company Complex*, S. 2nd Ave. and S. 6th St.

Twin Falls, *McCollum, Robert, House*, 708 E. Shoshone St.

Washington County

Weiser vicinity, *Butterfield Livestock Company House (Tourtellotte and Hummel Architecture TR)*, N of Weiser on Jenkins Creek Rd.

Weiser vicinity, *Larsen, Archie, House (Tourtellotte and Hummel Architecture TR)*, S of Weiser on Larsen Rd.

Weiser, *Haas, Herman, House (Tourtellotte and Hummel Architecture TR)*, 253 W. Idaho St.

Weiser, *Kurtz-Van Sicklin House (Tourtellotte and Hummel Architecture TR)*, 439 W. 3rd. St.

Weiser, *Nesbit, G. V., House (Tourtellotte and Hummel Architecture TR)*, 308 W. Liberty

Weiser, *Numbers, Dr. J. R., House (Tourtellotte and Hummel Architecture TR)*, 240 W. Main St.

Weiser, *Sommer, Morris, House (Tourtellotte and Hummel Architecture TR)*, 548 W. 2nd St.

Weiser, *Sommercamp, Mary Elizabeth, House (Tourtellotte and Hummel Architecture TR)*, 411 W. 3rd St.

Weiser, *Varian, B. S., House (Tourtellotte and Hummel Architecture TR)*, 241 Main St.

Weiser, *Weiser Post Office (Tourtellotte and Hummel Architecture TR)*, Main and W 1st Sts.

KENTUCKY

Jefferson County

Louisville, *Crescent Hill Historic District*, Roughly bounded by Brownsboro and Lexington Rds, Peterson, Zorn, and Frankfort Aves., and Crabbs Lane

Louisville, *Lower West Market Street District*, 1500–2200 W. Market St.

LOUISIANA

Tangipahoa Parish

Hammond, *Stevenson House*, 113 S. Pine

MISSISSIPPI

Adams County

Natchez vicinity, *Beechland*, S of Natchez off US 61

Natchez, *Ravenna*, 601 S. Union St.

Washington, *Meadvilla*,

NEW YORK

Albany County

Guilderland, *Freeman House (Guilderland MRA)*, 136 Main St.

Bronx County

New York, *Spaulding, Henry F., Coachman's House*, 4970 Independence Ave.

Cortland County

Cortland, *Tompkins Street/Main Street Historic District*, Main St. from Thompkins St. to Clinton Ave. (Boundary Increase)

Dutchess County

Beacon vicinity, *Mount Gulian*, N of Beacon off I–84

Jefferson County

Alexandria Bay, *Longue Vue Island*, St. Lawrence River

Kings County

New York, *Friends Meetinghouse and School*, 110 Schermerhorn St.

New York, *Public School 71K*, 119 Heyward St.

New York, *South Bushwick Reformed Protestant Dutch and Church Complex*, 855–857 Bushwick Ave.

New York, *South Congregational Church*, President and Court Sts.

New York County

New York, *Beacon Theater and Hotel*, 2124 Broadway

New York, *Empire State Building*, 350 fifth Ave.

Oneida County

Rome, *Jervis Public Library*, 613 N. Washington St.

Ostego County

Gilbertsville, *Gilbertsville Historic District*, Roughly bounded by incorporated village boundary (Boundary increase)

Schenectady County

Schenectady, *Union Street Historic District*, Union St. from Hudson River to Pheonix Ave.

St. Lawrence County

Ogdenburg, *Library Park Historic District*, 303–323 Washington St., 100–112 Carolina St. and Liberty Park

Pierrepont Center, *Pierrepont Town Buildings*, Main St.

Potsdam vicinity, *French Family Farm*, SW of Potsdam on US 11

Ulster County

Rosendale, *Binnewater Historic District*, Sawdust Ave., Breezy Hill, and Binnewater Rds.

Westchester County

Mount Kisco, *United Methodist Church and Parsonage*, 300 E. Main and 31 Smith Ave.

Pelham Manor, *Pelhamdale*, 45 Iden Ave.

OHIO

Belmont County

Brookside, *Frasier, Thomas T. and Wesley B. Houses*, 898 and 920 National Rd.

Carroll County

Oneida, *Hull, Patrick, House*, 8187 Blade Rd.

Clermont County

Neville vicinity, *Maple Creek Site, 33 CT 52*,

Geauga County

Chesterland, *Chester Township District School #2*, 7798 Mayfield Rd.

Montgomery County

Dayton, *Eagles Building*, 320 S. Main St.

Preble County

Eaton vicinity, *Christman, Daniel, Homestead*, W of Eaton on US 35

Summit County

Akron, *Young Women's Christian Association*, 146 S. High St.

SOUTH CAROLINA

Richland County

Columbia, *Arcade Building (Columbia MRA)*, 1332 Main St.

Columbia, *Brown Building (Columbia MRA)*, 1730 Main St.

Columbia, *Greyhound Bus Depot (Columbia MRA)*, 1200 Blanding St.

Spartanburg County

Glenn Springs, *Glen Springs Historic District*, SC 150 and Rich Hil Rd.

UTAH

Cache County

Wellsville, *Bradshaw, George, House and Joshua Salisburg/George Bradshaw Barn*, 73 S. Center St.

Wellsville, *Mitton, Samuel Crowthers, House*, 242 E. Main St.

Salt Lake County

Salt Lake City, *Langton, James and Susan R., House*, 648 E. 100 South

Salt Lake City, *Royle, Jonathan C. and Eliza K., House*, 635 E. 100 South

San Juan County

Bluff, *Decker, James Bean, House*, UT 47

Bluff, *Redd, Lemuel H., Jr., House*, UT 47

WYOMING

Laramie County

Chenenne, *Boeing/United Airlines Terminal Building, Hangar and Fountain*, 200 E 8th Ave.

[FR Doc. 82-28702 Filed 10-18-82; 8:45 am]

BILLING CODE 4310-70-M

INTERSTATE COMMERCE COMMISSION

[Ex Parte No. 387]

Exemptions for Contract Tariffs

AGENCY: Interstate Commerce Commission.

ACTION: Notices of Provisional Exemptions.

SUMMARY: Provisional exemptions are granted under 49 U.S.C. 10505 from the notice requirements of 49 U.S.C. 10713(e), and the below-listed contract tariffs may become effective on one day's notice. These exemptions may be revoked if protests are filed.

DATES: Protests are due within 15 days of publication in the **Federal Register**.

ADDRESS: An original and 6 copies should be mailed to: Office of the Secretary, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT: Douglas Galloway (202) 275-7278 or Tom Smerdon (202) 275-7277.

SUPPLEMENTARY INFORMATION: The 30-day notice requirement is not necessary in these instances to carry out the transportation policy of 49 U.S.C. 10101a or to protect shippers from abuse of market power; moreover, the transaction is of limited scope. Therefore, we find that the exemption requests meet the requirements of 49 U.S.C. 10505(a) and are granted subject to the following conditions:

These grants neither shall be construed to mean that the Commission has approved the contracts for purposes of 49 U.S.C. 10713(e) not that the Commission is deprived of jurisdiction to institute a proceeding on its own initiative or on complaint, to review these contacts and to determine their lawfulness.

Sub-No.	Name of railroad, contract number, and specifics	Review Bd.[1]	Decided date
312	Southern Pacific Transportation Co., ICC-SP-C-0205, (Synthetic plastics, resins or gums, hydrogen peroxide)	2	10-13-82
313	Norfolk and Western Railway Co., ICC-NW-C-0027, (Superphosphate and phosphate compounds)	3	10-13-82
314	Missouri Pacific Railroad Co., ICC-MP-C-0149, (Wheat flour)	1	10-13-82
315	Consolidated Rail Corp., ICC-CR-C-0166, 0189, 0190, and 0194, (All commodities, with exceptions)	2	10-13-82
316	Consolidated Rail Corp., ICC-CR-C-0176, (Fluxing limestone, crude, foundry or furnace)	3	10-13-82

[1] Review Board No. 1, Members Parker, Candler, and Fortier. Review Board No. 2, Members Carleton, Williams, and Ewing. Review Board No. 3, Members Krock, Joyce, and Dowell, Member Dowell not participating.

This action will not significantly affect the quality of the human environment or conservation of energy resources.

Authority: 49 U.S.C. 10505.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-28603 Filed 10-18-82; 8:45 am]

BILLING CODE 7035-01-M

Motor Carriers; Finance Applications

The following applications, filed on or after July 3, 1980, seek approval to consolidate, purchase, merge, lease operating rights and properties, or acquire control of motor carriers pursuant to 49 U.S.C. 11343 or 11344. Also, applications directly related to these motor finance applications (such as conversions, gateway eliminations, and securities issuances) may be involved.

The applications are governed by Special Rule 240 of the Commission's Rules of Practice (49 CFR 1100.240). See Ex Parte 55 (Sub-No. 44), *Rules Governing Applications Filed By Motor Carriers Under 49 U.S.C. 11344 and 11349*, 363 I.C.C. 740 (1981). These rules provide among other things, that opposition to the granting of an application must be filed with the Commission in the form of verified statements within 45 days after the date of notice of filing of the application is published in the **Federal Register.** Failure seasonably to oppose will be construed as a waiver of opposition and participation in the proceeding. If the protest includes a request for oral hearing, the request shall meet the requirements of Rule 242 of the special rules and shall include the certification required.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.241. A copy of any application, together with applicant's supporting evidence, can be obtained from any applicant upon request and payment to applicant of $10.00, in accordance with 49 CFR 1100.241(d).

Amendments to the request for authority will not be accepted after the date of this publication. However, the Commission may modify the operating authority involved in the application to conform to the Commission's policy of simplifying grants of operating authority.

We find, with the exception of those applications involving impediments (e.g., jurisdictional problems, unresolved fitness questions, questions involving possible unlawful control, or improper divisions of operating rights) that each applicant has demonstrated, in accordance with the applicable provisions of 49 U.S.C. 11301, 11302, 11343, 11344, and 11349, and with the Commission's rules and regulations, that the proposed transaction should be authorized as stated below. Except where specifically noted this decision is neither a major Federal action significantly affecting the quality of the human environment nor does it appear to qualify as a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient protests as to the finance application *or* to any application directly related thereto filed within 45 days of publication (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (unless the application involves impediments) upon compliance with certain requirements which will be set forth in a notification of effectiveness of this decision-notice. To the extent that the authority sought below may duplicate an applicant's existing authority, the duplication shall not be construed as conferring more than a single operating right.

Applicant(s) must comply with all conditions set forth in the grant or grants of authority within the time period specified in the notice of effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

Dated: October 13, 1982.

By the Commission, Heber P. Hardy, Director, Office of Proceedings.

Agatha L. Mergenovich,

Secretary.

Republication

MC-F-14216, filed November 13, 1979, and amended October 5, 1982. FRANK TEDESCO AND JOSEPHINE TEDESCO (1515 Jefferson Street, Hoboken, NJ 07030)—CONTINUANCE IN CONTROL—CONSOLIDATED BUS SERVICE, INC., (1515 Jefferson Street, Hoboken, NJ 07030) (CBS). Applicants' Representative: Sidney J. Leshin, 3 East 54th Street, New York, NY 10022. (212) PL-9-3700. Frank Tedesco and Josephine Tedesco individuals controlling New

York-Keansburg-Long Branch Bus Co., Inc, (NKL), of Leonardo, NJ, through ownership of its outstanding stock seek to continue in control of CBS upon issuance of a permit in No. MC-144124 (Sub-No. 1) and institution of operations thereunder. NKL is a motor common carrier operating pursuant to Certificate No. MC-106207 and subnumbers thereunder. The carriers' operating authorities have not been described, but complete descriptions are on file at the Commission's office in Washington, DC.

MC-F14963, filed September 28, 1982. CLEAR WATER TRUCK COMPANY, INC. (Clear Water) (9101 N. West St., Valley Center, KS 67147)—PURCHASE—CHAR-LINE CORPORATION (Char-Line) (11113 W. 17th St., Wichita, KS 67212). Clear Water seeks authority to purchase the interstate operating rights and property of Char-Line. Clear Water is purchasing the interstate operating rights contained in Char-Line's certificates, No. MC-153395 (Sub-Nos. 1 and 2), which authorize the transportation, as a motor common carrier, over irregular routes, of (1) *rubber and plastic articles,* between points in Sedgwick and Butler Counties, KS, on the one hand, and, on the other, points in AR, CO, KS, MO, NE, OK, and TX; and (2) *furniture and fixtures, pulp and paper, chemicals and related products,* and *plastic articles,* between specified points such as Oklahoma City, OK, Sedgwick and Shawnee Counties, KS, Chicago, IL, Wyandotte County, KS, Cuyahoga and Preble Counties, OH, Liberty County, TN, Polk County, IA, Marion County, IN, Johnson County, KS, Denver County, CO, and Scott County, KY, on the one hand, and, on the other, points in KS, KY, MO, AR, CO, IL, IN, IA, NE, OK, TX, OH, TN, CA, AZ, and NM. Clear Water holds motor common carrier authority pursuant to Certificates issued in No. MC-134966 and sub-numbers thereunder and Permits issued in No. MC-127304 and sub-numbers thereunder. Clear Water is affiliated with Claude Harpster, Jr., who operated, as a carrier, under Docket No. MC-126968. Condition: Approval and authorization of this transaction is conditioned upon the prior receipt by the Commission of an Affidavit signed by Claude Harpster, Jr., stating that he is the person in control of transferee and that he joins in this application.

Note.—TA has Been filed.

MC-F-14921, filed July 29, 1982 (CORRECTION, Previously published in the **Federal Register** issue of September 9, 1982). R.E.T.E.N.O. CARRIERS, INC.—PURCHASE (PORTION)—ECKLEY TRUCKING, INC. Representatives: William J. Monheim, P.O. Box 1756, Whittier CA 90609; and A.J. Swanson, P.O. Box 1103, Sioux Falls, SD 57101. The purpose of this republication is to correct two errors. First, reference was made to Eckley's Certificate No. MC-5227 (Sub-No. 54). It should be (Sub-No. 53). Second, in part (2)(a) Grand Rapids, MN, is shown. It should be Grand Rapids, MI.

[FR Doc. 82-28605 Filed 10-18-82; 8:45 am]
BILLING CODE 7035-01-M

[Volume No. OP5-212]

Motor Carriers; Permanent Authority Decision

Decided: October 12, 1982.

The following applications, filed on or after July 3, 1980, seek approval to consolidate, purchase, merge, lease operating rights and properties, or acquire control of motor carriers pursuant to 49 U.S.C. 11343 or 11344. Also, applications directly related to these motor finance applications (such as conversions, gateway eliminations, and securities issuances) may be involved.

The applications are governed by Special Rule 240 of the Commission's Rules of Practice (49 CFR 1100.240). See Ex Parte 55 (Sub-No. 44), *Rules Governing Applications Filed By Motor Carriers Under 49 U.S.C. 11344 and 11349,* 363 I.C.C. 740 (1981). These rules provide among other things, that opposition to the granting of an application must be filed with the commission in the form of verified statements within 45 days after the date of notice of filing of the application is published in the **Federal Register.** Failure seasonably to oppose will be construed as a waiver of opposition and participation in the proceeding. If the protest includes a request for oral hearing, the request shall meet the requirements of Rule 242 of the special rules and shall include the certification required.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.241. A copy of an application, together with applicant's supporting evidence, can be obtained from any applicant upon request and payment to applicant of $10.00, in accordance with 49 CFR 1100.241(d).

Amendments to the request for authority will not be accepted after the date of this publication. However, the Commission may modify the operating authority involved in the application to conform to the Commission's policy of simplifying grants of operating authority.

We find, with the exception of those applications involving impediments (e.g., jurisdictional problems, unresolved fitness questions, questions involving possible unlawful control, or improper divisions of operating rights) that each applicant has demonstrated, in accordance with the applicable provisions of 49 U.S.C. 11301, 11302, 11343, 11344, and 11349, and with the Commission's rules and regulations, that the proposed transaction should be authorized as stated below. Except where specifically noted this decision is neither a major Federal action significantly affecting the quality of the human environment nor does it appear to qualify as a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient protests as to the finance application or to any application directly related thereto filed within 45 days of publication (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (unless the application involves impediments) upon compliance with certain requirements which will be set forth in a notification of effectiveness of this decision-notice. To the extent that the authority sought below may duplicate an applicant's existing authority, the duplication shall not be construed as conferring more than a single operating right.

Applicant(s) must comply with all conditions set forth in the grant or grants of authority within the time period specified in the notice of effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

By the Commission, Review Board Number 3, Krock, Joyce and Dowell.

Agatha L. Mergenovich,

Secretary.

MC-F-14961, filed September 23, 1982. PETER PICKNELLY AND LOUIS MAGNANO, A PARTNERSHIP d.b.a. VIP COACH SERVICES (1776 Main St., Springfield, MA 01103)—CONTINUANCE—IN-CONTROL—U.S. BUS, INC. (5400 Tuxedo Rd., Tuxedo, MD); SUNSHINE BUS LINES, INC.; PETER PAN BUS LINES, INC. (1776 Main St., Springfield, MA); TRAVEL TIME BUS LINES, INC. (99 Arnold St., Springfield, MA); EXECUTIVE COACH CORPORATION (20 Providence St., Boston, MA); PETER PAN WORLD TRAVEL, INC. (1778 Main St., Springfield, MA); BLUE BIRD COACH LINES, INC. (502 N. Barry St., Olean, NY); BLUE BIRD CAB CO., INC. (502 N. Barry St., Olean, NY). Representative: Robert J. Brooks, 1828 L St., N.W., Suite 1111, Washington, D.C. 20036. Individuals seek authority, upon their

institution of operations in interstate or foreign commerce as a motor contract carrier under the name of VIP COACH SERVICES, to continue in control of certain motor carriers, which they own, either jointly or separately. Peter Picknelly currently controls Peter Pan Bus Lines, Inc. (MC 61016), Peter Pan World Travel, Inc. (MC-130223 Sub-1), Travel Time Bus Lines, Inc. (14777 Sub-2), and Executive Coach Corporation (MC-155921). Louis Magnano currently controls Blue Bird Coach Lines, Inc. (MC-108531), Blue Bird Cab Co., Inc. (MC-117633). Individuals jointly control VIP Coach Services (MC-150519 Sub-1), Sunshine Bus Lines, Inc. (MC-150649), and U.S. Bus, Inc. (MC-14076 Sub-1). Applicants have been granted authority to operate as a motor contract carrier in MC-150519 Sub.-1, which authorizes the transportation of *passengers and their baggage*, in the same vehicle with passengers, in charter and special operations, between the facilities of Boardwalk Regency Hotel and Casino, at Atlantic City, NJ, on the one hand, and, on the other, points in CT, DE, MD, PA, NY, VA, and DC, under contract with Happy Day Tours, Inc.

Note.—Individuals are cautioned not to begin operations under MC-150519 Sub.-1 until common control has been approved.

[FR Doc. 82-28604 Filed 10-18-82; 8:45 am]

BILLING CODE 7035-01-M

[Volume No. OP5-215]

Motor Carriers; Permanent Authority Republications of Grants of Operating Rights Authority Prior to Certification

The following grants of operating rights authorities are republished by order of the Commission to indicate a broadened grant of authority over that previously noticed in the **Federal Register**.

An original and one copy of petition for leave to intervene must be filed with the Commission within 30 days after the date of this Federal Register notice addressing specifically the issue(s) indicated as the purpose for republication.

Agatha L. Mergenovich,

Secretary.

MC 110948 (Sub-7) (Republication), filed January 19, 1982, published in the **Federal Register** issue of February 9, 1982, and republished this issue. Applicant: MOTORWAYS (1980) LIMITED, P.O. Box 738, 60 Eagle Drive, Winnipeg, Manitoba, R2R 1V5 CD. Representative: Stephen F. Grinnell, 1600 TCF Tower, 121 So. 8th Street, Minneapolis, MN 55402. An Order of the Commission, Division 1, decided August 31, 1982, and served September 7, 1982, finds that the present and future public convenience and necessity require operations by applicant in interstate of foreign commerce as a *common carrier*, by motor vehicle, in foreign commerce only, over iregular routes, transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points on the international boundary line between the United States and Canada, in Washington, Idaho, Montana, North Dakota, Minnesota, Michigan, and New York, on the one hand, and, on the other, points in Idaho, Iowa, Illinois, Indiana, Michigan, Minnesota, Missouri, Montana, Nabraska, North Dakota, New York, Ohio, Oregon, Pennsylvania, South Dakota, Washington, Wisconsin, and Wyoming, that applicant is fit, willing, and able properly to perform such service and to conform to the requirements of the Interstate Commerce Act and the Commission's rules and regulations. The purpose of this republication is to indicate the applicant's actual grant of authority.

[FR Doc. 82-28606 Filed 10-18-82; 8:45 am]

BILLING CODE 7035-01-M

Motor Carriers; Permanent Authority Decisions; Decision-Notice

The following applications, filed on or after February 9, 1981, are governed by Special Rule of the Commission's Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the **Federal Register** on December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the **Federal Register** issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. Applications may be protested *only* on the grounds that applicant is not fit, willing, and able to provide the transportation service or to comply with the appropriate statutes and Commission regulations. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminary, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication (or, if the application later become unopposed), appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract".

Please direct status inquiries to Team 2, (202) 275-7030.

Volume No. OP2-257

Decided: October 8, 1982.

By the Commission, Review Board Number 1, Members Parker, Chandler, and Fortier. (Member Chandler not participating.)

MC 164102, filed October 5, 1982. Applicant: RONALD SPRAGUE, d.b.a. SPRAGUE COMPANY, 355 South Fall Creek Rd., P.O. Box 610, Wilson, WY 83014. Representative: Donna Sprague (same address as applicant), 307-733-6482. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural*

limestone and fertilizers, and other soil conditioners, by the owner of the motor vehicle in such vehicle, between points in the U.S. (except AK and HI).

For the following, please direct status inquiries to Team 4 (202) 275-7669.

Volume No. OP4-002

Decided: October 13, 1982.

By the Commission, Review Board Number 2, Members Carleton, Williams, and Ewing.

MC 164007, filed September 27, 1982. Applicant: STASI TRANSPORTATION CO., 1418 W 9th, Kansas City, MO 64101. Representative: George Stasi (same address as applicant), (816) 221-2175. Transporting, for or on behalf of the United States Government, *general commodities* (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S. (except AK and HI).

MC 164036, filed September 29, 1982. Applicant: RADIAL SERVICE, INC., 444 Lafayette Rd., St. Paul, MN 55101. Representative: James E. Ballenthin, 1016 Conwed Tower, 444 Cedar St., St. Paul, MN 55101, (612) 227-7731. As a *broker of general commodities* (except household goods), between points in the U.S. (except AK and HI).

For the following, please direct status inquiries to Team 5, (202) 275-7289.

Volume No. OP5-214

Decided: October 8, 1982.

By the Commission, Review Board Number 3, Members Krock, Joyce, and Dowell.

MC 144628 (Sub-2), filed September 29, 1982. Applicant: ELKHORN BUS SERVICE, INC., 511 South Lincoln St., Elkhorn, WI 53121. Representative: Patrick H. Smyth, 105 West Madison—Suite 1008, Chicago, IL 60602, 312-263-2397. Transporting (1) *shipments weighing 100 pounds or less*, if transported in a motor vehicle in which no one package exceeds 100 pounds, between points in the United States (except AK and HI), and (2) as a *broker of general commodities* (except household goods), between points in the U.S. (except AK and HI).

MC 164018, filed September 28, 1982. Applicant: CONTINENTAL SHIPPERS, INC., P.O. Box 2809, Allentown, PA 18001. Representative: Eugene M. Malkin, Suite 1832, 2 World Trade Center, New York, NY 10048, (212) 466-0220. As a *broker of general commodities* (except household goods), between points in the U.S. (except AK and HI).

MC 164028, filed September 29, 1982. Applicant: HERMANN LEASING COMPANY, P.O. Box 1, North Brunswick, NJ 08902. Representative: Maxwell A. Howell, 1100 Investment Bldg., 1511 K St., NW., Washington, DC 20005, (202) 783-7900. As a *broker of general commodities* (except household goods), between points in the U.S. (except AK and HI).

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-28608 Filed 10-18-82; 8:45 am]

BILLING CODE 7035-01-M

Motor Carriers; Permanent Authority Decisions, Decision-Notice

The following applications, filed on or after February 9, 1981, are governed by Special Rule of the Commission's Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the **Federal Register** of December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the **Federal Register** issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication, (or if the application later becomes unopposed) appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Please direct status inquiries to Team 2, (202) 275-7030.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract".

Volume No. OP2-256

Decided: October 8, 1982.

By the Commission, Review Board No. 1, members Parker, Chandler, and Fortier. (Member Chandler not participating.)

MC 682 (Sub-40), filed October 4, 1982. Applicant: BURNHAM VAN SERVICE, INC., 5000 Burnham Blvd., Columbus, GA 31907. Representative: David Earl Tinker, 1000 Connecticut Ave. NW., Suite 1112, Washington, DC 20036-5391, 202-887-5868. Transporting *household goods*, between points in the U.S., under continuing contract(s) with Employee Transfer Corporation, of Chicago, IL.

MC 73533 (Sub-28), filed October 1, 1982. Applicant: KEY WAY TRANSPORT, INC., 820 S. Oldham St., Baltimore, MD 21224. Representative: Gerald K. Gimmel, Suite 200, 444 N. Frederick Ave., Gaithersburg, MD 20877, 301-840-8565. Transporting *general commodities* (except classes A and B explosives, commodities in bulk, and household goods), between Baltimore, MD, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 135763 (Sub-1), filed October 4, 1982. Applicant: ARKANSAS LOUISIANA LIMESTONE CORPORATION, P.O. Box 70, Foreman, AR 71836. Representative: James M. Duckett, 221 W. 2nd, Suite 411, Little Rock, AR 72201, 501-375-3022. Transporting *commodities in bulk*, between points in the U.S. (except AK and HI), under continuing contract(s)

with Arkansas Cement Corporation, of Little Rock, AR.

MC 135953 (Sub-28), filed October 1, 1982. Applicant: CHEROKEE LINES, INC., P.O. Box 152, 1113 North Little St., Cushing, OK 74023. Representative: D. D. Middlebrook (same address as applicant), 918–225–2002. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI).

MC 144122 (Sub-85), filed October 4, 1982. Applicant: CARRETTA TRUCKING, INC., South 160, Rte. 17 North, Paramus, NJ 07652. Representative: Charles J. Williams, P.O. Box 186, Scotch Plains, NJ 07076, 201–322–5030. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points, in AL, AZ, AR, CO, FL, ID, IA, KS, KY, LA, ME, MI, MN, MS, MT, NE, NV, NH, NM, NC, ND, OH, OK, SC, SD, TN, UT, VT, WV, WY, and DC, on the one hand, and, on the other, points in the U.S. (including AK, but excluding HI).

MC 146213 (Sub-20), filed October 4, 1982. Applicant: WISCONSIN FARM LINES, LTD., P.O. Box 76, Wisconsin Dells, WI 53965. Representative: Stanley C. Olsen, Jr., 5200 Willson Rd., Suite 307, Edina, MN 55424, 612–927–8855. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI).

MC 147443 (Sub-2), filed September 28, 1982. Applicant: ROGER E. SCHAGER, d.b.a. SCHAGER TRUCKING CO., Box 391, Genoa, NE 68640. Representative: Donald R. Treadway, 407 3rd., Fullerton, NE 68638, 308–536–2426. Transporting *salt and salt products*, between points in IA, KS, MO, NE, and SD.

MC 147492 (Sub-10), filed October 4, 1982. Applicant: MEL MOTOR EXPRESS, INC., P.O. Box 29–58, New Orleans, LA 70189. Representative: Sandra H. Roberson, (same address as applicant), (504) 246–8221. Transporting *such commodities* as are used to manufacture water heaters, air conditioners, and heating units, between points in the U.S. (except AK and HI), under continuing contract(s) with Rheem Manufacturing, Inc., of Houston, TX.

MC 152402 (Sub-3), filed October 5, 1982. Applicant: DALE KOTTWITZ, d.b.a. KOTTWITZ HAULING SERVICE, 1710 West Eight St., Hastings, ND 68901. Representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, NE 68501, (402) 475–6761. Transporting *chemicals and related products*, between points in Lea and Eddy Counties, NM, and Jasper County, MO, on the one hand, and, on the other, points in AR, KS, MO, NE, and OK.

MC 156942 (Sub-2), filed October 4, 1982. Applicant: RAYMOND M. CHENOWETH, d.b.a. BEST WEST EXPRESS, 1900 Westland Dr., Las Vegas, NV 89102. Representative: Robert G. Harrison, 4299 James Dr., Carson City, NV 89701, (702–882–5649). Transporting *passengers and their baggage*, in special and charter operations, between points in Clark County, NV, on the one hand, and, on the other, points in AZ, UT, OR, WA, CA, CO, ID, and NM.

MC 161942, filed October 5, 1982. Applicant: UNIVERSAL TRUCKING OF SPARTANBURG, INC., P.O. Box 1241, Spartanburg, SC 29304. Representative: Dixie C. Newhouse, 1329 Pennsylvania Avenue, P.O. Box 1417, Hagerstown, MD 21740, 301–797–6060. Transporting *metal and metal products*, between those points in the U.S. in and east of MN, IA, MO, OK, and TX.

MC 162973, filed October 1, 1982. Applicant: JERRY WALLACE, d.b.a. JERRY WALLACE TRANSPORT SERVICE, Rte. 3, Box 210, Conroe, TX 77303. Representative: Billy R. Reid, 1721 Carl St., Fort Worth, TX 76103, 817–332–4718. Transporting *such commodities* as are dealt in or used by novelty and specialty stores, between points in CA and TX.

MC 163573 (Sub-1), filed October 4, 1982. Applicant: LAND SPAN, INC., P.O. Box 1636, Lakeland, FL 33802. Representative: Paul M. Daniell, 235 Peachtree St., N.E., Suite 1200, Atlanta, GA 30303. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Montgomery Ward Company, of Chicago, IL. Condition: The person or persons who appear to be engaged in common control of another regulated carrier must either file an application under 49 U.S.C. 11343(A) or submit an affidavit indicating why such approval is unnecessary to the Secretary's office. In order to expedite issuance of any authority please submit a copy of the affidavit or proof of filing the application(s) for common control to team 2, Room 2379.

Volume No. OP2–258

Decided: October 12, 1982.

By the Commission, Review Board No. 1, Members Parker, Chandler, and Fortier. (Member Chandler not participating.)

FF 622, filed October 5, 1982. Applicant: ABLE FORWARDERS, INC., 2308 100th Ave., Edmund, WA 98020. Representative: Robert J. Gallagher, 1000 Connecticut Ave. NW, Suite 1200, Washington, DC 20036, 202–785–0024. *As a freight forwarder*, in connection with the transportation of *household goods and unaccompanied baggage*, between points in AL, AK, AZ, AR, CA, CO, CT, DE, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, WA, WV, WI, WY, and DC.

MC 143762 (Sub-4), filed October 1, 1982. Applicant: RIGGS & ALLEN TRANSPORTATION, INC., P.O. Box 182, West Sacramento, CA 95691. Representative: Fred R. Covington, 2150 Franklin St., Suite 554, Oakland, CA 94612, 415–893–4102. Transporting *lumber and wood products, pulp, paper and related products, rubber and plastic products, metal products, machinery, transportation equipment, and building materials*, between points in CA, OR, WA, MT, ID, NV, AZ, NM, UT, CO, WY, and TX.

MC 160592, filed October 5, 1982. Applicant: BACK TRUCKING CO., P.O. Box 293, Denison, IA 51442. Representative: D. Douglas Titus, 340 Insurance Exchange Bldg., Sioux City, IA 51101, 712–277–1434. Transporting *food and related products*, between points in IL, IA, KS, MN, NE, and SD, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 164073, filed September 27, 1982. Applicant: NIAGARA FRONTIER SCENIC TOURS, INC.,7900 Niagara Falls Blvd., Niagara Falls, NY 14304. Representative: Robert D. Gunderman, Can-Am Bldg., 101 Niagara St., Buffalo, NY 14202, (716) 854–5870. Transporting *passengers and their baggage*, in special operations in round-trip sightseeing or pleasure tours, limited to the transportation of not more than 14 passengers in any one vehicle, but not including the driver thereof and not including children under 10 years of age who do not occupy a seat or seats, beginning and ending at points in Niagara County, NY, and extending to ports of entry on the United States-Canadian International Boundary line on the Niagara River.

MC 164122, filed October 5, 1982. Applicant: FRANK T. YARASEZSKI, d.b.a., FRANK'S OF AMSTERDAM, R.D. #4 Perth Rd., Amsterdam, NY 12010. Representative: Edward R. Lembo, Holliston Medical Center, 118 Washington St. (Rte. 16), P.O. Box 639, Holliston, MA 01746, 617–429–5888.

Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in MA, ME, VT, RI, CT, NH, NY, NJ, PA, DE, VA, WV, OH, IN, NC, KY, and MI.

For the following, please direct status inquiries to Team 3 (202) 275–5223.

Volume No. OP 3-153

Decided: October 8, 1982.
By the Commission, Review Board No. 2, Members Carleton, Williams, and Ewing.

MC 113165 (Sub-14), filed September 20, 1982. Applicant: PENINSULA TRUCK LINES, INC., 6314 7th Ave., S., P.O. Box 80038, Seattle, WA 98108. Representative: Jerry R. Woods, 1600 One Main Pl., 101 SW Main St., Portland, OR 97204, (503) 224–5525. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in CA, ID, NV, OR, UT, and WA.

MC 126965 (Sub-8), filed September 22, 1982. Applicant: CLIFFORD B. FINKLE, JR., P.O. Box 682, Clifton, NJ 07012. Representative: Robert B. Pepper, 168 Woodbridge Ave., Highland Park, NJ 08904, (201) 572–5551. Transporting (1) *paper and paper products and chemical and related products,* between points in the U.S. (except AK and HI), under continuing contracts with Westvaco Corporation, of New York, NY, and Simkins Industries, Inc., of West Hempstead, NY (2) *food and related products,* between points in the U.S. (except AK and HI), under continuing contact(s) with A. Zeraga's Sons, Inc., of Fairlawn, NJ, and (3) *chemicals and related products and hospital supplies,* between points in the U.S. (except AK and HI), under continuing contract(s) with Colgate-Palmolive Company, of New York, NY.

MC 135364 (Sub-53), filed September 24, 1982. Applicant: MORWALL TRUCKING, INC., R.D. #3, Box 76–C, Moscow, PA 18444. Representative: Raymond A. Talipski, 121 S. Main St., Taylor, PA 18517, (717) 344–8030. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Maloney Enterprises, Inc., of Mt. Sterling, KY.

MC 138805 (Sub-15), filed September 24, 1982. Applicant: S&L SERVICES, INC., R.D. No. 1, Milton, PA 17847. Representative: Terrence D. Jones, 2033 K St., N.W., Washington, DC 20006, (202) 429–9090. Transporting *general commodities* (except classes A and B explosives, household good, and commodities in bulk), between points in the U.S. (except AK and HI).

MC 139434 (Sub-14), filed September 24, 1982. Applicant: MID-AMERICA EXPRESS, INC., P.O. Box 9, Nebraska City, NE 68401. Representative: Arthur J. Cerra, 2100 Charter Bank Center, P.O. Box 19251, Kansas City, MO 64141, (816) 842–8600. Transporting *such commodities* as are dealt in or used by grocery, drug and convience stores, restaurants and institutions, between points in AL, AR, AZ, CA, CO, CT, FL, GA, ID, IL, IN, IA, KS, KY, LA, MD, MA, MI, MS, MN, MO, NE, NJ, NY, OH, OR, PA, TN, TX, WA, and WI.

MC 141514 (Sub-4), filed September 27, 1982. Applicant: BURGENER CONTRACT CARRIERS, LTD., Rt. 2, Prairie River Ave., Merrill, WI 54452. Representative: Edward J. Gerrity, P.O. Box 914, Appleton, WI 54912, (414) 734–5608. Transporting (1) *clay, concrete, glass or stone products,* between points in the U.S. (except AK and HI), under continuing contract(s) with Merrill Monument Co., of Merrill, WI, (2) *lumber and wood products,* between points in the U.S. (except AK and HI), under continuing contract(s) with Semling-Menke Company, Inc., of Merrill, WI, (3) *lumber and wood products, metal products, furniture and fixtures,* and *petroleum, natural gas and their products,* between points in the U.S. (except AK and HI), under continuing contract(s) with Trantow Building Center, Inc., of Merrill, WI, (4) *food and related products, tobacco products, pulp, paper and related products, chemicals and related products, lumber and wood products, rubber and plastic products, clay, concrete or stone products,* between points in the U.S. (except AK and HI), under continuing contract(s) with Merrill Candy & Distributing Co., Inc., of Merrill, WI, and (5) *metal products,* between points in the U.S. (except AK and HI), under continuing contract(s) with Merrill Manufacturing Corporation, of Merrill, WI.

MC 145465 (Sub-10), filed September 24, 1982. Applicant: GURN ENTERPRISES, INC., Rt. 6, Box 8, Allegan, MI 49010. Representative: Dixie C. Newhouse, 1329 Pennsylvania Ave., P.O. Box 1417, Hagerstown, MD 21740, (301) 797–6060. Transporting *furniture and fixtures,* between points in the U.S. (except AK and HI), under continuing contract(s) with Country Roads, Inc., of Beling, MI.

MC 147524 (Sub-10), filed September 22, 1982. Applicant: SINED LEASING, INC., 106 High Street, Mt. Holly, NJ 08060. Representative: Daniel J. Sweeney, 1750 Pennsylvania Ave., N.W., Washington, DC 20006, (202) 393–5710. Transporting (1) *farm products and* (2) *food and related products,* between points in the U.S., under continuing contract(s) with General Commodities Company, Inc., of Rochester, NY and Archer Daniels Midland Company of Decatur, IL.

MC 147965 (Sub-10), filed September 30, 1982. Applicant: GUNTHER H.M. KLIESE, d.b.a., P & M ENTERPRISES, 10650 S.W. Wilsonville Rd., Wilsonville, OR 97070. Representative: Lawrence V. Smart, Jr., 419 N.W. 23rd Ave., Portland, OR 97210, (503) 226–3755. Transporting (1) *transportation equipment,* (2) *rubber and plastic products,* (3) *metal products,* and (4) *such commodities* as are dealt in or used by truck stop service stations, between points in the U.S. (except AK and HI).

MC 151915 (Sub-2), filed September 24, 1982. Applicant: KELWORTH TRUCKING COMPANY, INC., Hwy 50 South, Hodgen, OK 74939. Representative: Don A. Smith, P.O. Box 43, Fort Smith, AR 72902, (501) 782–1001. Transporting (1) *calcium carbonate,* (2) *clay, concrete, glass or stone products,* and (3) *sand and gravel,* between points in AR, KS, LA, MS, MO, OK, and TX.

MC 152744 (Sub-12), filed September 27, 1982. Applicant: CITADEL TRANSPORT, INC., 180 N. Michigan Ave., Suite 400, Chicago, IL 60601. Representative: Thomas M. O'Brien, 180 N. Michigan Ave., Suite 1700, Chicago, IL 60603, (312) 263–1600. Transporting *such commodities* as are dealt in or used by manufacturers and distributors of food related products, between points in the U.S. (except AK and HI), under continuing contract(s) with Schreiber Foods, Inc., of Green Bay, WI.

MC 152935 (Sub-11), filed September 22, 1982. Applicant: HILL-ROM COMPANY, INC., Hwy 46, Batesville, IN 47006. Representative: Steve A. Oldham (same address as applicant), (812) 934–7169. Transporting *rubber and plastic products,* between points in the U.S. (except AK and HI), under continuing contract(s) with Texas Polydrums, Inc. of Houston, TX.

MC 153005 (Sub-2), filed September 27, 1982. Applicant: MILES LAND, LTD., 4822 S. Shenandoah Way, Aurora, CO 80015. Representative: Lee E. Lucero, 601 E. 18th Ave., Suite 107, Denver, CO 80203, (303) 861–8046. Transporting (1) *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in CO, NE, NM, SD, and WY, on the one hand, and, on the other, points in the U.S. (except AK and HI), and (2) *food and related products,* between points in

CA, on the one hand, and, on the other, points in AR, CO, GA, IL, LA, MI, MS, OH, OK, and TX.

MC 159404 (Sub-1), filed September 27, 1982. Applicant: OMNI BUS SERVICE, INC., 3419 Craig, Wichita, KS 67216. Representative: Brad T. Murphree, 814 Century Plaza Bldg., Wichita, KS 67202, (316) 265-2634. Transporting *passengers and their baggage*, in special and charter operations, between points in KS, on the one hand, and, on the other, points in the U.S. (except HI).

MC 160674 (Sub-1), filed September 29, 1982. Applicant: PIONEER PIPE STRINGING, INC., 925 S. Main, Suite 201, Grapevine, TX 76051. Representative: J. Michael Alexander, 5801 Marvin D. Love Freeway, Suite 301, Dallas, TX 75237-2385, (214) 339-4108. Transporting *machinery*, between points in the U.S. (except HI).

MC 162895, filed September 23, 1982. Applicant: PARRIS TRUCKING COMPANY, INC., P.O. Box 3799, Oxford, AL 36203. Representative: Tony Parris (same address as applicant), (205) 831-8450. Transporting (1) *clay, concrete, glass and stone products*, between points in Calhoun County, AL, on the one hand, and, on the other, points in TN, MI, IN, PA, WI, OH, IA, TX, IL, NY, MO, KY, LA, NE, MA, MN, MD, KS, CT, NC, SC, RI, GA, MS, VA, WV, CO, AR, and NJ; (2) *metal products*, between points in Calhoun County, AL, on the one hand, and, on the other, points in GA, MS, LA, TX, AR, MO, IA, TN, IL, KY, OK, FL, and VA; (3) *lumber and wood products*, between points in Clay County, AL, on the one hand, and, on the other, points in GA; and (4) *refractories and refractory materials*, between points in Jackson County, OH, on the one hand, and, on the other, points in TN and AL.

MC 163054, filed September 22, 1982. Applicant: PETER B. McCONAHAY, d.b.a. McCONAHAY TRUCKING, P.O. Box 5722, Lafayette, IN 47903. Representative: Robert W. Loser II, 1101 Chamber of Commerce Bldg., 320 N. Meridian St., Indianapolis, IN 46204, (317) 635-2339. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Aluminum Company of America, of Pittsburgh, PA.

MC 163314, filed September 27, 1982. Applicant: TRI-COASTAL DISTRIBUTION, INC., 13905 Maryton, Santa Fe Springs, CA 90670. Representative: Miles L. Kavaller, 315 S. Beverly Drive, Suite 315, Beverly Hills, CA 90212, (213) 277-2323. Transporting *food and related products*, between points in CA, on the one hand, and, on the other, points in the U.S.

MC 163565, filed August 26, 1982. Applicant: HOLY TEMPLE CHURCH OF CHRIST, INC., 439 12th St., SE., Washington, D.C. 20003. Representative: Everett K. Hobson (same address as applicant), (202) 547-8365. Transporting *passengers and their baggage*, in charter and special operations, between the District of Columbia, on the one hand, and, on the other, points in AL, CT, DE, GL, GA, IL, IN, KY, LA, MA, MD, NC, NJ, NY, OH, PA, SC, TN, VA and WV.

MC 163914, filed September 17, 1982. Applicant: FIESTA BUS CORPORATION, 78 Ramona Ave., Staten Island, NY 10312. Representative: Antonio LaBoy (same address as applicant), (212) 356-7605. Transporting *passengers and their baggage*, in the same vehicle with passengers, in charter operations, beginning and ending at points in New York, NY, and extending to points in the U.S. (except HI).

MC 16395, filed September 20, 1982. Applicant: AMERICAN SIGHTSEEING TOURS, INC., 4300 N.W. 14th Street, Miami, FL 33126. Representative: Lou Cicerone (same address as applicant), (305) 871-2370. Transporting *passengers and their baggage*, in charter and special operations, beginning and ending at points in FL and extending to points in the U.S.

MC 163955, filed September 22, 1982. Applicant: FLOOD AUTO DELIVERY AND PROCESSING SERVICE, 801 North Second St., P.O. Box 1503, Killen, TX 76540. Representative: Leo P. Flood, Jr., 2502 Lohse Rd., Killeen TX 76543, (817) 634-8178. Transporting *automobiles*, between points in TX, on the one hand, and, on the other, New Orleans, LA.

MC 163984, filed September 24, 1982. Applicant: BROCK MOTOR FREIGHT, INC., Rt. 1, Virginia Rd., Travelers Rest, SC 29690. Representative: Mitchell King, Jr., P.O. Box 5711, Greenville, SC 29606, (803) 288-6000. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Alabama Metal Industries Corp. (AMICO Cold Drawn Division), of Taylors, SC.

MC 163994, filed September 27, 1982. Applicant: BUNNELL WOOD PRODUCTS, INC., P.O. Box 1, 210 S. State St., Bunnell, FL 32010. Representative: Sol H. Proctor, 1101 Blackstone Bldg., Jacksonville, FL 32202, (904) 632-2300. Transporting (1) *building materials*, between points in FL, GA, and SC, and (2) *Machinery*, between points in Flagler County, FL, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 163995, filed September 27, 1982. Applicant: COASTAL TRANSPORTATION CO., P.O. Box 829, Weldon, NC 27890. Representative: R. P. Phillips, Jr., P.O. Box 829, Weldon, NC 27890, (919) 536-4211. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Coastal Lumber Co., of Weldon, NC.

MC 164014, filed September 28, 1982. Applicant: KENNETH MEYER, d.b.a. MEYER TRUCKING, R.R. 1, North River Rd., New Haven, IN 46774. Representative: Charles W. McNagny, P.O. Box 2263, Third Floor, Lincoln Bank Tower, Fort Wayne, IN 46801, (219) 423-9551. Transporting (1) *furniture and fixtures, and fibre padding articles*, between points in the U.S., under continuing contract(s) with Wolf Corp.; (2) *rubber and plastic articles*, between points in the U.S., under continuing contract(s) with ORE Corporation; and (3) *metal articles*, between points in the U.S., under continuing contract(s) with Midwest Pipe and Steel, Inc., all of Fort Wayne, IN.

For the following please direct status inquiries to Team 4, (202) 275-7669.

Volume No. OP4-001

Decided: October 13, 1982.

By the Commission, Review Board No. 2, Members Carleton, Williams, and Ewing.

MC 135936 (Sub-38), filed September 29, 1982. Applicant: C & K TRANSPORT, INC., P.O. Box 205, Webster City, IA 50595. Representative: Kenneth F. Dudley, P.O. Box 279, Ottumwa, IA 52501, (515) 682-8154. Transporting *food and related products*, between points in the U.S. (except AK and HI).

MC 164046, filed September 30, 1982. Applicant: M. L. TOWNS ENTERPRISES, INC., Route 1, Box 38, Gibsland, LA 71028. Representative: Kathy T. Towns (same address as applicant), (318) 843-6244. Transporting (1) *paper and related products*, (2) *oilfield supplies equipment*, (3) *metal products*, (4) *machinery*, (5) *farm equipment*, and (6) *ores and minerals*, between points in AL, AR, LA, MS, OK, TN, and TX.

For the following, please direct status inquiries to Team 5 at 202-275-7289.

Volume No. OP5-213

Decided: October 8, 1982.

By the Commission, Review Board No. 3 Members Krock, Joyce, and Dowell.

MC 151118 (Sub-25,), filed September 24, 1982. Applicant: M.D.R. CARTAGE, INC., 516 West Johnson St., Jonesboro, AR 72401. Representative: Douglas C. Wynn, P.O. Box 1295, Greenville, MS 38701, (601) 335-3576. Transporting (1) *ores and minerals*, (2) *food and related products*, (3) *chemicals and related products*, (4) *clay, concrete, glass or stone products*, between Memphis, TN and points in Scott County, MO, on the one hand, and, on the other, points in the U.S. (except AK and HI), (5) *pulp, paper and related products*, between Memphis, TN and points in De Soto County, MS, and Scott County, MO, on the one hand, and, on the other, points in the U.S. (except AK and HI), (6) *printed matter*, between Dallas, TX, Memphis, TN, and points in De Soto County, MS and Scott County, MO, on the one hand, and, on the other, points in the U.S. (except AK and HI), (7) *metal products*, between Memphis, TN and points in Pulaski County, AR and Scott County, MO, on the one hand, and, on the other, points in the U.S. (except AK and HI), and (8) *rubber and plastic products*, between Memphis, TN, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 152509 (Sub-27), filed September 27, 1982. Applicant: CONTRACT TRANSPORTATION SYSTEMS CO., 1370 Ontario St., Cleveland, OH 44113. Representative: J. L. Nedrich (same address as applicant), (216) 566-2677. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with Lawson Products Company of Des Plaines, IL.

MC 162678, filed September 30, 1982. Applicant: JOHN W. PEPPER, d.b.a. COMMERCIAL TRANSPORTATION, 3017 Dodge St., P.O. Box 15020, Kansas City, KS 66115. Representative: Arthur J. Cerra, 2100 CharterBank Center, P.O. Box 19251, Kansas City, MO 64141, 816-842-8600. Transporting (1) *containers*, between St. Joseph, MO, on the one hand, and, on the other, Des Moines, IA; Kansas City, Topeka and Wichita, KS and points in Dakota County, NE, and (2) *paper and related products*, between Kansas City, KS; Indianapolis, IN and points in Ballard County, KY, on the one hand, and, on the other, points in AR, CO, IN, LA, IL, KS, KY, LA, MO, MN, MS, NE, OK, TN, TX, and WI.

MC 163978, filed September 29, 1982. Applicant; DANIEL M. BISHOP AND LINDA B. BISHOP, d.b.a. GONALOT TRUCKING, 1679 Suite A Sage Rd., Medford, OR 97502. Representative: Mike Pavlakis, P.O. Box 646, Carson City, NV 8970 702-882-0202. Transporting *building materials, metal products* and *machinery*, between points in AZ, CA, CO, ID NV, NM MT, OR, TX, UT, WA, and WY.

Agatha L. Mergenovich

Secretary.

[FR Doc. 82-28609 Filed 10-18-82; 8:45 am]

BILLING CODE 7035-01-M

[No. 38878]

Rail Carrier; Atchison, Topeka and Santa Fe Railway Company; Petition for Exemption

AGENCY: Interstate Commerce Commission.

ACTION: Notice of provisional exemption.

SUMMARY: In response to a petition filed by the Atchison, Topeka and Santa Fe Railway Company, the Commission has decided to exercise its authority under 49 U.S.C. 10505 and exempt the Santa Fe from tariff requirements and discrimination prohibitions for certain movements of unit trains being transported for experimental purposes.

DATES: Comments are due on November 3, 1982. The sought relief will become effective on November 18, 1982 unless, in response to comments filed, the Commission issues a further decision withdrawing this relief.

ADDRESS: Send an original and, if possible, 15 copies of comments to: Room 5340, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT:

Douglas Galloway, (202) 275-7278,

or

Tom Smerdon, (202) 275-7277

SUPPLEMENTARY INFORMATION: On July 28, 1982, the Atchison, Topeka and Santa Fe Railway Company (Santa Fe) requested relief from the requirements of 49 U.S.C. 10741, 10761 and 10762. The sought exemption would apply to "ferry" movements of unit coal trains owned by another railroad moving between Pueblo, CO, and the DOT test facility at Avondale, CO, a distance of 15.9 miles over Santa Fe's lines, for a period of 90 days. The purpose of the movements is not to provide unit coal service for the public, but to transport rail cars needed for fuel consumption tests at the DOT test facility. The cars will actually carry ballast rather than coal.

A railroad which ships property (here, unit trains) over the lines of another railroad is a "shipper" within the meaning of the Interstate Commerce Act; and the transportation in issue is subject to regulation by the Commission. Section 10741 prohibits discrimination by common carriers, section 10761 prohibits transportation without a tariff, and section 10762 sets forth the general tariff requirements. The last section would require Santa Fe to apply existing tariff rates or establish new rates to the subject transportation.

Petitioner argues that existing rates may be inappropriate. Time limitations, it further contends, mitigate against establishing new rates (20-day notice period) or contract rates (30-day notice period).

The exemption under 49 U.S.C. 10505 is warranted. We find that regulation of these ferry movements is not necessary to carry out the transportation policy of section 10101a, is of limited scope, and is not needed to protect shippers from the abuse of market power. The exemption sought is of limited duration (90 days). It involves only one shipper and a few "ferry" movements. This exemption will enable petitioner to move these shipments as soon as needed without the necessity of waiting for the administrative notice period.

The Staggers Act amended 49 U.S.C. 10505 to eliminate the requirement for a proceeding prior to granting exemptions in appropriate cases. This proposal, affecting an insignificant amount of rail traffic, is such a case, and we therefore provisionally grant the sought exemption. If we receive timely filed adverse comments, we will issue a further decision addressing them and whether this tentative approval ought to be withdrawn.

This action does not significantly affect either the quality of the human environment or the conservation of energy resources.

(49 U.S.C. 10505, 5 U.S.C. 553)

Dated: October 12, 1982.

By the Commission, Division 2, Commissioners Andre, Gilliam, and Taylor. Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-28601 Filed 10-18-82; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-167 (Sub-No. 137N)]

Rail Carriers; Conrail Abandonment Between Lancaster Junction and Columbia, PA; Findings

In a notice published August 6, 1982, in the **Federal Register** the value of the

portions of the Columbia Industrial Track approved for abandonment was established at $111,447. At the request of Conrail and interested parties seeking to buy a portion of the line, the net liquidation value of the line is revised in the following manner: the value of the line between (1) milepost 32.3 and milepost 33.75 is $14,650 and (2) mileposts 28.3 and 30.75 and mileposts 33.75 and 37.2 is a total of $59,610. If, within 120 days from the date of the original on August 6, 1982, publication, Conrail receives bona fide offers for the sale, for 75 percent of the net liquidation value, of these lines it shall sell such lines and the Commission shall, unless the parties otherwise agree, establish an equitable division of joint rates for through routes over such lines.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-28607 Filed 10-18-82; 8:45 am]

BILLING CODE 7035-01-M

[No. 38893]

Rail Carriers; Roberts & Oake, Inc.; Petition for Relief From Tariff Filing Requirements

AGENCY: Interstate Commerce Commission.

ACTION: Notice of provisional exemption.

SUMMARY: Roberts & Oake, Inc., a motor contract carrier, has requested exemption from the requirement of 49 U.S.C. 10702, 10761, and 10762. The sought relief is provisionally granted.

DATES: Comments are due by November 3, 1982. The sought relief will become effective on November 18, 1982, if no adverse comments are received.

ADDRESS: Send an original and, if possible, 15 copies of comments to Room 5340, Interstate Commerce Commission, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT:

Douglas Galloway, (202) 275-7278,

or

Tom Smerdon, (202) 275-7277

SUPPLEMENTARY INFORMATION: Section 10702(b) of the Interstate Commerce Act requires contract carriers to file with the Commission actual and minimum rates for the transportation they provide. Section 10761 prohibits transportation without a tariff on file with the Commission, and section 10762 sets forth general tariff requirements including contract carrier authority to file only minimum rates. Each of these sections authorizes the Commission to grant exemptions to contract carriers when relief is consistent with the public interest and the transportation policy of section 10101. 49 U.S.C. 10702(b), 10761(b) and 10762(f).

Roberts & Oake, Inc. (R&O), is a motor contract carrier with three schedules of rates currently on file with this Commission. It seeks relief from the financially and otherwise onerous statutory requirements noted above. R&O argues that tariff-filing requirements are an undue financial burden and cause the loss of time of key personnel. Also, it alleges that these requirements cause it deadhead mileage and a loss of business due to the lack of flexibility.

Petitioner's request is well grounded. We see no reason to deny the carrier the savings to be realized from a tariff-filing exemption. It appears that the requirement that this carrier file schedules is not in the public interest and that relief will promote the transportation policies of 49 U.S.C. 10101.

We therefore provisionally grant the sought exemption. If we receive timely filed adverse comments, we will issue a further decision addressing them and deciding whether this tentative approval ought to be made final.

This decision would not appear to have a significant effect on either the quality of the human environment or conservation of energy resources. However, comments may be submitted on these issues.

(49 U.S.C. 10702(b), 10761(b), and 10762(f))

Decided: October 12, 1982.

By the Commission, Division 1, Commissioners Sterrett, Simmons, and Gradison.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-28602 Filed 10-18-82; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 30034]

Union Pacific Railroad Co. and Oregon-Washington Railroad & Navigation Co.; Abandonment and Discontinuance Exemption—in Adams County, WA

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission exempts Union Pacific Railroad Company and Oregon-Washington Railroad & Navigation Company from the requirements of 49 U.S.C. 10903-10906 concerning their discontinuance of service and abandonment, respectively, of a 0.28-mile segment of line in Adams County, WA.

DATES: Exemption effective on November 18, 1982. Petitions for reconsideration must be filed by November 8, 1982. Petitions for stay must be filed by October 29, 1982.

Send pleadings to:

(1) Section of Finance, Room 5349, Interstate Commerce Commision, Washington, D.C. 20423

(2) Petitioner's representative: Joseph D. Anthofer, Union Pacific Railroad Company, 1416 Dodge Street, Omaha, NE 68179.

FOR FURTHER INFORMATION CONTACT: Louis E. Gitomer (202) 275-7245.

SUPPLEMENTARY INFORMATION: For further information, see the decision served concurrently in Finance Docket No. 30034. To purchase a copy of the full decision, contact T. S. InfoSystems, Inc., Room 2227, Interstate Commerce Commission, Washington, D.C. 20423, or call 289-4357 in the D.C. Metropolitan Area or toll free (800) 424-5403.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-28778 Filed 10-18-82; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF LABOR

Office of the Secretary

Steering Subcommittee of the Labor Advisory Committee for Trade Negotiations and Trade Policy; Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (P. L. 92-463 as amended), notice is hereby given of a meeting of the Steering Subcommittee of the Labor Advisory Committee for Trade Negotiations and Trade Policy.

Date, time and place: November 2, 1982, 9:30 a.m., Rm. N3437 A & B, Frances Perkins Department of Labor Building, 200 Constitution Avenue, NW., Washington, D.C. 20210.

Purpose: To discuss trade negotiations and trade policy of the United States.

This meeting will be closed under the authority of Section 10(d) of the Federal Advisory Committee Act. The Committee will hear and discuss sensitive and confidential matters concerning U.S. trade negotiations and trade policy.

For further information, contact: Joseph S. Papovich, Executive Secretary, Labor Advisory Committee, Phone: (202) 523-6171.

Signed at Washington, D.C., this 13th day of October 1982.

Robert W. Searby,

Deputy Under Secretary, International Affairs.

October 13, 1982

[FR Doc. 82-28663 Filed 10-18-82; 8:45 am]

BILLING CODE 4510-28-M

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act, The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than October 29, 1982.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than October 29, 1982.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 601 D Street, NW., Washington, D.C. 20213.

Signed at Washington, D.C., this 12th day of October 1982.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner (Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Aarving Displays, Inc. (company)	Linden, NJ	9/28/82	9/17/82	TA-W-13,835	Racks, garment, fixtures, displays, window.
B. L. Montague, Inc. (workers)	Greenville, SC	10/5/82	10/1/82	TA-W-13,836	Conveyers & steel structural, fabricated.
C & P Sportswear (ILGWU)	Bricktown, NJ	9/28/82	9/14/82	TA-W-13,837	Sportswear, ladies'.
Dehue Coal Company (UMWA)	Dehue, WV	9/28/82	9/9/82	TA-W-13,838	Coal, metallurgical, mining.
E.I. DuPont DeNemours & Co., Louisville Works (Neoprene Clerical Workers Union).	Louisville, KY	9/30/82	9/24/82	TA-W-13,839	Rubber, synthetic.
Ingersoll Rand Co., Proto Tool Div. (workers)	Los Angeles, CA	9/30/82	10/4/82	TA-W-13,840	Tools, hand, small.
Pacific Columbia Mills, Olympia Plant (workers)	Columbia, SC	10/4/82	9/29/82	TA-W-13,841	Cloth, sheeting, bed.
Peerless Tube Company (workers)	Bloomfield, NJ	10/4/82	9/17/82	TA-W-13,842	Containers, aersol, collapsible, metal.
Travko Coal Company (UMWA)	Man, WV	9/14/82	9/9/82	TA-W-13,843	Coal, metallurgical, mining.
U.S. Steel Corp., Oilwell Supply (USWA)	Garland, TX	10/4/82	9/29/82	TA-W-13,844	Products, oilfield: pumps, draw works sub-surface & parts, replacement.
Washington Garment Co. (ILGWU)	Washington, PA	10/6/82	9/22/82	TA-W-13,845	Sportswear, ladies'.

[FR Doc. 82-28664 Filed 10-18-82; 8:45 am]

BILLING CODE 4510-30-M

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period October 4, 1982 to October 8, 1982.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-13,119; Philips ECG, Inc., Ottawa, OH

TA-W-12,779; S & C Sportswear, Brooklyn, NY

Affirmative Determinations

TA-W-13,100; Dr. Scholl Shoe Factory, Falmouth, KY

A certification was issued in response to a petition received on November 17, 1981 covering all workers separated on or after June 27, 1981.

TA-W-13,312; Philips ECG, Inc., Seneca Falls, NY

A certification was issued in response to a petition received on January 20, 1982 covering all workers separated on or after January 13, 1982.

I hereby certify that the aforementioned determinations were issued during the period October 4, 1982 to October 8, 1982. Copies of these determinations are available for inspection in Room 10,332, U.S. Department of Labor, 601 D Street, NW., Washington, D.C. 20213 during normal business hours or will be mailed to persons who write to the above address.

Dated: October 12, 1982.

Glen M. Zech,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 82-28665 Filed 10-18-82; 8:45 am]

BILLING CODE 4510-30-M

Pension and Welfare Benefit Programs Office

[Application No. D-3614]

Proposed Exemption for Certain Transactions Involving the Ingles Markets, Incorporated, Employees' Stock Bonus Plan, Located in Asheville, North Carolina

AGENCY: Pension and Welfare Benefit Programs Office, Labor.

ACTION: Notice of proposed exemption.

SUMMARY: This document contains a notice of pendency before the Department of Labor (the Department) of a proposed exemption from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and the Internal Revenue Code of 1954 (the Code). The proposed exemption would exempt the proposed sale by the Ingles Markets, Incorporated Employees' Stock Bonus Plan (the Plan) of a partly improved parcel of real property (the Property) to Ingles Markets, Inc. (the Employer), the sponsor of the Plan. The proposed exemption, if granted, would affect the Plan and its participants and beneficiaries, the Employer, and any other persons participating in the proposed transaction.

DATES: Written comments and requests for a public hearing must be received by the Department on or before December 1, 1982.

ADDRESS: All written comments and requests for a hearing (at least three copies) should be sent to the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216, Attention: Application No. D-3614. The application for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue, NW., Washington, D.C. 20216.

FOR FURTHER INFORMATION CONTACT: Mr. David Stander of the Department, telephone (202) 523-8881. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Notice is hereby given of the pendency before the Department of an application for exemption from the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and from the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code. The proposed exemption was requested in an application filed on behalf of the Plan and the Employer, pursuant to section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, this notice of pendency is issued solely by the Department.

Summary of Facts and Representations

The application contains representations with regard to the proposed exemption which are summarized below. Interested persons are referred to the application on file with the Department for the complete representations of the applicant.

1. The Plan is a stock bonus plan with 1,786 participants. As of September 26, 1981, the Plan had net assets of $6,995,967. Messrs. Robert P. Ingle, F. William White and Ronald S. Woodberry serve as the trustees of the Plan (the Trustees) and have complete discretion with respect to the investment of Plan assets. The Trustees also serve as officers and directors of the Employer, a corporation engaged in the retail grocery business.

2. On May 21, 1975, the Plan purchased undeveloped land from Universal Investment Corporation, an unrelated party with respect to the Plan, for a total price of $107,500.

The Plan subsequently constructed buildings on, and made other improvements to the land, for a total cost for the land and improvements of $1,415,127. The Property consists of 24.9 acres of land, of which 15 acres remains unimproved, and is located on U.S. Highway #25 in Fletcher, North Carolina.

3. After completion of the construction of the improvements in mid-1976, the Plan leased portions of the Property to various lessees, one of which is the Employer. All of the other tenants in the Property are unrelated parties with respect to the Plan. The lease of 24,600 square feet of space in the Property to the Employer (the Lease) was entered into on June 1, 1976, and the Employer remains a lessee of the Property. By letter dated May 14, 1982, the Department's Area Administrator, Atlanta, Georgia, informed the Plan Trustees that the Lease constitutes a prohibited transaction as described in the Act, and that corrective action should be taken.

4. The applicants seek an exemption to allow the Plan to sell the Property to the Employer at its appraised fair market value. Messrs. Kenneth B. Compton, M.A.I., of Kenneth B. Compton & Associates, Inc., and Thomas L. Thomason of Professional Mortgage Co., Inc. appraised the Property, and determined that, as of May 25, 1982, it had a fair market value of $1,850,000. The sale will be for cash and the Plan will not incur any expenses with regard to the sale.

5. The applicants represent that the sale of the Property to the Employer is in the best interests of the Plan because (a) it would be difficult to lease the space currently occupied by the Employer to another suitable tenant and realize a fair market rental for the space; (b) the Plan would incur sales commissions and expenses if it sold the Property to an unrelated party; (c) it would be difficult for the Plan to realize the appraised fair market value of the Property in cash from an unrealted party; and (d) appraisals over the past few years indicate the fair market value of the Property has been decreasing.[1]

6. The applicants recognize that the Lease constitutes a prohibited transaction as described in the Act and represent that the Employer will pay, within 60 days from the date of the grant of an individual exemption by the Department for the sale of the Property by the Plan, all excise taxes which are applicable under section 4975(a) of the Code as a result of the Lease.

7. In summary, the applicant represents that the proposed transaction satisfies the statutory criteria of section 408(a) of the Act because (a) the Plan will be able to dispose of an asset which has been decreasing in value without incurring any expenses; (b) the Property will be sold for cash at its appraised fair market value; (c) the Trustees represent that the sale will be in the best interests of the Plan.

Notice to Interested Persons

Within 10 days after publication of this notice in the **Federal Register** notice will be provided to all Plan participants and all current Plan beneficiaries by personal delivery or mailed return receipt requested. Such notice will include a copy of this notice of pendency and inform interested persons of their right to comment on and/or request a hearing with regard to the proposed exemption.

[1] In this proposed exemption the Department expresses no opinion as to whether the Plan's acquisition and holding of the Property violates any provision of Part 4 of Title I of the Act.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) The proposed exemption, if granted, will not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code;

(3) Before an exemption may be granted under section 408(a) of the Act and section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(4) The proposed exemption, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemption to the address above, within the time period set forth above. All comments will be made a part of the record. Comments and requests for a hearing should state the reasons for the writer's interest in the pending exemption. Comments received will be available for public inspection with the application for exemption at the address set forth above.

Proposed Exemption

Based on the facts and representations set forth in the application, the Department is considering granting the requested exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply to the cash sale of the Property by the Plan to the Employer for $1,850,000, provided that this amount is not less than the fair market value of the Property as of the date of sale.

The proposed exemption, if granted, will be subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to the exemption.

Signed at Washington, D.C., this 14th day of October, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards

[FR Doc. 82-28695 Filed 10-18-82; 8:45 am]

BILLING CODE 4512-29-M

[Application No. D-3452]

Proposed Exemption for Certain Transactions Involving the Automotive Industries Pension Trust Fund Located in San Francisco, California

AGENCY: Pension and Welfare Benefit Programs Office, Labor.

ACTION: Notice of proposed exemption.

SUMMARY: This document contains a notice of pendency before the Department of Labor (the Department) of a proposed exemption from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and the Internal Revenue Code of 1954 (the Code). The proposed exemption would exempt (1) the past sale (the Sale) to the Automotive Industries Pension Trust Fund (the Plan) of a 50% interest in certain real property (the Property) by Safeway Stores, Inc. (Safeway), a party in interest with respect to the Plan; and (2) the subsequent leasing (the Lease) of the Property by the Plan to Safeway. The proposed exemption, if granted, would affect Safeway, the participants and beneficiaries of the Plan and other persons who participated in the transactions.

EFFECTIVE DATE: If granted, the exemption will be effective from September 4, 1975.

DATE: Written comments must be received by the Department on or before November 29, 1982.

ADDRESS: All written comments (at least three copies) should be sent to the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20216, Attention: Application No. D-3452. The application for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue, NW., Washington, D.C. 20216.

FOR FURTHER INFORMATION CONTACT: Richard Small of the Department, telephone (202) 523-7222. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Notice is hereby given of the pendency before the Department of an application for exemption from the restrictions of section 406(a) of the Act and from the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (D) of the Code. The proposed exemption was requested in an application filed by the trustees (the Trustees) of the Plan, pursuant to section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, this notice of pendency is issued solely by the Department.

Summary of Facts and Representations

The application contains representations with regard to the proposed exemption which are summarized below. Interested persons are referred to the application on file with the Department for the complete representations of the applicant.

1. The Plan is a multi-employer pension plan which as of December 31, 1980 had 23,122 participants. Since January 1, 1975, McMorgan & Company (McMorgan), an independent investment advisory firm located in San Francisco,

California, has had full discretion and responsibility in determining investments made by the Plan. The investment authority of McMorgan is subject only to the general policy of the Trustees with respect to the categories of investments to be made and held by the Plan.

2. In August 1975, McMorgan was approached by Safeway with an offer to sell and leaseback from the Plan the Property which consisted of a new supermarket located in San Francisco, California. In November 1975, McMorgan negotiated for the Plan the Sale of a 50% undivided interest in the Property for cash in the amount of $1,053,500 and the Lease of the Property to Safeway. At the time of the Sale, $1,053,500 represented an amount equal to less than 2% of the Plan's assets. No real estate commissions were paid in the Sale. With respect to the Lease, McMorgan contacted three major brokerage houses and inquired what a corporation with Safeway's credit standing would have to pay if they sought to borrow money in the long term (20 years) bond market. The consensus of Salomon Bros., Lehman Bros., and Goldman Sachs was 8.75% per annum. McMorgan then represented to Safeway that it wanted an annual rental constant which would pay the Plan an annual return of 8.75% plus an amount sufficient to completely amortize the $1,053,500 investment over the Lease term of twenty (20) years. Based upon tables prepared by the Financial Publishing Company of Boston, Massachusetts, this required an annual rental constant of 10.61. Accordingly, the Lease provided for a 20 year rental factor based upon a 10.61 annual rental constant to be paid monthly in advance which would produce a yield to the Plan of 8.75% per annum.

3. Subsequent to the Sale and Lease, it was discovered that because Safeway was and is one of 1200 contributory employers to the Plan, the Sale and Lease were prohibited transactions under the Act. The applicants represent that at the time of the transactions no Trustee or other fiduciary of the Plan had any knowledge of the investment and that McMorgan dealt directly at arm's length with Safeway. The Trustees, who represent that the transactions were in the best interests of the participants and beneficiaries of the Plan, are requesting an exemption for such transactions. McMorgan, an independent fiduciary, represents that the Sale and Lease were safe and prudent investments. The investment yielded the Plan a rate return of two hundred and seventy five basis points above the Plan's actuarial interest assumption. McMorgan represented that the quality of the income stream was and is excellent (Safeway has paid dividends on its common stock without interruption since 1927), and that the investment was secured not only by Safeway's credit but by the Property. In addition, McMorgan represents that it expects the residual value of the Property to be significant at the expiration of the Lease.

4. The applicants represent that the transactions met the statutory criteria of section 408(a) of the Act as follows: (1) the Trustees represent that the transactions were in the best interests of the participants and beneficiaries of the Plan; (2) the transactions were originated and negotiated by an independent fiduciary of the Plan; and (3) the terms and conditions of the transactions were negotiated on an arms-length basis.

Notice to Interested Persons

Within ten days of its publication in the **Federal Register** a copy of the notice of pendency and a statement advising participants and beneficiaries of the Plan of their right to comment will be posted in all appropriate union halls. The same information, within the same time frame will be mailed to participants and beneficiaries of the Plan who do not have access to such posting.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) The proposed exemption, if granted, will not extend to transactions prohibited under section 406(b) of the Act and section 4975(c)(1) (E) and (F) of the Code;

(3) Before an exemption may be granted under section 408(a) of the Act and section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(4) The proposed exemption, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthemore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

Written Comments

All interested persons are invited to submit written comments on the pending exemption to the address above, within the time periods set forth above. All comments will be made a part of the record. Comments should state the reasons for the writer's interest in the pending exemption. Comments received will be available for public inspection with the application for exemption at the address set forth above.

Proposed Exemption

Based on the facts and representations set forth in the application, the Department is considering granting the requested exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (D) of the Code shall not apply to: (1) the past sale to the Plan of a 50% interest in the Property for $1,053,500 by Safeway; and (2) the subsequent Lease of the Plan's interest in the Property to Safeway provided that the terms and conditions of the Sale and Lease were at least as favorable to the Plan as those which the Plan could have received in a similar transaction at that time with an unrelated party.

The proposed exemption, if granted, will be subject to the express conditions that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transactions that are the subject of this exemption.

Signed at Washington, D.C., this 14th day of October, 1982

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards.

[Fr Doc. 82-28636 Filed 10-18-82; 8:45 am]

BILLING CODE 4510-29-M

[Application No. D-3203]

Proposed Exemption for Certain Transactions Involving the Design Master Homes, Inc. Profit Sharing Plan and Trust Located in Phoenix, Arizona

AGENCY: Pension and Welfare Benefit Programs Office, Labor.

ACTION: Notice of proposed exemption.

SUMMARY: This document contains a notice of pendency before the Department of Labor (the Department) of a proposed exemption from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and the Internal Revenue Code of 1954 (the Code). The proposed exemption would exempt a loan (the Loan) by the Design Master Homes, Inc. Profit Sharing Plan and Trust (the Plan) of $350,000 to Design Master Homes, Inc. (the Employer), a party in interest with respect to the Plan. The proposed exemption, if granted, would affect the participants and beneficiaries of the Plan, Plan fiduciaries, and other persons participating in the transaction.

DATES: Written comments and requests for a public hearing must be received by the Department of Labor on or before December 8, 1982.

ADDRESS: All written comments and requests for a hearing (at least three copies) should be sent to the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20216, Attention: Application No. D-3203. The application for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue, N.W., Washington, D.C. 20216.

FOR FURTHER INFORMATION CONTACT: Ms. Jan Broady of the Department of Labor, telephone (202) 523-8971. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Notice is hereby given of the pendency before the Department of an application for exemption from the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and from the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code. The proposed exemption was requested in an application filed on behalf of the Employer, pursuant to section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, this notice of pendency is issued solely by the Department.

Summary of Facts and Representations

The application contains representations with regard to the proposed exemption which are summarized below. Interested persons are referred to the application on file with the Department for the complete representations of the applicant.

This notice of pendency was originally published in the **Federal Register** on July 20, 1982 at 47 FR 31466. Because the Employer wishes to change the interest rate for the proposed Loan and increase the Loan amount, the notice of pendency is being republished as follows:

1. The Employer is an Arizona corporation, engaged in the development of commercial and residential properties. The Plan is a profit sharing plan which was established by the Employer in 1969. As of November 30, 1981, the Plan had 74 participants and total assets of $1,495,916. Messrs. Max W. Wilson and W.D. Long, who are employees of the Employer, serve as the Plan trustees (the Trustees) As Trustees these individuals are authorized to make investment decisions for the Plan.

2. The Employer requests an exemption to borrow $350,000 from the Plan in order to discharge the $342,000 principal balance remaining of a $394,000 total indebtedness owed to Continental Bank of Phoenix, Arizona since June 6, 1979. The proposed Loan will be for a ten year period, with payments of principal and interest made quarterly based upon a twenty year amortization schedule. At the end of ten years, all remaining principal and accrued interest will become due and payable. The Loan will carry interest at the greater of 12 percent per annum or the prime rate of interest charged by the Valley National Bank of Arizona as redetermined each January 1st and July 1st by the independent fiduciary designated to oversee the Loan, until the Loan amount plus accrued interest are discharged in full.

3. The Employer owns approximately 112 gross acres of unimproved real property (the Real Property), located in Peoria, Arizona. Roughly 15 acres of the Real Property are located on the south side of Olive Avenue, 330 feet west of 107th Avenue; approximately 97 acres are located on the northwest corner of 107th Avenue and Butler Drive. Of the total acreage, the Employer will offer approximately 60 acres of the Real Property as the collateral (the Collateral) for the proposed Loan. The Loan will be evidenced by a promissory note and secured by a duly recorded deed of trust, thereby giving the Plan a first lien interest in the Collateral. The deed of trust will contain certain release provisions to the effect that portions of the collateral will be released as payments of principal and interest are made. However, in no event will the value of the Collateral be permitted to fall below 150 percent of the outstanding Loan balance.

4. The Collateral underlying the proposed Loan has been appraised in 1978 and 1982 by Mr. Jim Homan (Mr. Homan), an M.A.I. appriaser with the firm, Burke, Hansen and Homan located in Phoenix, Arizona. Mr. Homan and his firm are totally unrelated to the Plan, Employer or to any other party in interest to the proposed transaction. In two appraisals prepared by Mr. Homan on October 26, 1978, he placed the value of the land parcel containing the 97 acres at $1,265,000 and the land parcel containing the 15 acres at $196,000 or $13,000 per acre. Based on these computations, the 60 acres of Real Property offered as the Collateral were valued at $780,000.

In a letter of May 7, 1982, Mr. Homan has updated his earlier valuation of the Real Property. Mr. Homan represents he has reviewed the prior appraisal of the 97 acres to ascertain whether or not the value determined is still applicable, but he concludes the figure ascribed at that time is very conservative in the market today. Mr. Homan also says he has studied recent sales of comparable properties within the area of the Real Property and indicates current prices for land range from $15,000 to $35,000 per acre. Based on the data analyzed, Mr. Homan projects the 60 acres comprising the Collateral to fall within a range of $15,000 to $20,000 per acre or an average value of $17,500 per acre. Using the $17,500 amount as his basis, Mr. Homan values the Collateral at $1,050,000.

5. First American Title Insurance Company of America (First American), which is located in Phoenix, Arizona,

has formally agreed to serve as the independent fiduciary of the proposed Loan. First American represents it is completely unrelated to the Plan and Employer. First American also states it has expertise in the area of loan administration.

As the independent fiduciary, First American will monitor and service the proposed Loan pursuant to the terms of a servicing agreement (the Agreement) which it will enter into with the Plan and Employer. The Agreement empowers First American to take all steps it deems necessary to protect and enforce the interests of the Plan and those of its participants and beneficiaries. These steps will include ensuring that the interest rate for the Loan is adjusted at the designated intervals and having the Collateral appraised as frequently as First American considers it necessary, to ensure the fair market value of the Collateral is at all times at least equal to or in excess of 150 percent of the outstanding Loan balance. In addition, First American will be authorized to approve any release provisions concerning the Collateral. The Employer will pay all costs and expenses incurred in connection with the preparation and execution of the Agreement.

6. Mr. Robert N. Tellier, Jr. (Mr. Tellier), an actuary with the pension, profit sharing and actuarial consulting firm of Scott, Tellier and Company, located in Phoenix, Arizona, has determined, as a Plan fudiciary, that the proposed transaction is in the best interests of the Plan's participants and beneficiaries.[1] Mr. Tellier is unrelated to the Plan and the Employer. Mr. Tellier says he believes the Plan will have little difficulty in advancing funds to the Employer or in receiving the payments accruing from the transaction. He indicates the rate of return (although reduced below the 20 percent per annum interest rate in the prior exemption request) reflects the prevailing interest rate and can ultimately become more favorable to the Plan's participants should the prime rate return to levels in excess of 20 percent. At the present time, he states, the interest rate is 13.56 percent, which represents the prime rate of interest, and this amount exceeds current rates of return that can be obtained on most secure types of investments. He further indicates the Collateral poses no significant difficulty as it relates to the administration of the Plan's assets. He believes the Collateral should be appraised periodically to provide assurance that the Collateral amounts are an appropriate safeguard for the Plan's participants.

To support his opinion, Mr. Tellier has concluded the proposed Loan will give the Plan a more than fair rate of return. He says the Loan will not impair the Plan's liquidity position as the majority of the Plan's assets are invested in liquid assets. He states that in the event the Plan's assets are distributed to the Plan's participants or beneficiaries, sufficient safeguards are in place to allow for the adequacy of payments without a potential nonliquidity problem occurring. He notes that if the Employer continues its practice of making sufficient contributions to the Plan, the proper liquidity for disbursement of benefits will be enhanced and the percentage of assets that would be held in an investment such as the Loan will be diminished.

7. In summary, the applicant has represented that the proposed transaction meets the statutory criteria for an exemption under section 408(a) of the Act because: (a) the Loan will be secured by the Real Property which has an appraised value of over three times the amount of the funds to be loaned, and in no event will the value of the Collateral be less than 150 percent of the outstanding Loan Balance; (b) the Loan will be monitored by an independent fiduciary who will take actions necessary to protect the interests of the Plan and those of its participants and beneficiaries; and (c) another independent fiduciary, Mr. Tellier, has reviewed the terms of the transaction and believes the Loan will be in the best interests and protective of the Plan's participants and beneficiaries.

Notice to Interested Persons

Notice of the pending exemption will be provided to all Plan participants and the Trustees within fifteen (15) days of the publication of the notice of pendency in the **Federal Register.** The notice shall include a copy of the notice of pendency as published in the **Federal Register** and will inform interested persons of their right to comment and/or to request a hearing with respect to the pending exemption. Notice will be provided by posting copies of the pending exemption in conspicuous places within the administrative offices of the Employer and by first class mail.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certin other provisions of the Act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fidudicary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) The proposed exemption, if granted, will not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code;

(3) Before an exemption may be granted under section 408(a) of the Act and section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of particiants and beneficiaries of the plan; and

(4) The proposed exemption, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemption to the address above, within the time period set forth above. All comments will be made a part of the record. Comments and requests for a hearing should state the reasons for the writer's interest in the pending exemption. Comments received will be available for public inspection with the application for exemption at the address set forth above.

Proposed Exemption

Based on the facts and representations set forth in the application, the Department is considering granting the requested

[1] While the Department is relying upon the judgment of Mr. Tellier with respect to the decision to enter into the transaction, as stated in 5 above, First American, which has experience in monitoring transactions of this type, will represent the Plan's interests throughout the duration of the transaction.

exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the Loan of $350,000 by the Plan to the Employer, provided the terms of the transaction are not less favorable to the Plan than those obtainable in an arm's length transaction with an unrelated party at the time of consummation of the transaction.

The proposed exemption, if granted, will be subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application, accurately describes all material terms of the transaction to be consummated pursuant to the exemption.

Signed at Washington, D.C., this 13th day of October, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards.

[FR Doc. 82-28697 Filed 10-18-82; 8:45 am]

BILLING CODE 4510-29-M

[Application No. D-2794]

Proposed Exemption for Certain Transactions Involving the Deferred Benefits Corporation Pension Plan Located in Atlanta, Georgia

AGENCY: Pension and Welfare Benefit Programs Office, Labor.

ACTION: Notice of proposed exemption.

SUMMARY: This document contains a notice of pendency before the Department of Labor (the Department) of a proposed exemption from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and the Internal Revenue Code of 1954 (the Code). The proposed exemption would permit the receipt of brokerage commissions by the Deferred Benefits Corporation (the Employer) and employees of the Employer (the Employees) for the purchases of certain investment media by the Employees through their individual accounts in the Deferred Benefits Corporation Pension Plan (the Plan). The proposed exemption, if granted would affect participants and beneficiaries of the Plan, the Employees, the Employer and other persons participating in the transactions.

DATE: Written comments and requests for a public hearing must be received by the Department on or before November 29, 1982.

ADDRESS: All written comments and requests for a hearing (at least three copies) should be sent to the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20216, Attention: Application No. D-2794. The application for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue, N.W., Washington, D.C. 20216.

FOR FURTHER INFORMATION CONTACT: Paul R. Antsen of the Department, telephone (202) 523-6915. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Notice is hereby given of the pendency before the Department of an application for exemption from the restrictions of section 406(a)(1) (A) through (D), and 406(b) of the Act and from the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (F) of the Code. The proposed exemption was requested in an application filed by counsel on behalf of the Employer, pursuant to section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, this notice of pendency is issued solely by the Department.

Summary of Facts and Representations

The application contains representations with regard to the proposed exemption which are summarized below. Interested persons are referred to the application on file with the Department for the complete representations of the applicant.

1. The Plan is a prototype target benefit plan which was adopted by the Employer with an effective date of October 1, 1980. As of May 1, 1981 the Plan had five participants. Section 6.04 of the Plan permits participants to direct the investment of their individual plan accounts. Based on the Plan structure, the applicants seek an exemption permitting each of the Employees (this term would consist of both present and future Plan participants) to purchase investment media for their respective separate accounts.[1]

2. The principal business activity of the Employer and each of the Employees is the provision of insurance and investment consulting services and the marketing of investment media. These services and products are particularly suited for investment by qualified plans. In connection with the marketing of these investment media, the Employer and the Employees are paid sales commissions. Each of the Employees has an employment agreement with the Employer governing compensation. The Employees are paid a base salary plus additional compensation based on bonus points which are earned in a number of ways including gross sales commissions generated. Although the amount of compensation received by each of the Employees is affected by the commissions generated, there is no direct flow through of commissions. All commission income is paid to the Employer who apportions and distributes it to the Employees in accordance with an annually established formula. Commissions paid in connection with transactions effected pursuant to the requested exemption will be allocated under the Employer's fee sharing arrangement in the same manner as all other commissions earned by the Employees in the sales of investment media to unrelated third parties in the ordinary course of business. Each of the Employees is licensed for the sale of life insurance and annuity products and each is registered as a salesman of investment products through a member firm of the National Association of Security Dealers (NASD). The applicant has represented that the exemptive relief would only be available to current participants and those future participants of the Plan who have the requisite licensing qualifications to sell the investment product in question.

3. The investment media to be purchased pursuant to the exemption are comparable to those marketed by the Employees in their ordinary course of business. Certain of the investment media are marketed at uniform

[1] For purposes of this exemption the term "investment media" is intended to encompass the entire spectrum of investment products including insurance. The applicant notes that the Department had previously published a class exemption for certain transactions involving employee benefit plans maintained by insurance agents and brokers (PTE 79-60, 44 FR 59018, October 12, 1979). It is not intended that this exemption provide any relief with respect to transactions involving insurance products beyond that available under the class exemption.

commission rates which are fixed on an industry wide basis, and are not subject to the discretion of the Employees or the Employer. In many cases the investment media marketed by the Employees are filed with and supervised by the Securities and Exchange Commission and policed by the NASD. As a result of this independent regulatory process, it would be impossible, and conceivably illegal, for the institutions offering the various investment media to do so without payment of all sales charges which are inherent in the purchase by other buyers of the product. In other instances where the investment media to be purchased involves stocks or bonds traded on an exchange or over-the-counter the Employer will not serve as broker. Such securities are acquired through the brokerage house of Thompson, McKinnon Securities, Inc. Commissions to be allocated to the Employees for these types of transactions are based on an existing agreement between the Employer and the brokerage house involved. Commission income would then be paid to the Employer who would apportion and distribute it in accordance with the established formula for fee sharing contained in the employment agreement.

The Employer has represented that it will never serve as principal in a transaction involving the acquisition of investment media for Plan accounts covered by the requested exemption. Additionally, the Employer represents that no acquisition under the exemption will involve securities of the Employer.

4. In view of the fact that the Employees may only effect purchases of investment media for their own individual accounts and that commissions would be paid solely from such accounts, there is no opportunity for the investment decision or the payment of compensation to any one of the Employees to prejudice the interests of any other participant in the Plan. Additionally, such purchases would represent only an incidental amount (5%) of the total commission income of the respective Employees in any given plan year.

5. In summary, the applicant represents that the transactions for which relief is requested meet the statutory criteria for an exemption under sectin 408(a) of the Act because: (1) the commissions derived from purchases of investment media for the Employees' respective individual accounts will be controlled by the Employer's free sharing agreement in the same manner as all other commissions earned by the Employees from similar sales to unrelated third parties in the ordinary course of business;

(2) absent the exemption, the Employees who desire to direct the investment of their individual accounts in investment media that would be covered by the requested exemption would be forced to effect such purchases through competitiors; and (3) the exempted transactions involve only directed purchases for the Employees' respective Plan account; therefore, a directed investment effected under the exemption cannot prejudice the rights of other participants in the Plan.

Notice to Interested Persons

Within ten (10) days of its publication in the **Federal Register** a copy of the notice of pendency and a statement informing participants and beneficiaries of the Plan of their right to comment or request a bearing within the prescribed time period will be provided to all participants and beneficiaries of the Plan. Notice will be either by personal delivery or first class mail.

General Information

The attention of interested persons is directed to the following: (1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and section 4975 (c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(3) The proposed exemption, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemption to the address above, within the time period set forth above. All comments will be made a part of the record. Comments and requests for a hearing should state the reasons for the writer's interest in the pending exemption. Comments received will be available for public inspection with the application for exemption at the address set forth above.

Proposed Exemption

Based on the facts and representations set forth in the application, the Department is considering granting the requested exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a)(1)(A) through (D) and 406(b) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (F) of the Code shall not apply to the receipt of brokerage commissions by the Employer and Employees incidental to the purchase of certain investment media by the Employees through their individual accounts in the Plan provided:

(a) The terms of the sales will be at least as favorable to the Plan as the terms offered for similar purchases by unrelated third parties in the normal course of the Employees' business;

(b) The purchases by the Employees will only be made for the respective Employee's individual account in the Plan;

(c) During no plan year will the commissions paid by the Plan as a result of purchases by the Employees for their respective individual account excceed five percent (5%) of the commissions earned by such Employee during the plan year in similar purchases by unrelated third parties; and

(d) Payment of commissions by the Plan in connection with such purchases will be treated under the Employer's fee sharing agreement in the same manner as all other commissions earned by the Employees in sales of investment media

by unrelated third parties in the ordinary course of business.

The proposed exemption, if granted, will be subject to the express condition that thematerial facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transactions to be consummated pursuant to the exemption.

Signed at Washington, D.C., this 13th day of October, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards.

[FR Doc. 82-28698 Filed 10-18-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 82-171; Exemption Application No. D-3127]

Exemption From the Prohibitions for Certain Transactions Involving the DLD Distributing Company of Wyoming Employee Profit Sharing Retirement Plan Located in Salt Lake City, Utah

AGENCY: Pension and Welfare Benefit Programs Office, Labor.

ACTION: Grant of individual exemption.

SUMMARY: This exemption permits the proposed sale of certain real property (the Parcel) by the DLD Distributing Company of Wyoming Employees Profit Sharing Retirement Plan (the Plan) to DLD Distributing Company (the Employer), the sponsor of the Plan.

FOR FURTHER INFORMATION CONTACT: Ms. Katherine D. Lewis of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20216. (202) 523-8972. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On September 3, 1982, notice was published in the **Federal Register** (47 FR 39008) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(a), 406(b)(1) and 406(b)(2) of the Employee Retirement Income Security Act of 1974 (the Act) and from the sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1)(A) through (E) of the Code, for the above-described transaction. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition, the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. The applicant has represented that a copy of the notice has been provided to interested persons in compliance with the provisions set forth in the notice of pendency. No public comments and no requests for a hearing were received by the Department. The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

Accordingly, the restrictions of section 406(a), 406(b)(1) and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed cash sale of the Parcel by the Plan to the Employer for $591,000, provided that such amount is not less than the fair market values of the Parcel on the date of the sale.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 14th day of October, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards.

[FR Doc. 28699 Filed 10-18-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 82-172; Exemption Application No. D-3290]

Exemption From the Prohibition, for Certain Transactions Involving the Shefsky, Saitlin & Froelich, Ltd. Employees' Profit Sharing Plan Located in Chicago, Illinois

AGENCY: Pension and Welfare Benefit Programs Office, Labor.

ACTION: Grant of Individual Exemption.

SUMMARY: This exemption exempts the proposed purchase by the individual account of Mr. Cezar M. Froelich (the Account) in the Shefsky, Saitlin & Froelich, Ltd. Employees' Profit Sharing Plan (the Plan) of an interest (the Interest) in certain real estate which is adjacent to property currently owned by Mr. Cezar M. Froelich.

FOR FURTHER INFORMATION CONTACT: Ms. Katherine D. Lewis of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20216. (202) 523-8972. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On August 13, 1982, notice was published in the **Federal Register** (47 FR 35379) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of section 406(a), 406(b)(1) and 406(b)(2) of the Employee Retirement Income Security Act of 1974 (the Act) and from the sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code) by reason of section 4975(c)(1)(A) through (E) of the Code, for the above-described transaction. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition, the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. No public comments and no requests for a hearing were received by the Department. The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975, and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

Accordingly, the restrictions of section 406(a), 406(b)(1) and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed purchase of the Interest by the Account, provided that the purchase price of the Interest is not in excess of its fair market value on the date of sale.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 14th day of October, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards.

[FR Doc. 82-28700 Filed 10-18-82; 8:45 am]

BILLING CODE 4510-29-M

[Prohibited Transaction Exemption 82-173; Exemption Application No. D-3478]

Exemption From the Prohibitions for Certain Transactions Involving the Ralph D. Anderson, M.D., Inc. Defined Benefit Pension Plan Located in Newport Beach, California

AGENCY: Pension and Welfare Benefit Programs Office, Labor.

ACTION: Grant of individual exemption.

SUMMARY: This exemption exempts the sale of an $85,000 face value note (the Note) by Ralph D. Anderson, M.D. (Anderson), the owner of 100% of the capital stock of Ralph D. Anderson, M.D., Inc., to the Ralph D. Anderson M.D., Inc. Defined Benefit Pension Plan (the Plan). Because Anderson is the only participant in the Plan, there is no jurisdiction under Title I of the Employee Retirement Income Security Act of 1974 (the Act) pursuant to 29 CFR 2510.3-3(b). However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Internal Revenue Code of 1954 (the Code).

FOR FURTHER INFORMATION CONTACT: Ms. Linda M. Hamilton of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20216. (202) 523-8881. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On September 3, 1982, notice was published in the **Federal Register** (47 FR 39003) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the sanctions resulting from the application of section 4975 of the Code by reason of section 4975(c)(1)(A) through (E) of the Code, for the above-described transaction. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The

notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. No public comments and no requests for a hearing were received by the Department.

The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption granted under section 4975(c)(2) of the Code does not relieve a fiduciary or other disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Code. These provisions include any prohibited transaction provisions to which the exemption does not apply; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 4975(c)(1)(F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 4975(c)(2) of the Code and the procedures set forth in Rev. Proc. 75-26, 1975-1 C.B. 722, and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Plan and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Plan.

Accordingly, the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the sale of the Note by Anderson to the Plan so long as the terms of the sale are no less favorable to the Plan than those obtainable in an arm's-length transaction with an unrelated party.

The availability of this exemption is subject to the express condition that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to this exemption.

Signed at Washington, D.C., this 10th day of October, 1982.

Alan D. Lebowitz,

Assistant Administrator for Fiduciary Standards.

[FR Doc. 82-28701 Filed 10-18-82; 8:45 am]

BILLING CODE 4510-29-M

NATIONAL ADVISORY COMMITTEE ON OCEANS AND ATMOSPHERE

Notice of Meeting Change

October 14, 1982.

The location and time of the Coast Guard Panel meeting of the National Advisory Committee on Oceans and Atmosphere (NACOA), scheduled to meet on Sunday, October 24, 1982 and published in the **Federal Register** of October 8, 1982 (Page 47 FR 44643) has been changed. The Panel will meet from 1:00 p.m. to 6:00 p.m. in the Canal Room at the Holiday Inn—Georgetown, 2101 Wisconsin Avenue, NW., Washington, D.C.

Additional information concerning this meeting may be obtained through the NACOA Executive Director, Mr. Steven N. Anastasion. The mailing address is: NACOA, 3300 Whitehaven Street, NW. (Suite 348, Page Building #1), Washington, D.C. 20235. The telephone number for NACOA is 202/653-7818.

Dated: October 14, 1982.

Steven N. Anastasion,

Executive Director.

[FR Doc. 82-28659 Filed 10-18-82; 8:45 am]

BILLING CODE 3510-12-M

NATIONAL COMMUNICATIONS SYSTEM

National Security Telecommunications Advisory Committee; Closed Meeting

A meeting of the National Security Telecommunications Advisory Committee (NSTAC) Industry Points of Contact will be held at 8:45 a.m. on Tuesday, November 9, 1982 in the Westgate Building of the MITRE Corporation, 1820 Dolley Madison Boulevard, McLean, Virginia. The agenda is as follows:

A. NSTAC Governing Directives
B. Internal Organization and Rules of Procedure
C. NSTAC Issues
  1. PD-53 Relationships
  2. Communications System Survivability
  3. Automated Information Processing
  4. Single Point of Contact
D. Annual Work Plan

The NSTAC Issue session is devoted to the discussion of classified telecommunications issues as they relate to national security communications and therefore will be closed to the public in the interest of National Defense. Any person desiring information about the meeting may telephone (Area Code 202-692-9274) or write the Manager of the National Communications System, 8th Street and South Courthouse Road, Arlington, Virginia 22204.

Joseph C. Wheeler,

Colonel, USAF, NCS Joint Secretariat.

[FR Doc. 82-28658 Filed 10-18-82; 8:45 am]

BILLING CODE 3610-05-M

NATIONAL SCIENCE FOUNDATION

Subpanel on Regulation and Policy Analysis Advisory Panel for Social and Economic Science; Meeting

In acordance with the Federal advisory Comittee Act, P.L. 92-463, as amended, the National Science Foundation announces the following meeting:

Name: Subpanel on Regulation & Policy Analysis of the Advisory Panel for Social and Economic Science.

Date/time: November 5, 1982-9:00 a.m. to 6:00 p.m.; November 6, 1982-9:00 a.m. to 1:00 p.m.

Place: National Science Foundation, 1800 G St., NW (Rm. 421), Washington, DC 20550.

Type of meeting: Closed-9:00 a.m. to 6:00 p.m. November 5, 1982; 9:00 a.m. to 1:00 p.m. November 6, 1982.

Contact person: Dr. Laurence C. Rosenberg, Program Director, Regulation and Policy Analysis, National Science Foundation Room 310—Phone: (202) 357-7417.

Purpose of subpanel: To provide advice and recommendations concerning research in Regulation and Policy Analysis.

Agenda: Closed: to review and evaluate research proposals as part of the selection process for awards.

Reason for closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority to close meeting: This determination was made by the Committee Management Officer pursuant to provisions of Section 10(d) of P.L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Director, NSF on July 6, 1979.

M. Rebecca Winkler,

Committee Management Coordinator.

October 14, 1982.

[FR Doc 82-28615 Filed 10-18-82; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Subcommittee on Waterford Steam Electric Station Unit No. 3; Meeting

The ACRS Subcommittee on Waterford Steam Electric Station Unit No. 3 will hold a meeting on November 9, 1982, at Arnaud's, 813 Bienville Street, New Orleans, LA. The Subcommittee will review the Operator Training Program with the Licensee, the Region IV Office, and the cognizant NRC Staff members. Notice of this meeting was published September 22, 1982.

In accordance with the procedures outlined in the **Federal Register** on October 1. 1982, (47 FR 43474), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the Designated Federal Employee as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The entire meeting will be open to public attendance except for those sessions which will be closed to protect proprietary information (Sunshine Act Exemption 4). One or more closed sessions may be necessary to discuss such information. To the extent practicable, these closed sessions will be held so as to minimize inconvenience to members of the public in attendance.

The agenda for subject meeting shall be as follows:

Tuesday, November 9, 1982—8:30 a.m. until 12:30 p.m.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, will exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the Louisiana Power and Light Company, NRC Staff, their consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been canceled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant Designated Federal Employee, Mr. Gary Quittschreiber or the Staff Engineer, Mr. Don Bucci (telephone 202/634-3267) between 8:15 a.m. and 5:00 p.m., EDT.

I have determined, in accordance with Subsection 10(d) of the Federal Advisory Committee Act, that it may be necessary to close portions of this meeting to public attendance to protect proprietary information. The authority for such closure is Exemption (4) to the Sunshine Act, 5 U.S.C. 552b(c)(4).

Dated: October 12, 1982.

John C. Hoyle,

Advisory Committee Management Office.

[FR Doc. 82-28692 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

Advisory Committee on Reactor Safeguards, Subcommittee on Procedures and Administration; Meeting

The ACRS Subcommittee on Procedures and Administration will hold a meeting on November 3, 1982 in Room 1010, 1717 H Street, NW, Washington, DC. Notice of this meeting was published September 22, 1982.

In accordance with the procedures outlined in the **Federal Register** on October 1, 1982, (47 FR 43474), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the Designated Federal Employee as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The entire meeting will be open to public attendance except for those sessions during which the Subcommittee finds it necessary to discuss information of a personal nature and information which relates solely to internal personnel rules and practices. One or more closed sessions may be necessary to discuss such information. (SUNSHINE ACT EXEMPTIONS 2 and 6). To the extent practicable, these closed sessions will be held so as to minimize inconvenience to members of the public in attendance.

The agenda for subject meeting shall be as follows:

Wednesday, November 3, 1982—1:00 p.m. until 5:00 p.m.

The Subcommittee will hold discussions regarding ACRS activities including the following topics:

(a) Activities of ACRS members including participation on Working Groups, attendance at ACRS meetings and comments by members as individuals prior to ACRS consideration of a matter.

(b) Review and distribution of ACRS documents.

(c) Working relations with NRC Regional and Headquarters Offices.

(d) Basis for appointment of ACRS members.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant Designated Federal Employee, Mr. Raymond F. Fraley (telephone 202/634-3265) between 8:15 a.m. and 5:00 p.m., EDT.

I have determined, in accordance with Subsection 10(d) Public Law 92-463 that it may be necessary to close some portions of this meeting to discuss information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy and which concurs solely to internal personnel rules and practices. The authority for such closure are Exemptions (2) and (6) to the Sunshine Act, 5 U.S.C. 552b(c)(2)(6).

Dated: October 12, 1982.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 82-28693 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

Advisory Panel for the Decontamination of Three Mile Island, Unit 2

Notice is hereby given pursuant to the Federal Advisory Committee Act that the Advisory Panel for the Decontamination of Three Mile Island, Unit 2 will be meeting on November 17, 1982, from 7:00 p.m. to 10:00 p.m. in the Holiday Inn, 23 South Second Street, Harrisburg, Pennsylvania. The meeting will be open for public observation.

At this meeting the Panel will discuss the current status of cleanup activities at TMI. The issue of processed water disposition will also be discussed by the Panel at this meeting.

Further information on the meeting may be obtained from Dr. William Travers, Three Mile Island Program Office, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone 301/492-7466.

Dated: October 14, 1982.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 82-28694 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-206]

Southern California Edison Co. and San Diego Gas and Electric Co.; Issuance of Amendment to Provisional Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 64 to Provisional Operating License No. DPR-13, to Southern California Edison Company and San Diego Gas and Electric Company (the licensees), which revised the Technical Specifications for operation of the San Onofre Nuclear Generating Station, Unit No. 1 (the facility), located in San Diego County, California. This amendment is effective as of its date of issuance. However, the technical specification provisions approved by the amendment are to be implemented within 30 days after the date of issuance.

The amendment revises the Appendix A Technical Specifications and Bases to reflect (1) revised normally required time intervals for entering various subcritical operational modes when a limiting condition for operation and/or the associated action statement cannot be satisfied and (2) revised reactivity criteria requiring a prompt report to the Commission. Both of these changes were made to provide consistency with the Standard Technical Specifications.

The application for amendment 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. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendent will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment dated December 8, 1981, (2) Amendment No. 64 to License No. DPR-13, and (3) the Commission's related Safety Evaluation. These items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and the San Clemente Branch Library, 242 Avenida Del Mar, San Clemente, California 92676. A single copy of items (2) and (3) may be obtained by request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 6th day of October 1982.

For the Nuclear Regulatory Commission.

Dennis M. Crutchfield,

Chief, Operatiing Reactors Branch No. 5, Division of Licensing.

[FR Doc. 82-28687 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-537]

Department of Energy, Project Management Corp., Tennessee Valley Authority, (Clinch River Breeder Reactor Plant); Resumption of Evidentiary Hearings

October 13, 1982

Please take notice that resumptions of evidentiary hearings will be held in this licensing proceeding before an Atomic Safety and Licensing Board, pursuant to the Atomic Energy Act of 1954, as amended, and the Regulations in Title 10, Code of Federal Regulations, Part 50, "Licensing of Production and Utilization Facilities," Part 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection," and Part 2, "Rules of Practice." Prior portions of the evidentiary hearing were held August 23-27, 1982 in Oak Ridge, Tennessee.

These continuations of evidentiary hearings on LWA-1 matters will be held November 16-19 and December 13-17, 1982. These hearings will be held at the Executive Seminar Center Building, 301 Broadway, Oak Ridge, Tennessee, commencing at 8:30 a.m., local time, each day.

These resumed LWA-1 hearings will receive evidence on matters in controversy on all admitted contentions *except* Contentions 1(b) and 3(a) (*see* Order of April 22, 1982), and 9, 10, and 11(a) (*see* Order of April 14, 1982, as corrected at Tr. 435-37 and 440-42).

Written limited appearance statements may be submitted to the Board at any time prior to closing the record in this phase of the proceeding. Oral statements will only be received at times designated by the Board in order not to interfere with the taking of evidence in this adjudicatory proceeding. Both oral and written statements will be made a part of the official record.

It is so ordered.

For the Atomic Safety and Licensing Board.

Marshall E. Miller,

Chairman, Administrative Judge.

[FR Doc. 82-28691 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-280]

Virginia Electric and Power Co.; Granting of Relief From ASME Code Section XI Inservice Inspection Requirements

The U.S. Nuclear Regulatory Commission (the Commission) has granted relief from certain requirements of the ASME Code, Section XI, "Rules for Inservice Inspection of Nuclear Power Plant Components," to Virginia Electric and Power Company (the licensee) for the Surry Power Station, Unit No. 1 located in Surry County, Virginia. The ASME Code requirements are incorporated by reference into the Commission's rules and regulations in 10 CFR Part 50.

This relief allows the licensee to replace a 1½ inch drain valve upstream of the main steam trip valve without performing a hydrostatic test for the entire steam generator and a considerable portion of the main steam piping. A leakage test will be performed instead.

The request for this granting of relief 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 Evaluation of Relief Request.

The Commission has determined that the granting of this relief will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with this action.

For further details with respect to this action, see (1) the request for relief dated September 15, 1982; (2) the letter to the licensee dated October 1, 1982; and (3) the Commission's related Evaluation of Relief Request. These items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555, and at the Swem Library, College of William and Mary, Williamsburg, Virginia 23185. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland this 1st day of October 1982.

For the Nuclear Regulatory Commission.

Steven A. Varga,

Chief, Operating Reactors Branch No. 1, Division of Licensing.

[FR Doc. 82-28688 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-266 and 50-301]

Wisconsin Electric Power Co. (Point Beach Nuclear Plant, Units 1 and 2); Exemption

I.

Wisconsin Electric Power Company (the licensee) is the holder of Facility Operating Licenses Nos. DPR-24 and DPR-27 (the licenses) which authorize operation of the Point Beach Nuclear Plant, Units 1 and 2, respectively (the facilities) at steady state reactor power level not in excess of 1518 megawatts thermal (rated power). The facilities consist of Westinghouse Electric Corporation designed pressurized water reactors (PWRs) located at the licensee's site in Manitowoc County, Wisconsin.

The license is subject to all rules, regulations and orders of the Commission.

II.

10 CFR 50.54(q) requires a licensee authorized to operate a nuclear power reactor to follow and maintain in effect emergency plans which meet the standards of § 50.47(b) and the requirements of Appendix E to 10 CFR Part 50. Section IV.F.1 of Appendix E requires each licensee to conduct a full-scale emergency preparedness exercise at least annually.

By letter dated June 30, 1982 as supplemented by letter dated August 9, 1982, the licensee requested an Exemption from the schedular requirements of Section IV.F.1 of Appendix E. The last full scale emergency preparedness exercise was conducted at the Point Beach Nuclear Plant on March 9, 1982. The next full-scale annual exercise, therefore, is due to be conducted in March of 1983. The licensee requests that it be granted an exemption on a one-time basis to allow the next full scale exercise to be conducted on September 20, 1983.

The licensee states that major scheduling constraints experienced by the State of Wisconsin Division of Emergency Government (DEG), the Federal Emergency Management Agency (FEMA) Region V, Manitowoc and Kewaunee Counties and the Point Beach Nuclear Plant (steam generator tube sleeving and annual refueling outages) have limited the available schedule times for the annual exercises.

The licensee further states that Wisconsin's DEG has assured them that it is able to respond to any actual accident situation at the Point Beach Nuclear Plant at any time. The licensee's August 9, 1982 letter includes as an attachment Wisconsin DEG's July 15, 1982 letter illustrating DEG's schedular constraints.

The last full-scale exercise at the Point Beach Nuclear Plant was held on March 9, 1982. Assurance has been given the licensee by Wisconsin's DEG that it is able to respond to any actual accident situation at the Point Beach Nuclear Plant at any time. It is the NRC staff's judgment that the most effective and beneficial annual exercises are those involving the full-scale participation of State and local government organizations.

Based on the above, we conclude that the licensee's request for a one time delay of the next full-scale emergency preparedness exercise at the Point Beach Nuclear Plant until September 20, 1983 is reasonable and that granting the request will not significantly affect the state of emergency preparedness at Point Beach. We conclude, therefore, that the licensee's request for exemption should be granted.

III.

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption requested by the licensee's letter of June 30, 1982 as supplemented by letter dated August 9, 1982 as discussed above, is authorized by law and will not endanger life or property or the common defense and security, and is otherwise in the public interest. The requested exemption is hereby granted, modified as follows:

In order to allow for minor schedule changes, the next full-scale emergency preparedness exercise atthe Point Beach Nuclear Plant shall be conducted not later than September 30, 1983.

The Commission has determined that the granting of this Exemption will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with this action.

This Exemption is effective upon issuance.

Dated at Bethesda, Maryland, this 7th day of October, 1982.

For the Nuclear Regulatory Commission.

Darrell G. Eisenhut,

Director, Division of Licensing.

[FR Doc. 82-28689 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-305]

Wisconsin Public Service Corp., (Kewaunee Nuclear Power Plant); Exemption

I I11The Wisconsin Public Service Corporation (the licensee) holds Operating License No. DPR-43, which authorizes operation of the Kewaunee Nuclear Power Plant (the facility). This license provides, among other things, that it is subject to all rules, regulations and Orders of the Commission now or hereafter in effect.

The facility is a pressurized water reactor located in Kewaunee County, Wisconsin.

II

Section III.L of Appendix R to 10 CFR Part 50 requires, among other things, that alternative or dedicated shutdown capability provided for a specific fire area shall be able to (a) achieve and maintain subcritical reactivity conditions in the reactor; (b) maintain reactor coolant inventory; (c) achieve and maintain hot standby conditions for a PWR; (d) achieve cold shutdown conditions within 72 hours; and (e) maintain cold shutdown conditions thereafter.

By letter dated December 22, 1981, the NRC staff transmitted a Fire Protection

Safety Evaluation Report to the licensee for the facility informing the licensee that their proposed design for fire protection of safe shutdown capability was in compliance with items III.G.3 and III. L of Appendix R with three exceptions. To complete compliance, the licensee was required to commit to resolution of these exceptions. The licensee responded on January 22, 1982 and made such a commitment.

The December 22, 1981 letter also informed the licensee that the proposed design was an "alternative" system which was to be installed according to the schedule in 10 CFR 50.48(c)(4). This regulation requires implementation before startup after the earliest of the following events commencing 180 days or more after NRC approval:

(1) The first refueling outage

(2) Another planned outage that lasts for at least 60 days

(3) An unplanned outage that lasts for at least 120 days

Our review of the licensee submittals indicates that the modifications proposed are of an extensive nature, numerous, and require a significant amount of new equipment. The licensee felt that the system modifications were extensive enough to be considered a dedicated system. The staff disagreed in that regard but did agree that the system was acceptable as an alternative shutdown system and that it met the requirements of Appendix R to 10 CFR 50.

In the submittal dated January 22, 1982 the licensee provided the justifications for the schedule proposed and requested that the implementation date specified in 10 CFR 50.48(c)(4) for the proposed fire protection modification at the Kewaunee Nuclear Power Plant be extended until the end of the refueling outage scheduled for the spring of 1984.

Prior to the issuance of Appendix R, the Kewaunee facility had been reviewed against the criteria of Appendix A to the Branch Technical Position 9.5-1 (BTP 9.5-1). The BTP 9.5-1 was developed to resolve the lessons learned for the fire at the Browns Ferry Nuclear Plant. It is broader in scope than Appendix R, formed the nucleus of the criteria developed further in Appendix R and in its present, revised form constitutes the section of the Standard Review Plan used for the review of applications for construction permits and operating licenses of new plants. The review was completed by the NRC staff and its fire protection consultants and a Fire Protection Safety Evaluation (FPSE) was issued on December 12, 1978. A few items remained unresolved. Further discourse between the licensee and the NRC staff resulted in resolution of these items as documented in a supplement to the FPSE issued on February 13, 1981. The FPSE and its supplement supported the issuance of an amendment to the operating license of the Kewaunee facility on December 12, 1978 which required modifications to be made to plant physical features, systems, and administrative controls to meet the criteria of Appendix A to BTP 9.5-1. All of these modifications have been completed.

In addition, our review of the facility against the criteria of Appendix A to BTP 9.5-1 concluded that adequate instrumentation and procedures were provided for use in effecting safe shutdown independent of equipment and cabling in the relay and control room. This capability will be available during the period of exemption. Requirements of Section III.L of Appendix R to 10 CFR 50 includes additional measures such as the separation of cables and equipment. Some of these will be completed by the refueling outage of 1983, others will not, however, the shutdown capability approved for the Appendix A to BTP 9.5-1 review will be available during the exemption period. Therefore, the Kewaunee facility has been upgraded to a high degree of fire protection already and the extensive modification involved in this request for additional time is to incorporate the differences between what was previously approved and the specific requirements of Sections III.G and III.L to Appendix R of 10 CFR 50.

In a submittal dated August 4, 1982, the licensee confirmed information which had been presented to the staff in a meeting June 23, 1982. This letter presented a detailed schedule of the work to be completed, and the complexity of the schedule. It also shows the effects of the enforcement of the NRC schedule, the most noticeable of which is the five and one half month additional down time required for the NRC required schedule.

As a showing of good faith effort the licensee has provided a preliminary schedule of additional improvements to safety which are part of the approved alternative shutdown system. Those proposed to be completed before startup from the Spring 1983 refueling outage even though the exemption is granted include the following:

Containment Fire Suppression Spray
Separation of Diesel Generator Support Components (oil cooling, electrical)
Containment Radiant Energy Shields
Separation of Pressurizer Heater Power
Auxiliary Building Fire Wall
One Train of Instrument Air Tubing Separated

Those proposed to be completed during the exemption period, the time between the Spring 1983 refueling outage and the Spring 1984 refueling outage, and those which can safely be done while the plant is operating, are as follows:

Residual Heat Removal Pumps Backup Power Available
Screen House Power Separated
Turbine Building Fire Wall
Charging Pumps Power Separated
Auxiliary Feedwater Pumps Power Separated
Safety Injection Pumps Power Separated
Containment Fan Coil Units Power Separated

Remaining items for the Spring 1984 refueling outage are:

Component Cooling Water Pumps Power Separated
Dedicated Shutdown Panel Wired and Tested

It can be seen that work on the alternative shutdown system will proceed during the exemption period and that safety will be improved over and above the current alternate shutdown capability assured by meeting Appendix A to BTP 9.5-1.

The August 4, 1982 submittal also documents the considerations of the impact on the plant during the modifications for the alternative shutdown. Many items have extensive lead times, in particular, the dedicated shutdown panel (optimistically estimated to be 10 months). The procurement times of various components are shown by the schedule to be a critical factor. About 71 of the 136 components need the panel installed in order to complete the termination and perform final check out. Measures such as shop overtime and bonus payments are being taken to accelerate the procurement schedules or least assure that they can be met.

The effect of interdependence of other work such as the 10 year inservice inspection program tests and the containment integrated leak rate tests on other portions of the shutdown systems has been considered by the licensee. Other plant modifications which affect the same plant areas, cables and equipment must be prepared for installation during the same outage as those for Appendix R. Work on certain equipment can only be accomplished during specific modes of operation, such as cooldown or shutdown. Although a complicating factor, these items have been worked into the implementation schedule.

There is a constraint on the number of contract people that can actually be properly managed by licensee personnel or for that matter, the number that can actually work in the confined areas involved at any one time. Increase of labor force can be only a limited help and that has been considered by the licensee. There is a limit on the amount of work that can be safely undertaken at any given time considering the reviews and approvals which are necessary.

Finally, there is significant amount of time required for updating drawings and procedures and subsequently providing time for the operators and other plant staff to comprehend the changes.

The above considerations documented by the licensee are a visible showing of a good faith effort being made. Indeed, the fact that this licensee is the first to have an alternative shutdown system approved (December 1981) with a schedule this far advanced is evidence of the previous good faith efforts they have made. A large number of other licensees have submitted design descriptions for an alternative shutdown system on July 1, 1982. Given the time for review and approval by the NRC, the completion of modifications at most of those plans in accordance with 10 CFR 50.48(c)(4) will not occur prior to the time requested in this exemption. This licensee's good faith effort also shows with regard to regulatory requirements in general. The recent NRC Systematic Assessment of Licensing Performanee evaluation of the day-to-day operation of the plant is further evidence of the quality of operation and management of this plant.

We have reviewed the licensee submittals, in particular, the improvements in safety realized with the proposed schedule, as outlined in attachment 1 of the submittal dated August 4, 1982. In this submittal the licensee documented the information presented at a meeting with the staff on June 23, 1982, which includes, among other things, an implementation schedule for the alternative shutdown system required by Appendix R to 10 CFR Part 50.

Based on the above considerations, we find that the licensee has completed a substantial part of the fire protection features at the Kewaunee plant in conformance with the requirements of the Fire Protection Rule and is applying significant effort to complete the remaining modifications necessary for strict conformance with Sections III.G and III.L. We find that because of the already-completed upgrading of these facilities, there is no undue risk to the health and safety of the public involved with continued operation until the completion of this implementation during the Spring 1984 refueling outage.

III.

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, an exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest and therefore grants an exemption from the schedular requirements of 10 CFR 50.48(c)(4) until prior to startup from the second refueling outage commencing more than 180 days after December 1981, the date of approval for the modifications.

The NRC staff has determined that the granting of this exemption will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with this action.

For further details with respect to this action see (1) the licensee's request dated January 22, 1982, as supplemented August 4, 1982, and (2) NRC approval dated December 22, 1981, which are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. and at the Kewaunee Public Library, 822 Juneau Street, Kewaunee, Wisconsin 54216.

Dated at Bethesda, Maryland this 7th day of October 1982.

For the Nuclear Regulatory Commission.

Harold R. Denton,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 82-28690 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-364]

Alabama Power Company; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 18 to Facility Operating License No. NPF-8 issued to Alabama Power Company (the licensee), which revised Technical Specifications for operation of the Joseph M. Farley Nuclear Plant, Unit No. 2 (the facility) located in Houston County, Alabama. The amendment is effective as of the date of issuance.

The amendment modifies Technical Specifications for turbine valve testing to grant a waiver during the remainder of the first fuel cycle scheduled to end about October 22, 1982.

The application for the amendment 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. Prior public notice of this amendment was not required since this amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment dated October 8, 1982, (2) Amendment No. 18 to License No. NPF-8, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the George S. Houston Memorial Library, 212 W. Burdeshaw Street, Dothan, Alabama 36303. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 8th day of October 1982.

For the Nuclear Regulatory Commission.

Steven A. Varga,

Chief, Operating Reactors Branch No. 1, Divison of Licensing.

[FR Doc. 82-28678 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

Applications for Licenses To Import/Export; Nuclear Facilities or Materials

Pursuant to 10 CFR 110.70(b) "Public notice of receipt of an application", please take notice that the Nuclear Regulatory Commission has received the following applications for import/export licenses. A copy of each application is on file in the Nuclear Regulatory Commission's Public Document Room located at 1717 H Street, NW., Washington, D.C.

A request for a hearing or a petition for leave to intervene may be filed within 30 days after publication of this notice in the **Federal Register.** Any request for hearing or petition for leave to intervene shall be served by the

requestor or petitioner upon the applicant, the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, the Secretary, U.S. Nuclear Regulatory Commission and the Executive Secretary, Department of State, Washington, D.C. 20520.

In its review of applications for licenses to export production or utilization facilities, special nuclear material or source material, noticed herein, the Commission does not evaluate the health, safety or environmental effects in the recepient nation of the facility or material to be exported. The table below lists all new major applications.

Dated this 8th day of October at Bethesda, Maryland.

For the Nuclear Regulatory Commission.

James V. Zimmerman,

Assistant Director, Export/Import and International Safeguards, Office of International Programs.

FEDERAL REGISTER (EXPORT/IMPORT)

Name of applicant, date of application, date received, application number	Material type	Material in kilograms		End-Use	Country of destination
		Total element	Total isotope		
Transnuclear, Inc., September 30, 1982, September 30, 1982, ISNM82022.	0.85 pct. enriched uranium	13,500	114.75	U.S.-supplied material (from UES/EU/25). To be used as feed for UES-4104-DUE.	From France.
Mitsui & Co., September 27, 1982, September 30, 1982, XSNM01987.	3.95 pct. enriched uranium	11,279	337	Routine reload fuel—Fukushima II, Unit I	Japan.
Transunuclear, October 4, 1982, October 4, 1982, XSNM01988.	93.3 pct. enriched uranium	15,038	14.030	HEU for use in DR3 Research Reactor at Riso	Denmark.

[FR Doc. 82-28679 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-247-SP 50-286-SP]

Consolidated Edison Co. of New York (Indian Point, Unit No. 2) and Power Authority of The State of New York (Indian Point, Unit No. 3); Order (Scheduling Prehearing Conference)

October 12, 1982.

This Board's Memorandum and Order restating contentions, issued on Friday, October 1, 1982, indicated that a prehearing conference to hear oral argument on responses to the order would be held about 25 days following service of the order. The Memorandum and Order was served on Monday, October 4, 1982. Therefore, we have determined that the prehearing conference should be held the first week in November.

Upon consideration of the foregoing and the entire record in this matter, it is, this 12th, day of October, 1982;

Ordered

That a prehearing conference will be held on November 3 and 4, 1982, beginning at 9:30 a.m., in the Ceremonial Courtroom, Westchester County Courthouse, Grove Street, White Plains, New York 10601.

For the Atomic Safety and Licensing Board.

James P. Gleason,

Chairman, Administrative Judge.

Bethesda, Maryland.

[FR Doc. 82-28680 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-373]

Commonwealth Edison Co.; Notice of Issuance of Amendment of Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 8 to Facility Operating License No. NPF-11, issued to Commonwealth Edison Company, which revised Technical Specifications for operation of the La Salle County Station, Unit No. 1 (the facility) located in Brookfield Township, La Salle County, Illinois. The Amendment is effective as of the date of issuance.

The Amendment consists of a revision to the license in that the completion dates of the Safety Parameter Display System and Emergency Operations Facility were changed from October 1, 1982 to December 31, 1982.

The application for amendment 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. Prior public notice of this Amendment was not required since the Amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this Amendment will not result in any significant environmental impact and that pursuant to 10 CFR Section 51.5(d)(4) an environmental impact statement, or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this Amendment.

For further details with respect to this action, see (1) the application for amendment dated September 21, 1982 and (2) Amendment No. 8 to License No. NPF-11 dated October 6, 1982. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. 20555, and the Public Library of Illinois Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348. A copy of items (1) and (2) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 6th day of October 1982.

For the Nuclear Regulatory Commission.

A. Schwencer,

Chief, Licensing Branch No. 2, Division of Licensing.

[FR Doc. 82-28681 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-498 and 50-499]

Houston Power & Lighting Company, et al. (South Texas Project, Units 2 and 2); Request for Action Under 10 CFR 2.206

Notice is hereby given that by its Petition to Suspend Construction of the South Texas Project dated August 4, 1982 (Petition), Citizens Concerned About Nuclear Power, Inc. (CCANP)

requested that certain actions by taken by the Nuclear Regulatory Commission with respect to the South Texas Project of the Houston Power & Lighting Company, et al., in light of certain alleged design deficiencies. The relief requested included immediate suspension of construction at the South Texas Project, an independent third party review of the project design, and consideration by the Atomic Saftety & Licensing Board to examine the alleged design deficiencies. The Petition is being treated pursuant to 10 CFR 2.206 of the Commission's regulations, and accordingly, action will be taken on the Petition within a reasonable time. Copies of the Petition are available for inspection in the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555, and in the Local Public Document Room, for the South Texas Project, located at the Bay City Library, 1900 Fifth Street, Bay City, Texas 77414, and the Austin Public Library, 810 Guadalupe Street, Austin, Texas 78768

Dated at Bethesda, Maryland, this 12th day of October, 1982.

Before the Nuclear Regulatory Commission.

Harold R. Denton,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 82-28682 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-263]

Northern States Power Co.; Notice of Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 11 to Facility Operating License No. DPR-22, issued to Northern States Power Company, which revised the license and the Technical Specifications for operation of the Monticello Nuclear Generating Plant (the facility) located in Wright County, Minnesota. The amendment is effective as of its date of issuance.

The amendment modifies the Technical Specification as a result of the long-term modifications to the Scram Discharge Volume that will improve system reliability. The amendment also authorizes changes to the Technical Specifications to clarify limiting conditions of operation for the control rod accumulators. The amendment further authorizes the removal of interim conditions that were implemented by the Commission's Order of January 9, 1981.

The applications for amendment comply 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. Prior public notice of the amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appaisal need not be prepared in connection with the issuance of the amendment.

For further details with respect to this action, see (1) the applications for amendment dated July 12, 1982 and September 17, 1982, as supplemented September 7 and 23, 1982, (2) Amendment No. 11 to License No. DPR-22, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the Environmental Conservation Library, Minneapolis Public Library, 300 Nicollet Mall, Minneapolis, Minnesota. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 8th day of October 1982.

For the Nuclear Regulatory Commission.

Domenic B. Vassallo,

Chief, Operating Reactors Branch No. 2, Division of Licensing.

[FR Doc. 82-28683 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-244]

Rochester Gas and Electric Corp.; R.E. Ginna Nuclear Power Plant; Issuance of Amendment to Provisional Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 54 to Provisional Operating License No. DPR-18, to Rochester Gas and Electric Corporation (the licensee), which revised the Technical Specifications for operation of the R.E. Ginna Nuclear Power Plant (facility) located in Wayne County, New York. This amendment is effective as of its date of issuance.

The amendment approves provisions which update the containment isolation valve Table 3.6-1, to reflect the installation of a new air-operated valve.

The application for the amendment 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. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment notarized September 28, 1982, (2) Amendment No. 54 to License No. DPR-18, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the Rochester Public Library, 115 South Avenue, Rochester, New York 14627. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C., 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 7th day of October, 1982.

For the Nuclear Regulatory Commission.

Dennis M. Crutchfield,

Chief, Operating Reactors Branch No. 5, Division of Licensing.

[FR Doc. 82-28684 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-244]

Rochester Gas and Electric Corp.; Notice of Issuance of Amendment—Provisional Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 55 Provisional Operating License No. DPR-18, to Rochester Gas and Electric Corporation (the Licensee), which revised the license for operation of the R. E. Ginna Nuclear Power Plant (facility) located in Wayne County, New York. This amendment is effective as of its date of issuance.

The amendment incorporates a new license condition which confirms the schedule for the next steam generator inspection.

The licensee's letter dated October 6, 1982, which is being handled by the Commission as an 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. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the licensee's letter dated October 6, 1982, (2) Amendment No. 55 to License No. DPR-18, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the Rochester Public Library, 115 South Avenue, Rochester, New York 14627. A copy of items (2) and (3) may be obained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Behtesda, Maryland, this 8th day of October, 1982.

For the Nuclear Regulatory Commission.

Dennis M. Crutchfield,

Chief, Operating Reactors Branch No. 5, Division of Licensing.

[FR Doc. 82-28685 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-361]

Southern California Edison Company, et al.; Issuance of Amendment, Facility Operating License No. NPF-10

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 9 to Facility Operating License No. NPF-10, issued to Southern California Edison Company, San Diego Gas and Electric Company, The City of Riverside, California and The City of Anaheim, California (licensees) for the San Onofre Nuclear Generating Station, Unit 2 (the facility) located in San Diego County, California. This amendment is effective as of the date of issuance.

Amendment No. 9 changes the Technical Specifications to allow operation in MODES 2 and 3 with the turbine overspeed protection system inoperable, provided that steam is isolated from the turbine.

Issuance of this amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations. The Commission has made appropriate findings as required by the Act and the Commission's regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement, or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) Southern California Edison Company's letter dated September 30, 1982, (2) Amendment No. 9 to Facility Operating License No. NPF-10, and (3) the Commission's related Safety Evaluation.

These items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C., and the San Clemente Library, 242 Avenida Del Mar, San Clemente, California 92672. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 7th day of October, 1982.

For the Nuclear Regulatory Commission.

Victor Nerses,

Acting Chief, Licensing Branch No. 3, Division of Licensing.

[FR Doc. 82-28686 Filed 10-18-82; 8:45 am]

BILLING CODE 7590-01-M

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL

Forecasting Subcommittee Meeting

AGENCY: Pacific Northwest Electric Power and Conservation Planning Council (Northwest Power Planning Council).

ACTION: Notice of meeting.

STATUS: Open.

SUMMARY: The Northwest Power Planning Council hereby announces a forthcoming meeting of the Forecasting Subcommittee of its Scientific and Statistical Advisory Committee.

DATE: Thursday, October 28, 1982. 9:00 a.m.

ADDRESS: The meeting will be held at the Council's Central Office located at 700 S. W. Taylor Street, Suite 200, Portland, Oregon.

FOR FURTHER INFORMATION CONTACT: Annette Frahm, (503) 222-5161.

Edward Sheets,

Executive Director.

[FR Doc. 82-28618 Filed 10-18-82; 8:45 am]

BILLING CODE 0000-00-M

Resource Assessment Subcommittee Meeting

AGENCY: Pacific Northwest Electric Power and Conservation Planning Council (Northwest Power Planning Council).

ACTION: Notice of meeting.

STATUS: Open.

SUMMARY: The Northwest Power Planning Council hereby announces a forthcoming meeting of the Resource Assessment Subcommittee of its Scientific and Statistical Advisory Committee.

DATE: Friday, October 22, 1982. 9:00 a.m.

ADDRESS: The meeting will be held at the Council's Central Office located at 700 S. W. Taylor Street, Suite 200 Portland, Oregon.

FOR FURTHER INFORMATION CONTACT: Annette Frahm, (503) 222-5161.

Edward Sheets,

Executive Director.

[FR Doc. 82-28619 Filed 10-18-82; 8:45 am]

BILLING CODE 0000-00-M

DEPARTMENT OF THE TREASURY

Customs Service

Proposed Revocation of Landing Rights Designation of Melbourne Regional Airport; Solicitation of Comments

AGENCY: Customs Service, Treasury.

ACTION: Notice of proposed revocation of landing rights designation; solicitation of comments.

SUMMARY: This notice invites comments on a proposal to discontinue Customs

service at Melbourne Regional Airport in Melbourne, Florida, in view of the low level of international aircraft arrivals there and the significant expense involved in processing those arrivals.

DATE: Comments must be received on or before December 20, 1982.

ADDRESS: Written comments should be addressed to the Commissioner of Customs, Attention: Regulations Control Branch, U.S. Customs Service, 1301 Constitution Avenue, NW., Room 2426, Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Harry Carnes, Office of Passenger Enforcement and Facilitation, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229 (202-566-5607).

SUPPLEMENTARY INFORMATION:

Background

Under section 1109(b) of the Federal Aviation Act of 1958 (49 U.S.C. 1509(b)), the Secretary of the Treasury is authorized to designate places in the United States as ports of entry for civil aircraft arriving from any place outside of the United States and for merchandise carried on the aircraft. These airports are referred to as "international airports," and the location and name of each are listed in section 6.13, Customs Regulations (19 CFR 6.13).

In accordance with § 6.2, Customs Regulations (19 CFR 6.2), the first landing of every civil aircraft arriving in the United States must be at an "international airport" unless the aircraft has been specifically exempted from this requirement or permission to land elsewhere has been granted. Customs officers are assigned to all international airports to accept entries of merchandise, collect duties, and enforce Customs laws and regulations. If a civil aircraft desires to land at a "landing rights airport," which means an airport which has not been designated as an international airport, permission first must be obtained, and Customs must assign personnel to that airport for that aircraft.

The Melbourne Regional Airport at Melbourne, Florida, has been a "landing rights airport" since July 1971.

Arrivals of aircraft from outside the United States at Melbourne Regional Airport are handled by a small staff of Customs officers from Port Canaveral, Florida which is 30 miles from Melbourne. There are two other landing rights airports in the general area that process international arrivals: the St. Lucie County International Airport in Fort Pierce, Florida, which is approximately 50 miles south of Melbourne, and the Orlando International Airport in Orlando, Florida, which is approximately 50 miles northwest of Melbourne.

Since 1971, there has been a low level of international aircraft arrivals at Melbourne Regional Airport. The costs to Customs to process these arrivals have been significant. The excessive time spent by Customs officers in traveling to and from Melbourne for the limited number of arrivals is a nonproductive expenditure of scarce resources. In addition, Customs has recently implemented an intensified enforcement program in South and Central Florida, to combat the influx of narcotics into the United States by air. That program has necessitated a concentration of Customs resources into eight Florida airports.

Accordingly, after a review of airport operations in Florida, it is proposed to discontinue Customs service at Melbourne Regional Airport by revoking its landing rights designation. This is part of Customs continuing program to obtain more efficient use of its personnel, facilities, and resources, and to provide better service to carriers, importers, and the public.

Authority

The authority for this proposal is R.S. 251, as amended, section 624, 46 Stat. 759, section 1109, 72 Stat. 799, as amended (19 U.S.C. 66, 1624, 49 U.S.C. 1509).

Comments

Before adopting this proposal, consideration will be given to any written comments, preferably in triplicate, submitted timely to the Commissioner of Customs. Comments submitted will be available for public inspection in accordance with section 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m. at the Regulations Control Branch, Headquarters, U.S. Customs Service, 1301 Constitution Avenue, NW., Room 2426, Washington, D.C. 20229.

Drafting Information

The principal author of this document was Gerard J. O'Brien, Jr., Regulations Control Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

Dated: August 24, 1982.

William von Raab,

Commissioner of Customs.

[FR Doc. 82-28062 Filed 10-18-82; 8:45 am]

BILLING CODE 4820-02-M

Internal Revenue Service

[Delegation Order No. 198]

Delegation of Authority

AGENCY: Internal Revenue Service, Treasury.

ACTION: Delegation of Authority.

SUMMARY: This order authorizes Regional Commissioners, District Directors, Service Center Directors, and the Director, Data Center to redelegate to supervisors, GS-12 and above and to Disclosure Officers the authority granted to them by 26 CFR 301.7514-1 to affix the official seal of office. This order also grants the authority to these same officials to certify to the authenticity of documents. The text of the delegation order appears below.

EFFECTIVE DATE: October 8, 1982.

FOR FURTHER INFORMATION CONTACT: George Leda, PM:S:DS, Room 3619, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224, (202) 566-3370 (not a toll-free telephone number).

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the Treasury Directive appearing in the **Federal Register** for Wednesday, November 8, 1978.

R. L. Rizzo,

Director, Disclosure and Security Division.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[Order No. 198]

Delegation Order:

Date of issue: October 8, 1982.

Effective Date: October 8, 1982.

Subject: Authority to Affix the Official Seal of Office of the Internal Revenue Service and to Certify to the Authenticity of Official Documents.

(1) Pursuant to the Authority vested in the Commissioner of Internal Revenue by Treasury Department Order No. 150-37 and 26 CFR 301.7701-9, the authority granted to Regional Commissioners, District and Service Center Directors, and the Director, Data Center by 26 CFR 301.7514-1, to affix the official seal of office to any certificate or attestation required to be made by the officer for whose office such seal is established in authentication of originals and copies of books, records, papers, writings and documents of the Internal Revenue Service in the custody of such officers, for all purposes including the purpose of 28 U.S.C. 1733(b), Rule 44 of the Federal Rules of Civil Procedure, and Rule 27 of the Federal Rules of Criminal Procedure, may be redelegated to supervisors, GS-12 and above, and to Disclosure Officers.

(2) The authority delegated in paragraph (1) does not extend to:

(a) Affixing such seal to material to be published in the **Federal Register**, and

(b) Affixing the seal of the District Director to the certification of copies of books, records, papers, writings, or documents in his/her custody in any case in which, pursuant to Executive Order, Treasury Decision, or the Statement of Procedural Rules, such copies may be furnished to applicants only by the Commissioner.

(3) Under the authority granted to the Commissioner of Internal Revenue by 26 CFR 301.7622-1, there is hereby delegated to the following officials the authority to certify to the authenticity of originals and copies of books, records, papers, writings, and documents of the Internal Revenue Service in the custody of such officer, for all purposes, including the purpose of 28 U.S.C. 1733(b), Rule 44 of the Federal Rules of Civil Procedure, and Rule 27 of the Federal Rules of Criminal Procedure:

(a) Regional Commissioners.

(b) District Directors.

(c) Service Center Directors.

(d) Director, Data Center.

(4) The authority in paragraph (3) may be redelegated to supervisors, GS-12 and above, and to Disclosure Officers.

(5) To the extent that authority previously exercised consistent with this Order may require ratification, it is hereby affirmed and ratified.

James I. Owens,

Deputy Commissioner.

[FR Doc. 82-28590 Filed 10-18-82; 8:45 am]

BILLING CODE 4830-01-M

[Delegation Order No. 97 (Rev 21)]

Delegation of Authority

AGENCY: Internal Revenue Service, Treasury.

ACTION: Delegation of Authority.

SUMMARY: Authority is delegated to the Deputy Chief Counsel to enter into and approve a closing agreement with any person for a taxable period or periods ended prior to the date of agreement and related specific items affecting other taxable periods. The text of the delegation order appears below.

EFFECTIVE DATE: October 8, 1982.

FOR FURTHER INFORMATION CONTACT: Joseph DeStefanis, CC:AP:PT, Room 2309, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224, (202) 566-4881 (not a toll-free telephone number).

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the Treasury Directive appearing in the **Federal Register** for Wednesday, November 8, 1978.

Howard T. Martin,

Director, Appeals Division.

Delegation Order

Date of issue: October 8, 1982.

Effective Date: October 8, 1982.

Closing Agreements Concerning Internal Revenue Tax Liability

Pursuant to authority granted to the Commissioner of Internal Revenue by 26 CFR 301.7121-1(a); Treasury Department Order No. 150-32; Treasury Department Order No. 150-36; and Treasury Department Order No. 150-83, subject to the transfer of authority covered in Treasury Department Order No. 221, as modified by Treasury Department Order No. 221-3 (Rev. 2), 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 requests to the Chief Counsel for determination or ruling was made before any affected returns have been filed.

2. The Deputy Chief Counsel and the Assistant Commissioner (Examination), are 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) for a taxable period or periods ended prior to the date of agreement and related specific items affecting other taxable periods. The Associate Commissioner (Operations) 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. Regional Commissioners; Regional Counsel; Regional Directors of Appeals; Assistant Regional Commissioners (Examination); 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 Counsel (Technical); the Assistant Commissioner (Employee Plans and Exempt Organizations); Regional Commissioners; Regional Counsel; Regional Directors of Appeals; 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 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 Director, Foreign Operations District, 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) to provide for the mitigation of economic double taxation under section 3 of Revenue Procedure 64-54, C.B. 1964-2, 1008 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 Counsel (Technical) and to the technical advisors on the staff of the Associate Chief Counsel (Technical) for cases that do not involve precedent issues, the Assistant Commissioner (Examination) may redelegate the authority contained in paragraph 2 of this Order to the Deputy Assistant Commissioner (Examination), the Deputy Chief Counsel may redelegate the authority in paragraph 2 of this Order but not lower than the Deputy Associate Chief Counsel (Litigation), 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; and District Directors may redelegate the authority contained in paragraph 4 of this Order but not below the Chief, Quality Review Staff, or Section Chief, Quality Review Staff.

9. Delegation Order No. 97 (Rev. 20), issued September 7, 1982, is hereby superseded.

James I. Owens,

Deputy Commissioner.

[FR Doc. 82-28591 Filed 10-18-82; 8:45 am]

BILLING CODE 4830-01-M

Office of the Secretary

[Dept. Circular Public Debt Series-No. 27-82]

Treasury Notes of October 31, 1984, Series X-1984

Washington, October 14, 1982.

1. Invitation for Tenders

1.1. The Secretary of the Treasury, under the authority of the Second Liberty Bond Act, as amended, invites tenders for approximately $6,750,000,000 of United States securities, designated Treasury Notes of October 31, 1984, Series X-1984 (CUSIP No. 912827 NT 5). The securities will be sold at auction, with bidding on the basis of yeild. Payment will be required at the price equivalent of the bid yield of each accepted tender. The interest rate on the securities and the price equivalent of each accepted bid will be determined in the manner described below. Additional amounts of these securities may be issued to Government accounts and Federal Reserve Banks for their own account in exchange for maturing Treasury securities. Additional amounts of the new securities may also be issued at the average price to Federal Reserve Banks, as agents for foreign and international monetary authorities.

2. Description of Securities

2.1. The securities will be dated November 1, 1982, and will bear interest from that date, payable on a semiannual basis on April 30, 1983, and each subsequent 6 months on October 31 and April 30 until the principal becomes payable. They will mature October 31, 1984, and will not be subject to call for redemption prior to maturity. In the event an interest payment date or the maturity date is a Saturday, Sunday, or other nonbusiness day, the interest or principal is payable on the next-succeeding business day.

2.2. The income derived from the securities is subject to all taxes imposed under the Internal Revenue Code of 1954. The securities are subject to estate, inheritance, gift, or other excise taxes, whether Federal or State, but are exempt from all taxation now or hereafter imposed on the principal or interest thereof by any State, any possession of the United States, or any local taxing authority.

2.3. The securities will be acceptable to secure deposits of public monies. They will not be acceptable in payment of taxes.

2.4. Bearer securities with interest coupons attached, and securities registered as to principal and interest, will be issued in denominations of $5,000, $10,000, $100,000, and $1,000,000. Book-entry securities will be available to eligible bidders in multiples of those amounts. Interchanges of securities of different denominations and of coupon, registered, and book-entry securities, and the transfer of registered securities will be permitted.

2.5. The Department of the Treasury's general regulations governing United States securities apply to the securities offered in this circular. These general regulations include those currently in effect, as well as those that may be issued at a latter date.

3. Sale Procedures

3.1. Tenders will be received at Federal Reserve Banks and Branches and at the Bureau of the Public Debt, Washington, D. C. 20226, up to 1:30 p.m., Eastern Daylight Saving time, Wednesday, October 20, 1982. Noncompetitive tenders as defined below will be considered timely if postmarked no later than Tuesday, October, October 19, 1982, and received no later than Monday, November 1, 1982.

3.2. Each tender must state the face amount of securities bid for. The minimum bid is $5,000, and larger bids must be in multiples of that amount. Competitive tenders must also show the yield desired, expressed in terms of an annual yield with two decimals, e.g., 7.10%. Common fractions may not be used. Noncompetitive tenders must show the term "noncompetitive" on the tender form in lieu of a specified yield. No bidder may submit more than one noncompetitive tender, and the amount may not exceed $1,000,000.

3.3. Commercial banks, which for this purpose are defined as banks accepting demand deposits, and primary dealers, which for this purpose are defined as dealers who make primary markets in Government securities and report daily to the Federal Reserve Bank of New York their positions in and borrowings on such securities, may submit tenders for account of customers if the names of the cutomers and the amount for each customer are furnished. Others are only permitted to submit tenders for their own account.

3. 4. Tenders will be received without deposit for their own account from commercial banks and other banking institutions; primary dealers, as defined above; Federally-insured savings and loan associations; States, and their political subdivisions or instrumentalities; public pension and retirement and other public funds; international organizations in which the United States holds membership; foreign central banks and foreign states; Federal Reserve Banks; and Government accounts. Tenders from others must be accompanied by full payment for the amount of securities applied for (in the form of cash, maturing Treasury securities, or readily collectible checks), or by a payment guarantee of 5 percent of the face amount applied for, from a commercial bank or a primary dealer.

3. 5. Immediately after the closing hour, tenders will be opened, followed by a public announcement of the amount and yield range of accepted bids. Subject to the reservations expressed in Section 4, noncompetitive tenders will be accepted in full, and then competitive tenders will be accepted, starting with those at the lowest yields, through successively higher yields to the extent required to attain the amount offered. Tenders at the highest accepted yield will be prorated if necessary. After the determination is made as to which tenders are accepted, a coupon rate will be established, on the basis of a ⅛ of one percent increment, which results in an equivalent average accepted price close to 100.000 and a lowest accepted price above the original issue discount limit of 99.750. That rate of interest will be paid on all of the securities. Based on such interest rate, the price on each competitive tender allotted will be determined and each successful competitive bidder will be required to pay the price equivalent to the yield bid. Those submitting noncompetitive tenders will pay the price equivalent to the weighted average yield of accepted competitive tenders. Price calculations will be carried to three decimal places on the basis of price per hundred, e.g., 99.923, and the determinations of the Secretary of the Treasury shall be final. If the amount of noncompetitive tenders received would absorb all or most of the offering, competitive tenders will be accepted in an amount sufficient to provide a fair determination of the yield. Tenders received from Government accounts and Federal Reserve Banks will be accepted at the price equivalent to the weighted average yield of accepted competitive tenders.

3. 6. Competitive bidders will be advised of the acceptance or rejection of their tenders. Those submitting noncompetitive tenders will only be notified if the tender is not accepted in full, or when the price is over par.

4. Reservations

4. 1. The Secretary of the Treasury expressly reserves the right to accept or reject any or all tenders in whole or in part, to allot more or less than the amount of securities specified in Section 1, and to make different percentage

allotments to various classes of applicants when the Secretary considers it in the public interest. The Secretary's action under this Section is final.

5. Payment and Delivery

5. 1. Settlement for allotted securities must be made at the Federal Reserve Bank or Branch or at the Bureau of the Public Debt, wherever the tender was submitted. Settlement on securities allotted to institutional investors and to others whose tenders are accompanied by a payment guarantee as provided in Section 3.4., must be made or completed on or before Monday, November 1, 1982. Payment in full must accompany tenders submitted by all other investors. Payment must be in cash; in other funds immediately available to the Treasury; in Treasury bills, notes, or bonds, (with all coupons detached) maturing on or before the settlement date but which are not overdue as defined in the general regulations governing United States securities; or by check drawn to the order of the institution to which the tender was submitted, which must be received from institutional investors no later than Thursday, October 28, 1982. When payment has been submitted with the tender and the purchase price of allotted securities is over par, settlement for the premium must be completed timely, as specified in the preceding sentence. When payment has been submitted with the tender and the purchase price is under par, the discount will be remitted to the bidder. Payment will not be considered complete where registered securities are requested if the appropriate identifying number as required on tax returns and other documents submitted to the Internal Revenue Service (an individual's social security number or an employer identification number) is not furnished. When payment is made in securities, a cash adjustment will be made to or required of the bidder for any difference between the face amount of securities presented and the amount payable on the securities allotted.

5. 2. In every case where full payment has not been completed on time, an amount of up to 5 percent of the face amount of securities allotted, shall, at the discretion of the Secretary of the Treasury, be forfeited to the United States.

5. 3. Registered securities tendered in payment for allotted securities are not required to be assigned if the new securities are to be registered in the same names and forms as appear in the registrations or assignments of the securities surrendered. When the new securities are to be registered in names and forms different from those in the inscriptions or assignments of the securities presented, the assignment should be to "The Secretary of the Treasury for (securities offered by this circular) in the name of (name and taxayer identifying number)." If new securities in coupon form are desired, the assignment should be to "The Secretary of the Treasury for coupon (securities offered by this circular) to be delivered to (name and address)." Specific instructions for the issuance and delivery of the new securities, signed by the owner or authorized representative, must accompany the securities presented. Securities tendered in payment should be surrendered to the Federal Reserve Bank or Branch or to the Bureau of the Public Debt, Washington, D.C. 20226. The securities must be delivered at the expense and risk of the holder.

5. 4. If bearer securities are not ready for delivery on the settlement date, purchasers may elect to receive interim certificates. These certificates shall be issued in bearer form and shall be exchangeable for definitive securities of this issue, when such securities are available, at any Federal Reserve Bank or Branch or at the Bureau of the Public Debt, Washington, D.C. 20226. The interim certificates must be returned at the risk and expense of the holder.

5. 5. Delivery of securities in registered form will be made after the requested form of registration has been validated, the registered interest account has been established, and the securities have been inscribed.

6. General Provisions

6. 1. As fiscal agents of the United States, Federal Reserve Banks are authorized and requested to receive tenders, to make allotments as directed by the Secretary of the Treasury, to issue such notices as may be necessary, to receive payment for and make delivery of securities on full-paid allotments, and to issue interim certificates pending delivery of the definitive securities.

6. 2. The Secretary of the Treasury may at any time issue supplemental or amendatory rules and regulations governing the offering. Public announcement of such changes will be promptly provided.

Gerald Murphy,

Acting Fiscal Assistant Secretary.

[FR Doc. 82-28631 Filed 10-14-82; 2:39 pm]

BILLING CODE 4810-40-M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 202
Tuesday, October 19, 1982

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).

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1

CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 10 a.m., Thursday, October 21, 1982.

LOCATION: Room 456, Westwood Towers, 5401 Westbard Avenue, Bethesda, Maryland.

STATUS: Closed to the Public.

MATTER TO BE CONSIDERED:

Enforcement Matter OS# 4549
The Commission will consider enforcement matter OS# 4549.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Shelton D. Butts, Deputy Secretary, Office of the Secretary, Room 342, 5401 Westbard Avenue, Bethesda, Maryland 20207, (301) 492-6800.

[S-1495-82 Filed 10-15-82; 11:17 am]

BILLING CODE 6355-01-M

2

CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 10 a.m., Wednesday, October 20, 1982.

LOCATION: Third Floor Hearing Room, 1111-18th Street N.W., Washington, D.C. 20207.

STATUS: Open to the Public.

MATTERS TO BE CONSIDERED:

1. *Section 6(b), CPSA*
The Commission will consider issues related to a proposed rule which would establish the Commission policy and procedure for the public disclosure of information under Section 6(b) of the Consumer Product Safety Act.
2. *Flymo Power Mower Petition CP 82-4*
The Commission will consider issues related to a petition from Flymo, Inc. which requests an exemption for gasoline-fueled, air cushion mowers from the requirements of certain sections of the Safety Standard for Walk-Behind Power Lawn Mowers, 16 C.F.R. Part 1206.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Deputy Secretary Office of the Secretary, Room 342, 5401 Westbard Avenue, Bethesda, Maryland 20207, (301) 492-6800.

[S 1494-82 Filed 10-15-82; 11:17 am]

BILLING CODE 6355-01-M

3

FEDERAL COMMUNICATIONS COMMISSION

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, October 21, 1982, which is scheduled to commence at 9:30 A.M., in Room 856, at 1919 M Street, N.W., Washington, D.C.

Agenda, Item No., and Subject

General—1—Title: Memorandum Opinion and Order in the Matter of Amendment of Part I, Rules of Practice and Procedure to Provide for Certain Changes in the Commission's Discovery Procedures in Adjudicatory Hearings. Summary: The FCC will consider whether to adopt a Memorandum Opinion and Order revising some of the Commission's discovery rules. The Memorandum Opinion and Order follows a study by the Commission's staff of a report prepared by Max D. Paglin entitled "Report on Evaluation of the Federal Communications Commission's Discovery Procedures in Adjudicatory Hearings."

Private Radio—1—Title: Amendment of Section 90.555(b) of the Commission's Rules to Provide Geographic Reallocation of certain channels in the Detroit area to the Business Radio Service. Summary: This order would deny two petitions filed by Exposition Communications & Technology, Inc. for reconsideration of the Commission's decision and for stay of the effective date of the rule change adopted in this proceeding.

Private Radio—2—Title: Amendment of Part 97 of the rules to provide for full Morse code examination credit for commercial radiotelegraph operators applying for amateur radio operator licenses. Summary: The Commission will consider whether to amend its rules to give all persons who are or have been commercial radiotelegraph operators within the last five years telegraphy examination credit on all amateur radio operator examinations.

Private Radio—3—Title: Amendment of the Amateur Radio Service Rules (Part 97) regarding one-way transmissions for experimental and technical investigation. Summary: The Commission will consider whether to adopt an Order amending Part 97 of the Rules to define certain kinds of experimental transmissions by amateur radio stations as "beacon operation." The rule amendments would also authorize automatic control of stations in beacon operation.

Private Radio—4—Title: Amendment of the Amateur Radio Service Rules to eliminate requirements that licensees maintain a detailed log of station operation. Summary: The Commission will consider whether to adopt a Notice of Proposed Rulemaking proposing to amend Part 97 of the Rules to eliminate most recordkeeping requirements for licensees of amateur radio stations.

Private Radio—5—Title: In the Matter of Amendment of Part 97 of the Commission's Rules to Revise the Procedures for Determining Eligibility for the Novice Class Amateur Radio Operator License. Summary: The FCC will consider whether to adopt a Notice of Proposed Rulemaking proposing to amend Part 97 to eliminate the mail-back procedure in determining eligibility for the Novice Class amateur radio operator license.

Private Radio—6—Title: Amendment of Part 83 of the Commission's rules to allow the use of radio rescue devices in small vessels in the Maritime Services. Summary: The Commission will decide whether to adopt a Notice of Inquiry which invites the public to comment on the technical and non-technical requirements of radio rescue devices that could be used in small vessels, such as recreational boats.

Private Radio—7—Title: Three petitions for rulemaking requesting expansion and modification of the Citizens Band Radio Service and the establishment of new personal radio services. Summary: The Commission will consider an Order addressing three petitions for rulemaking. RM-3299, filed by *CB Magazine;* RM-3317, filed by the Washington State CB Radio Association; and a petition for rulemaking from the Personal Radio Operators International Federation of Vista, California.

Common Carrier—1—Title: Amendment to Annual Report of Licensees in Public Mobile Radio Services (FCC Form L). Summary: The Commission will consider whether to adopt a Report and Order to ease or eliminate the reporting requirements of annual reports for licensees in the Public Mobile Radio Services.

Common Carrier—2—Title: Applications to construct Cellular Communications Systems in Chicago, Illinois. Summary: The Commission will consider the three pending applications, one wireline and two nonwireline, to construct cellular radio systems in Chicago. The principal issues involved are the financial qualifications of the nonwireline applicants, the requests for deferral of the wireline authorizations, and

one nonwireline applicant's conformance with the Cellular Rules.

Renewal—1—Title: License Renewal Application of Provident Broadcasting Company for Station WQCK(FM), Manchester, Georgia. Summary: The East Central Alabama-West Central Georgia Minority Christian Broadcast Coalition filed a petition to deny alleging that licensee's programing does not serve the needs and interests of the local minority population and that licensee's employment practices regarding minorities do not comply with the Commission's EEO rules and policies. The Commission considers petitioner's allegations.

Television—1—Title: Motion for stay pending judicial review of the Commission's decision granting the applications of four Charleston, S.C., VHF stations for major changes in their facilities. Summary: Grant of the applications would improve VHF service in areas now served by UHF stations licensed to Columbia and Florence, S.C., and the petitioners allege that the grants are contrary to the UHF impact doctrine. The Commission will consider whether issuance of the stay is warranted.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Maureen Peratino, FCC Public Affairs Office, telephone number (202) 254–7674.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[S–1492–82 Filed 10–15–82; 10:46 am]

BILLING CODE 6712–01–M

4

FEDERAL COMMUNICATIONS COMMISSION

The Federal Communications Commission will hold a Closed Meeting on the subjects listed below on Thursday, October 21, 1982, following the Open Meeting which is scheduled to commence at 9:30 A.M., in Room 856, at 1919 M Street, N.W., Washington, D.C.

Agenda, Item No., and Subject

Hearing—1—Petitions for Reconsideration in the Gloucester, Massachusetts comparative FM renewal proceeding (Docket Nos. 21104 and 21105).

Hearing—2—Application for Review of Designation Order in the Bayamon, Puerto Rico, comparative TV proceeding (Docket Nos. 82–498, 82–499 and 82–500).

Hearing—3—Application for Review of a Memorandum Opinion and Order of the Review Board in the Tallulah, Louisiana FM proceeding (Docket Nos. 81–449 and 81–450).

Hearing—4—Draft Decision in the Hart, Michigan, comparative FM proceeding (Docket Nos. 80–688 and 80–689).

Hearing—5—Applications for Review of a Hearing Designation Order and questions certified by the ALJ in the Vallejo, California, comparative TV proceeding (Docket Nos. 81–912–16).

These items are closed to the public because they concern adjudicatory matters (See 47 CFR 0.603(j)).

The following persons are expected to attend:

Commissioners and their Assistants
General Counsel and members of his staff
Managing Director and members of his staff
Chief, Office of Public Affairs and members of his staff

Action by the Commission:

Hearing Items 1 thru 4 October 12, 1982. Commissioners Fowler, Chairman; Quello, Fogarty, Jones, Dawson and Rivera voting to consider these items in Closed Session.

Hearing Item 5 October 12, 1982. Commissioners Fowler, Chairman; Quello, Fogarty, Jones, Dawson, Rivera and Sharp voting to consider this item in Closed Session.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Maureen Peratino, FCC Public Affairs Office, telephone number (202) 254–7674.

Issued: October 14, 1982.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[S–1493–82 Filed 10–15–82; 10:45 am]

BILLING CODE 6712–01–M

5

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Change in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that the following matter is expected to be added to the "Discussion Agenda" for consideration by the Corporation's Board of Directors at its open meeting to be held at 11:00 a.m. on Monday, October 18, 1982:

Memorandum and Resolution re: Final amendment to Part 337 of the Corporation's rules and regulations, entitled "Unsafe and Unsound Banking Practices," which continues the requirement that the boards of directors of insured state nonmember banks approve extensions of credit to bank insiders which exceed $25,000 in the aggregate.

No earlier notice of the change in the subject matter of the meeting was practicable.

Dated: October 15, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S–1490–82 Filed 10–15–82; 3:32 pm]

BILLING CODE 6714–01–M

6

LEGAL SERVICES CORPORATION

Presidential Search Committee

TIME AND DATE: 8:00 a.m.–5:00 p.m., Thursday, October 28, 1982. Executive Session will continue as required.

PLACE: Ramada Inn Central, Cambridge Room, 1430 Rhode Island Avenue, N.W., Washington, D.C.

STATUS OF MEETING: Closed (except for approval of minutes and vote on authorization for closing the meeting to discuss a personnel matter under 45 CFR 1601.22 and 1622.5 (a) and (e).)

MATTERS TO BE CONSIDERED:

1. Minutes
2. Executive Session

CONTACT PERSON FOR MORE INFORMATION: LeaAnne Bernstein, Office of the President, (202) 272–4040.

DATE ISSUED: October 13, 1982.

[S–1490–82 Filed 10–15–82; 10:13 am]

BILLING CODE 6820–35–M

7

LEGAL SERVICES CORPORATION

MEETINGS OF THE BOARD OF DIRECTORS

TIME AND DATE: 2 p.m.–5 p.m., Friday, October 29, 1982; 9 a.m.–5 p.m., Saturday, October 30, 1982.

PLACE: Legal Services Corporation Headquarters, 733 15th Street, N.W., 8th Floor Conference Room, Washington, D.C. 20005.

STATUS OF MEETING: Open (Portion of the meeting may be closed to discuss a personnel matter under 45 CFR 1622.5(a) and 1622.5(3).)

MATTERS TO BE CONSIDERED:

- Adoption of agenda
- Approval of minutes
- Committee reports:

Presidential Search Committee

—Selection of LSC President

Operations and Regulations Committee

—Recommendation on S. 2393

—Recommendation on amendments to Part 1612.4 of the LSC Regulations regarding legislative and administrative representation

—Implementation of restrictions in the 1983 Continuing Resolution for the Corporation

Special Committee on Grant and Contract Procedures

—Implementation of restrictions in the 1983 Continuing Resolution for the Corporation

Provision of Legal Services Committee

—Implementation of restrictions in the 1983 Continuing Resolution for the Corporation

Audit and Appropriations Committee

—Implementation of restrictions in the 1983 Continuing Resolution for the Corporation
—Recommendation on fund balance policy
—1984 budget mark
—1983 budget allocation issues
—Single auditor issue

- Approval of regulation changing Board meeting date
- Approval of regulation establishing position of Vice Chairman of the Board
- President's Report (by LSC staff)
- Election of Board Chairman and Vice Chairman

CONTACT PERSON FOR MORE INFORMATION: Anne Tracy, Office of the President, (202) 272-4040.

DATE ISSUED: October 13, 1982.

Clinton Lyons,

Acting Vice President and Chief Executive Officer.

William F. Harvey,

Chairman of the Board.

[S-1491-82 Filed 10-15-82; 10:13 am]

BILLING CODE 6820-35-M

8

LEGAL SERVICES CORPORATION

JOINT MEETING OF THE PROVISION OF LEGAL SERVICES COMMITTEE AND THE SPECIAL COMMITTEE ON GRANT AND CONTRACT PROCEDURES

PREVIOUSLY ISSUED: October 6, 1982.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 9:30-4:00 P.M. Saturday, October 16, 1982.

CHANGE IN THE MEETING: Addition to the agenda. Matters to be considered will include as item 3: Discussion on the Implementation of the Continuing Resolution and Restrictive Riders: Nondecisional.

CONTACT PERSON FOR MORE INFORMATION: Anne Tracy, Office of the President, (202) 272-4040.

Date issued: October 15, 1982.

Clinton Lyons,

Acting Vice President and Chief Executive Officer.

[S-1497-82 Filed 10-15-82; 3:30 pm]

BILLING CODE 6820-35-M

9

PAROLE COMMISSION

TIME AND DATE: 10 a.m., Tuesday, October 19, 1982.

PLACE: Room 420-F, One North Park Building, 5550 Friendship Boulevard, Chevy Chase, Maryland 20815.

STATUS: Closed pursuant to a vote to be taken at the beginning of the meeting.

MATTERS TO BE CONSIDERED: Referrals from Regional Commissioners of approximately 3 cases in which inmates of Federal prisions have applied for parole or are contesting revocation of parole or mandatory release.

CONTACT PERSON FOR MORE INFORMATION: Linda Wines Marble, Chief Case Analyst, National Appeals Board, United States Parole Commission, (301) 492-5987.

[S-1496-82 Filed 10-15-82; 11:39 am]

BILLING CODE 4410-01-M

Federal Register

Tuesday
October 19, 1982

Part II

Department of Health and Human Services

Food and Drug Administration

New Drug and Antibiotic Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 312, 314, 430, 431, and 433

[Docket No. 82N-0293]

New Drug and Antibiotic Regulations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise its regulations governing the approval for marketing of new drugs and antibiotic drugs for human use. FDA is taking this action to improve the efficiency of the agency's drug approval process and to improve the agency's dealings with applicants for marketing approval of new drugs and antibiotic drugs, while still maintaining the high level of public health protection the drug approval process now provides. The improvements will help applicants prepare and submit higher quality applications and permit FDA to review them more efficiently and with fewer delays. This will benefit consumers through earlier availability of drugs and benefit applicants by permitting earlier marketing of new drugs and antibiotics. This action is one part of a larger effort by FDA to review all facets of the agency's drug approval process.

DATE: Comments by December 20, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michael C. McGrane, National Center for Drugs and Biologics (HFN-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220.

SUPPLEMENTARY INFORMATION:

Background

Federal law has long required that all new drugs and antibiotics be shown to be safe and effective before marketing. FDA is the Federal agency charged with the responsibility for preclearing new drugs and antibiotics in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 301 et seq.). FDA has promulgated regulations specifying requirements that apply both when new drugs are being investigated (21 CFR Part 312) and while an application for marketing approval is pending with the agency (21 CFR Part 314). The agency has also prepared various guidelines and internal procedures governing the drug development and approval process.

This country's drug approval process has been the subject of extensive debate over the past decade. Critics contend that FDA's regulations and testing requirements are excessive, thereby stifling innovation and depriving the American public of beneficial new therapies. They further contend that FDA's review of new drug applications (NDA's) takes much too long and that, as a result, new therapies are often available in foreign countries before they are available in this country.

Secretary of Health and Human Services (HHS) Richard S. Schweiker agreed that the drug approval system can and must be improved, and, in early 1981, pledged to make significant changes in that system, including: reduced paperwork burdens in new drug applications; broadened use of foreign data; increased communication between FDA and drug sponsors; and lessened regulation over the early stages of clinical research. The Secretary directed that a number of initiatives be undertaken to implement these goals, including an expedited revision of the applicable regulations, a fundamental review of the policies underlying the drug approval process, and an intensive examination of the management techniques and paperflow within the FDA's National Center for Drugs and Biologics. These priorities and directives made by the Secretary implement the mandates of Executive Order 12291 (46 FR 13193; February 19, 1981), which directed all Federal agencies to scrutinize their existing regulations, and of the President's Task Force on Regulatory Relief, chaired by Vice President George Bush, which designated the drug approval process as one of 20 government-wide regulatory programs in greatest need of reform.

This proposal constitutes the first segment of the Department's proposed revisions to regulations governing the new drug approval process. The proposal is directed at the regulations (21 CFR Part 314) that govern new drug applications, such as format of those applications, procedures followed by FDA in reviewing those applications, and responsibilities of drug manufacturers after applications are approved. Efforts to revise these regulations date back several years to when FDA made available concept papers for public comment (44 FR 58919; October 12, 1979) and held a public meeting to discuss them (November 7, 1979). Under Secretary Schweiker, efforts to revise these regulations intensified. The Secretary established a Department Task Force, chaired by FDA's Commissioner Arthur Hull Hayes, Jr., M.D., which carefully examined proposed revisions, with a sharpened eye toward eliminating unnecessary and execessive regulations and expediting the review of pending applications for marketing without compromising the safety and efficacy of marketed drugs. The same administrative review will be used in considering proposed revisions to the investigational new drug (IND) applications (21 CFR Part 312) now underway within the agency.

In addition to the review of the regulations, FDA's Commissioner Hayes established a separate Task Force to examine wide-ranging policy issues affecting the new drug approval process. This Task Force, which Commissioner Hayes also chaired, became known as the Commissioner's Task Force for the Review and Improvement of the Drug Approval Process and consisted of top-level officials from the agency and other constituents of HHS. The first issues addressed by this Task Force involved three key sections of this proposal: (1) Resolving scientific disputes between applicants and FDA reviewing officials; (2) use of foreign data; and (3) the necessary amount of supporting data for clinical studies. Other issues reviewed by this Task Force will be implemented through separate initiatives.

Finally, the Secretary directed the Assistant Secretary for Management and Budget to conduct an intensive review of the management techniques used in FDA's National Center for Drugs and Biologics for reviewing NDA's. A report from that study was made public in April 1982. The study found the review process for new drug applications to be "generally sound," but said the process was not being applied or managed as efficiently as possible. Accordingly, that study made several recommendations that have been or will be implemented promptly, including: (1) Assigning a senior manager to be accountable for overseeing the progress of each new drug application; (2) redesigning information systems to enable better monitoring of new drug applications; and (3) establishing closer communications between scientific reviewers in the agency and their counterparts in the industry while an NDA is under review.

Thus, this proposal regarding the regulations in 21 CFR Part 314 represents only one part of a larger, overall effort to reform the entire new drug development and approval process. As described more fully below, this proposal is intended to expedite the

time period between when an application is submitted for review and when the agency decides whether the drug is approvable. These proposed regulations do not address procedures during the investigational development of new drugs, procedures that will be reviewed in the IND portion of the rewrite. Nor does this proposal address broader questions that may be evaluated by the Task Forces and presented separately for public comment.

Highlights of the proposal are outlined in the following section. The remainder of this preamble, after a brief economic analysis and overview of FDA's current drug review and approval procedures, is devoted to a section by section analysis of the proposed regulatory changes.

Highlights of This Proposal

Despite the fact that it represents only one facet of the agency's current initiatives to improve its drug approval process, FDA believes that this proposal would make significant changes to expedite the process. These changes would provide significant benefits to consumers by making important new drugs available sooner. The changes would also lessen burdens on both researchers and the pharmaceutical industry without compromising the safety and effectiveness of new drugs.

1. *Streamlined format for applications.* The agency proposes to streamline the format of applications for marketing to facilitate more expeditious review within FDA's National Center for Drugs and Biologics. The new format would require an overall summary of the entire application (50 to 200 pages) and separate, detailed technical sections that contain summaries and analyses of the specific information needed by each of the reviewing disciplines: clinical, pharmacology, chemistry, statistics, and biopharmaceutics (as well as microbiology for anti-infective drugs). Each reviewer would then receive a copy of both the overall summary and the technical section for his or her particular discipline. The proposed format would permit parallel review by each of the five (or six) disciplines. In addition, detailed technical sections that synthesize and crystallize the important information about the drug would greatly facilitate review by National Center officials.

2. *Minimize supporting information.* The agency proposes to minimize the amount of supporting information required in applications. Case report forms would no longer be routinely submitted except in those limited instances where the patient dropped out or died during the study. Instead of case report forms, the proposal would substitute tabulations of essential individual patient information. The agency's experience has shown that the essential information from even a lengthy case report form can be reduced to a few lines in a well-organized tabulation. This would not only greatly decrease the bulk of an application, it would also facilitate review because information on different patients, all appearing on the same page, could be easily compared. Even tabulations could be omitted in certain instances, as explained below.

3. *Fewer supplements to approved applications.* FDA proposes to reduce substantially the number of supplements to approved applications which must be submitted to the agency for preclearance. First, some of the information now contained in supplements would no longer be required at all, because FDA has not found the information to serve a useful purpose. Second, other information now contained in supplements would be included only in the applicant's annual report. This is information that FDA needs to know, but time is not of the essence. Third, some information, although still the subject of a supplement, would no longer require agency preclearance. These supplements would describe changes placed into effect to correct concerns about newly discovered risks from the use of the drug. Finally, FDA would retain supplement preclearance requirements for those changes in marketed drugs which could be expected to affect adversely the agency's previous conclusions about safety and effectiveness. These proposed changes would help concentrate the agency's limited resources more on applications for marketing, and permit pharmaceutical manufacturers to institute certain postmarketing changes sooner.

4. *Reduce recordkeeping and reporting requirements on approved applications.* The agency proposes to eliminate excessive, duplicative, and unnecessary recordkeeping and reporting requirements on approved applications. This would reduce unnecessary paperwork burdens on the industry and, as with reducing supplements, would permit a greater proportion of reviewers' time to be spent evaluating applications for marketing.

5. *Clarify time frames for FDA review of applications and for filing applications.* FDA proposes to clarify in its regulations certain critical time frames pertaining to its review of applications. First, the proposal would give the agency 180 days from receipt of an application to issue either an approval letter, an approvable letter, or a not approvable letter. Although this time period would be extended when major amendments are received, the extension would be only for the extra time needed to review the amendment (rather than an automatic 180 additional days which is current policy). Second, the agency would determine, within 60 days of receipt of the application, whether the application is acceptable for "filing" within the meaning of section 505(c) of the act (21 U.S.C. 355(c)). If acceptable, the agency proposes to file the application on the 60th day. See *Newport Pharmaceuticals International, Inc.* v. *Schweiker,* Civil Action No. 81-1283 (D.D.C. December 1, 1981). The agency believes that codification of these time frames would help demonstrate its commitment to reviewing applications expeditiously in accordance with the statutory mandate.

6. *Clarify meaning of action letters.* In a further effort to clarify agency procedures for applicants, FDA proposes to incorporate into its regulations the significance of its three action letters: approval letters, approvable letters, and not approvable letters. The proposal would clarify, among other things, that only an approval letter grants permission for marketing.

7. *Expediting approval based on draft labeling.* The agency proposes to expedite approval of applications where the only outstanding issue is agency review of final printed labeling. Specifically, if the only issue holding up approval of an application is agency review of the final printed labeling, and the draft labeling that was reviewed by FDA is deficient in only editorial or other minor respects, then the agency proposes to issue an approval letter (rather than an approvable letter) on the condition that the deficiencies be corrected as requested before marketing.

8. *Expedited hearing procedures on refusals to approve an application.* The agency proposes an expedited hearing procedure when an applicant wishes to contest the agency's refusal to approve an application. The agency recognizes that its current procedures were drafted with withdrawal of marketed drugs in mind, in which case the manufacturer is not prejudiced by time delay. The proposal would establish specific time frames for issuance of the notice of opportunity for hearing and notice of hearing. The regulations concerning requests for a hearing on a refusal to approve an application have been revised to state that the applicant can

rely solely upon the summaries and analyses properly submitted in the application and does not have to resubmit that information. These changes are intended to minimize any delay experienced by an applicant whose product is not yet on the market.

9. *Improved procedure for resolving scientific disputes.* The agency proposes to establish a mechanism specifically designed for the resolution of scientific disputes that arise during the review process between an applicant and a reviewing official. Because the implementation of this mechanism does not require rulemaking, it will be implemented 30 days after publication of this proposal. Its incorporation into regulation, however, will provide notice, both within and outside the agency, that an applicant's wish to seek review of preliminary decisions is its right, and is acceptable conduct within the normal course of the approval process. The agency also hopes that the existence of this mechanism will promote the early exchange of scientific views between the agency and applicants. Details of this procedure for resolving disputes are contained in a Staff Manual Guide which is publicly available.

10. *Clarify policy on the acceptance and use of foreign data.* In the proposal, the agency states its policy to accept foreign studies in support of applications, providing the studies meet the agency's standards that apply to domestic studies. In addition, the proposal describes the circumstances under which an applicant may rely solely on foreign studies.

11. *New safety update reports for pending applications.* The agency proposes to establish a clear requirement for applicants to submit new safety information learned about a drug while an application is being reviewed by FDA. The reports would be required at 4-month intervals following submission of the application and following receipt of an approvable letter. These "safety update reports" would assure that approval decisions reflect the most recent safety information available to an applicant.

12. *Strengthened postmarketing surveillance for approved drugs.* FDA also proposes to strengthen its system for collecting safety information after approval by requiring applicants to submit 15-day "alert reports" about fatal and life-threatening adverse drug experiences that are not mentioned in the drug's current labeling, and to submit reports of all other experiences within 30 days. These changes will highlight the most significant public health dangers and keep the agency's drug experience data base up-to-date.

13. *Increased communication with applicants.* Finally, FDA intends to increase communication with applicants while an application for review is pending by giving applicants an opportunity for an informal meeting approximately 90 days into the review cycle. The purpose of the meeting will be to inform the applicant of the general progress and status of its application, and to advise applicants of important deficiencies identified to date. This meeting will be available on applications for all new chemical entities and major new indications of marketed drugs. Details of the meeting procedures are contained in a Staff Manual Guide that is publicly available. These meetings will begin for applications received by FDA after publication of this proposal.

Economic Analysis

The agency has examined the economic consequences of the proposed regulations in accordance with Executive Order 12291 and the Regulatory Flexibility Act. A preliminary regulatory impact analysis has been prepared and placed on file with the Dockets Management Branch (address above). The analysis indicates that the proposed regulations would reduce costs and speed approvals of new drug applications. The Result would provide benefits to consumers, researchers, and firms engaged in pharmaceutical development.

The regulatory impact analysis constructed the sequence and duration of review steps for all applications submitted in a recent year from their initial receipt in FDA to their ultimate disposition. It also examined an independent study which estimated the incremental costs of the existing regulations governing the submission and review of new drug applications. These measures of the performance and cost of the existing regulations provided a baseline from which to estimate the effects of the proposed changes.

The proposed regulations are expected to reduce the annual cost associated with new drug applications by about $2.5 million. The cost savings result primarily from the elimination of the requirement to submit supplements for certain postmarketing changes and reductions in the volume and detail of material required in applications.

Moreover, the agency's analysis estimates that the proposed regulations would enable FDA to meet the statutory objective of reviewing virtually all applications within 180 days. The proposed regulations would also shorten the total elapsed time required to approve the average application from about 27 months to 21 months—a savings of 6 months. The average approval time for applications involving important new chemical entities is projected to improve from about 19 months to 17 months—a savings of 2 months. The faster approval and smaller savings for new chemical entities reflect the special priority already accorded these applications.

Faster approvals for applications would benefit both consumers and pharmaceutical manufacturers. Consumers would have earlier access to important new drugs that have the potential to extend life, avoid hospitalization, or provide other significant health benefits. Firms developing new drugs would realize faster return on their research investments, thereby encouraging further investment in subsequent pharmaceutical research. The regulatory impact analysis examines some measures of these various benefits, although none are amenable to simple quantification in monetary terms.

The projected savings of $2.5 million per year and acceleration in the drug approval process of 6 months are not the only improvements expected from the comprehensive reassessment of the drug review process currently underway within HHS. The regulatory impact analysis considers only the changes in regulations, and excludes the effects of related changes in management policies, practices, guidelines, and priorities. Some of these changes may have substantial impact. For example, the regulatory impact analysis indicates that a reduction in the frequency of omissions and deficiencies in applications could shorten the approval process. Each 10-percent reduction in deficiencies is estimated to yield a 2-month savings in approval time. Because FDA's increased use of guidelines is designed to help applicants prepare more acceptable submissions, the response of applicants to these management initiatives may have a very important impact on the speed of the approval process.

The great majority of new drug application submittals are made by large drug companies. Thirty-four of the average 125 annual submissions are made by applicants who average less than one application every 2 years. These applicants are more likely to be small drug companies having less than 750 employees. While the impact on any individual drug company submitting an application may be substantial, that impact will be beneficial, reducing cost and burden, and the total number of small companies affected will not be

substantial. The agency, therefore, certifies that this rule will not have a significant economic consequence on a substantial number of small entities.

The recordkeeping and reporting requirements contained in this proposal are subject to clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35). FDA intends to submit to the Director, OMB, copies of this proposed regulation and other related materials during the comment period on this proposal. If OMB approves the proposed requirements, FDA intends to impose the requirements at the time a final regulation based on the proposal is made effective. If OMB does not approve, without change, the recordkeeping and reporting requirements contained in the proposal, FDA will revise the final regulation as necessary to comply with OMB's determination. Any comments received from OMB will become part of the administrative record for this matter and will be placed on file for public review in the Dockets Management Branch in Docket No. 82N-0293.

FDA's Current Review Procedure for Applications for New Drugs and Antibiotics

The term "new drug" is defined in section 201(p) of the act (21 U.S.C. 321(p)). A drug is a new drug under that section if its composition is not generally recognized by qualified experts to be safe and effective under the conditions of use set forth in its labeling. The "newness" of a drug is not determined by the length of time it has been in use, and a drug that has been marketed for many years may still be a "new drug." Most prescription drugs and some over-the-counter drugs are "new drugs," and an approved application is required for marketing. The act provides in section 505 that a "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved an application with respect to it.

FDA approves an application for a new drug only if the person submitting the application (the applicant) first shows by adequate scientific evidence that the drug is safe and by substantial evidence that the drug is effective for the conditions prescribed, recommended, or suggested in the product's proposed labeling. The act defines substantial evidence of effectiveness to consist of adequate and well-controlled investigations, including studies in humans, that are conducted by qualified experts. To obtain approval, moreover, an applicant is also required to show that the product it will manufacture will be manufactured properly.

The act contains additional premarket requirements for antibiotics, and antibiotic applications for marketing are called "Form 5" applications to distinguish them from "new drug" applications. In addition to obtaining approval for marketing, each batch of an antibiotic drug, unless exempt, has traditionally been "certified" before marketing. Soon after approval, the agency has established for each new antibiotic a regulation, referred to as a monograph, which contains specifications for potency, purity, and identity, as well as descriptions of specific test procedures under which the antibiotic may be certified.
Under the certification program, batches of the antibiotic have been tested to determine whether they comply with the specifications in the antibiotic regulations and, if they do, FDA has issued certificates which authorize the person requesting certification to market the antibiotic.

In the **Federal Register** of September 7, 1982 (47 FR 39155), FDA exempted under section 507(c) of the act (21 U.S.C. 357(c)), all classes of antibiotic drugs from batch certification requirements. Under this exemption, antibiotic drugs need no longer be certified, nor will certificates be issued, prior to marketing. A full discussion of the regulatory process applicable to antibiotic drugs may be found in the final rule exempting antibiotic drugs from certification (cited above), and in the proposed rule preceding that action which was published in the **Federal Register** of May 7, 1982 (47 FR 19954). The exemption from certification requirements, however, does not affect the other procedures for obtaining FDA approval to market an antibiotic drug.

To obtain the evidence needed to show whether a drug is safe and effective, the applicant generally must perform studies of the drug in animals and in humans. In connection with these studies, FDA has issued regulations on (1) the protection of human subjects in clinical investigations (21 CFR Part 50), (2) the composition, operation, and responsibility of institutional review boards that review clinical investigations (21 CFR Part 56), (3) good laboratory practice for conducting nonclinical laboratory studies (21 CFR Part 58), and (4) investigational new drug applications (21 CFR 312). FDA has also proposed regulations on the responsibilities of clinical investigators (43 FR 35210; August 8, 1978) and sponsors and monitors of investigations (42 FR 49612; September 27, 1977).

In addition, the agency has developed and made available a series of clinical guidelines that describe how applicants may conduct studies on particular classes of drugs so that the studies are likely to yield data that can be used to determine whether a drug product is safe and effective. The agency has developed approximately 25 guidelines with the help of its scientific advisory committees and others, including the American Academy of Pediatrics' Committee on Drugs and consultants to the Pharmaceutical Manufacturers Association. The guidelines contain generally accepted principles for reaching valid conclusions about the safety and effectiveness of drugs and they contain views of outstanding experts about appropriate methods for studying specific classes of drugs.

FDA has also established a drug classification system that permits the agency to identify promising drugs so that the agency can review them faster. When FDA receives an investigational new drug application or an application to market a new drug or an antibiotic, the agency makes determinations about the following: (1) The chemical type of the drug; for example, whether it is a new molecular entity, a new salt, or an already marketed drug; (2) the therapeutic potential of the drug; for example, whether it represents important, modest, or little or no therapeutic gain; and (3) other important information about the drug; for example, whether it is already marketed in a foreign country or is likely to be used in children. An alpha-numeric code is assigned to the drug based on the agency's initial determination. The agency may later change the classification on the basis of new information submitted in amendments to the application, in the medical literature, or from other sources. This classification of drugs under review is useful to the agency in assigning its resources and expediting the review of drugs that are likely to have the greatest impact on improving the public health. The agency recognizes that classification of drugs in this manner involves the exercise of scientific judgment, and that the resulting classifications are not perfect. However, individual sponsors who believe their drugs have been classified incorrectly may raise that issue with the appropriate officials either informally or through the request for reconsideration procedures described below.

When a person believes the investigational studies on a drug have shown that the drug is safe and effective under conditions that can be described in proposed labeling, the person submits

an application, either a new drug application or an antibiotic Form 5, to FDA to obtain approval to market the drug. By the time an application is submitted, the drug usually has been studied in several hundred to several thousand patients. The application, which currently often consists of thousands of pages of material, is reviewed by physicians, pharmacologists, chemists, microbiologists, statisticians, and other professionals within FDA's National Center for Drugs and Biologics who are experienced in evaluating new drugs. Their recommendations receive further review by management personnel within the National Center for Drugs and Biologics before a final determination is made to approve or refuse to approve an application. Applications for significant new drugs and antibiotics or for drugs presenting complex scientific problems may be referred to FDA advisory committees for their review and recommendations. Following review by FDA, the statute requires that the agency approve the application if it finds that none of the grounds specified in the act for denying approval applies. After FDA approves an application for an antibiotic, it issues a regulation to provide for its certification.

Generally, a person or company who wants to market a drug must submit the results of studies, including case report forms, and obtain FDA approval of a full application. If the studies relied upon are from reports in the scientific literature instead of studies conducted by or on behalf of the applicant, the application may be called a "paper NDA" and case report forms would not be required. For a duplicate of certain drugs, already approved and marketed, however, FDA has established an abbreviated procedure under which a second company wanting to market the duplicate drug is not required to repeat the extensive animal and human tests required for a full application; rather, the second company may submit an abbreviated application (for a new drug) or an antibiotic Form 6 (for an antibiotic). The agency accepts abbreviated applications only for new drugs for which it has made a determination that abbreviated applications are appropriate. Notices published in the **Federal Register** concerning drugs found to be effective under the agency's Drug Efficacy Study Implementation (DESI) program (a review of the effectiveness of drugs introduced to the market through the new drug procedures between 1938 and 1962) have specified when the agency considers an abbreviated application to be an appropriate form of application for a new drug. The agency accepts antibiotic Form 6's, however, for all antibiotic drugs that are comparable to an antibiotic drug for which the agency's regulations provide for certification.

Both the full and abbreviated applications for marketing approval of new drugs and antibiotics contain, among other things, detailed information about the composition of the drug, the methods of manufacture and quality control, facilities of the manufacuring plant, and copies of the drug's labeling. A manufacturer who wants to change the composition of the drug or its labeling, or change the way in which it is made, must inform FDA about the proposed change and in some cases obtain prior FDA approval of the change. For a new drug, the applicant usually submits a supplemental application and, depending upon the kind of change in the application, the applicant can make the change either when the supplement is submitted or after FDA approves it. For an antibiotic drug, the applicant generally can make the change only after FDA approves it.

Under certain circumstances (for example, if new information raises questions about the safety of a drug) FDA may withdraw approval of an application for the drug or revoke the provisions for its certification and, thus, prohibit its continued marketing. To facilitate FDA's surveillance of approved drugs, each applicant is required to keep records and make reports to the agency about new information relating to its safety and effectiveness. Currently, for routine information about a new drug or antibiotic drug, a manufacturer must report to FDA every 3 months during the first year after the approval, every 6 months during the second year, and then once each year. Immediate reports, however, are required when unusual or especially severe adverse reactions are known to the applicant.

Overview of This Proposal

FDA proposes to establish six new subparts in Part 314. New Subpart A describes the scope of the regulations and contains definitions of terms. Subpart B contains regulations about applications for new drugs and antibiotics and the responsibilities and rights of applicants concerning their applications. Subpart C contains regulations about actions the agency takes on applications, including both applications under review and those already approved. Subpart D contains regulations on the procedures for hearings on proposals by the agency to withdraw or refuse approval of applications for new drugs. Subpart E contains regulations on the procedures for issuing, amending, and repealing regulations for antibiotics. Subpart F contains regulations stating FDA's policy on administrative issues that frequently arise concerning applications.

Scope. The proposed regulations would apply to applications for marketing approval of new drugs and requests to provide for certification of antibiotic drugs. Although current Part 314 contains comprehensive regulations governing applications for new drugs, the regulations in Part 431 governing requests to provide for certification of antibiotic drugs are more abbreviated. As a practical matter, the agency interprets the act as requiring similar submissions and takes the same actions on requests for marketing approval of new drugs and antibiotics. Thus, the proposed revision of the regulations would apply them expressly to both new drugs and antibiotics. This is consistent with current practice and provides more guidance to persons seeking to market antibiotics.

Definitions. The regulations would define "applicant" to mean both a person who is seeking, and one who has obtained, FDA approval of an application. Currently, a person who has obtained approval of an application is referred to both as an applicant and as a holder of an approved application. The use of a single term is intended to avoid confusion.

The proposed regulations would also define "approval letter," "approvable letter," and "not approvable letter," terms the agency now uses to refer to action letters on applications. An applicant may market a new drug or seek certification or release of an antibiotic drug only if the applicant has received an approval letter. The agency expects that these definitions will clarify the purpose of each action letter and make clear that action letters other than approval letters do not confer any rights to market a drug.

Because the regulations will apply to both new drugs and antibiotics, the regulations no longer use the phrase "new drug application," but instead simply refer to an applicant's submission as an "application." When the regulations are applied to specific drugs, however, the agency, applicants, and others may be more specific by referring to a "new drug application" or an "antibiotic application." The term "application" is also used to apply to both the full application described under proposed § 314.50 (21 CFR 314.50) and the abbreviated application described under § 314.55 (21 CFR 314.55). An

abbreviated application provides a means for eliminating the submission of certain information that is not required because it is not essential to FDA's reaching a decision on whether an application for a drug is approvable. Generally, under an abbreviated application, the agency waives the submission of preclinical and clinical studies regarding the safety and effectiveness of the active ingredient because the agency already has sufficient available data and information in its files to make appropriate conclusions on those elements of the drug approval decision. Thus, an abbreviated application provides a means to eliminate unnecessary animal and human experimentation, to reduce the burdens on manufacturers in attempting to market duplicates of established drugs, and to ease the workload of FDA in reviewing and processing applications. In all other respects, such as an applicant's amendment of a pending application and FDA's actions in reviewing the application and sending action letters, the abbreviated application would be treated the same as the full application.

New Drug and Antibiotic Applications

The agency proposes to change significantly the content and format requirements for applications. The changes are intended to reduce significantly the amount of information applicants must submit, improve the quality of their submissions through greater use of summaries and analyses, and expedite FDA's review.

Unlike most FDA regulations, the current content requirements for a new drug application are contained in the new drug application Form FDA-356H, which is reprinted in the regulations. (The text of the antibiotic Form 5, although almost identical to the Form FDA-356H, does not appear in the regulations.) While the form identifies in detail the kinds of information an applicant must generally submit to obtain FDA approval of a drug that contains a new chemical entity, it does not reflect FDA's flexibility and judgment in applying those requirements to duplicates of marketed drugs. Thus, FDA proposes to remove the Form FDA-356H from the regulations and revise it to make it essentially no more than a check-list of the applicant's submission. The form would, as now, be signed by the applicant and, in the case of a foreign applicant, by a person within the United States who would be available for service of process. In addition, the revised application format would conform to the format generally acceptable to foreign drug regulatory agencies. The requirements for the contents of an application would be stated in the regulations in general terms and the agency would provide guidelines under § 10.90(b) (21 CFR 10.90(b)) to help applicants comply with those requirements. The guidelines do not establish requirements themselves, but an applicant may assume that, by following them, a submission will be in a form acceptable to FDA. An applicant may choose, however, to follow an alternative procedure.

An applicant currently submits three copies of the complete application, except case reports may be omitted from two of the copies and drug experience reports may be omitted from the third copy. FDA's National Center for Drugs and Biologics then divides its review of the application into five areas: chemistry, manufacturing, and controls; pharmacology and toxicology; bioavailability; clinical; and statistics. In addition, if the drug is an anti-infective (as are virtually all antibiotics), the agency conducts a microbiology review.

The current format of the application is unnecessarily burdensome for applicants to prepare and overly troublesome for the agency to review. Applicants are now required to duplicate technical information in each copy of the application that is reviewed by only one discipline in the agency. On the agency's part, some reviewing disciplines (generally biopharmaceutics and statistics) must glean the technical information they need from copies that are prepared for, and primarily assigned to, reviewers in other disciplines. The agency believes that requiring applications in a format that matches better the actual review process and permits parallel reviews by the different scientific disciplines would avoid the problems of the current format.

The agency proposes to require only two copies of an application, an archival copy and a review copy. This proposal is consistent with a petition to the agency from the Pharmaceutical Manufacturers Association (PMA), which suggested that FDA require applicants to submit a complete archival copy of the application and submit a review copy made up of separate sections that can be distributed for concurrent review in each reviewing area. This form of submission would reduce the amount of paperwork applicants would be required to submit to FDA, provide each reviewing unit with an overview of the entire application, as well as the specific data the unit is charged with reviewing, and give each reviewer access to the complete application.

Under this proposal, both copies of an application would contain five (six for anit-infectives) technical sections, one for each of the specific review areas. Each technical section in the review copy would contain a copy of a revised Form FDA-356H, the technical and scientific information needed by the specific review area, and a copy of the summary of the complete application. Both copies of an abbreviated application would contain only two technical sections and an overall summary would not be required.

The application summary would synthesize all of the information in the application and would provide reviewers in each review area, and other agency officials, with a good general understanding of the drug. It would contain an annotated copy of the proposed package insert for the drug, a discussion of the drug's benefits and risks, a description of the foreign marketing history of the drug (if any), and a summary of each technical section. The foreign marketing history would permit FDA to contact foreign drug regulatory officials about their experiences with the drug and, thus, expedite approval in this country of important drugs that are already available in other countries. The summary should be written in the same detail required for publication in, and meet the editorial standards generally applied by, referred scientific and medical journals. FDA believes that a good summary that pulls together well all the information in an application would contribute most to speeding FDA approval of the application. The agency intends to prepare a guideline about how an applicant can prepare a summary, which the agency believes would generally be 50 to 200 pages long. The agency would also prepare guidelines about how an applicant can prepare each of the technical sections.

In addition to requiring technical sections in the review copy of the application, the regulations would require the applicant to submit an archival copy of the application that contains a single copy of the application form and the summary, an index, and a copy of each review area's technical section. The archival copy would also contain copies of tabulations and case reports that are submitted and samples of the drug and its labeling. The applicant may choose to submit the archival copy on microfiche, but the applicant may only submit tabulations and case report forms on microfiche if the applicant and the agency agree to

that format. The archival copy would serve during the review of the application as a reference source for reviewers to find information not contained in the technical sections they receive, as a reference source for other agency officials, and as the repository of the copies of tabulations and case report forms on the clinical studies. After an application is approved, the review copy would either be destroyed or parts of it would be provided to FDA components as reference sources to meet their needs; for example, the chemistry, manufacturing, and controls section may be provided to the FDA field staff to refer to before inspecting a manufacturing site for the drug, and the clinical data section may be provided to the Division of Drug Experience to provide baseline data on drug experiences. The archival copy would then serve as the agency's sole copy of the approved application for monitoring the safety, effectiveness, and labeling of the drug, as the focus of supplements and changes contained in the annual reports, and as a source of documents for release under the agency's public information regulations (21 CFR Part 20).

The agency now furnishes colored binders to applicants free of charge for organizing their applications, and FDA would continue to do so under this proposal. FDA has found that its document control rooms can file and distribute submissions to appropriate offices more quickly and with fewer mistakes if uniform colored binders are used for each part of the submission. Using specific colors for particular parts of an application helps the document control room send them to the appropriate office and, if a part is misrouted, quickly alerts the recipient of the mistake. Although the proposal would not require applicants to use the agency's binders, FDA believes their use will expedite review of applications. Further information concerning the use of colored folders will be contained in a guideline that will also inform applicants about how to obtain binders from FDA.

The agency proposes to continue its current practice of permitting applicants to incorporate by reference information that they have previously submitted in drug master files (described below) or other applications. The incorporation by reference must identify specifically where the agency can find the information in the earlier submission. If an applicant incorporates by reference information submitted to the agency by another person, the applicant must obtain and include in the application a written statement from that person authorizing the reference. The agency would also retain the current requirements that an application contain an accurate and complete English translation of each part of the application that is in a foreign language and contain a copy of each original literature publication for which an English translation is submitted.

Review copy

As noted above, the review copy of the application would consist primarily of five or six sections that contain the technical and scientific information that FDA reviewers need to conduct their reviews. A description of the proposed requirements for each of the six sections that make up the application follows.

1. *Chemistry, manufacturing, and controls section.* This section would describe the composition, manufacturing methods, and specifications and test methods used for the drug substance and the drug product, and contain an environmental impact analysis of the manufacturing process and the ultimate use of the drug. FDA proposes to eliminate its current requirements that an application contain substantial information about manufacturing practices that are the subject of the agency's current good manufacturing practice (CGMP) regulations in Part 211 (21 CFR Part 211). The CGMP regulations were promulgated in 1963 and updated substantially in 1978. They set comprehensive standards for drug manufacturing that FDA enforces through statutorily required on-site inspections of drug manufacturers. The CGMP regulations eliminate the need for case-by-case review by the agency of some information about drug manufacturing practices.

Under this proposal, the following information that is currently required would no longer need to be submitted in an application because the agency already has access to that information under the CGMP regulations: (1) A description of the physical facilities, including the building and equipment used in manufacturing, packaging, and labeling the drug; (2) a description of the qualifications and responsibilities of technical and professional personnel; (3) a statement of whether each lot of raw materials is given a serial number to identify it, and the uses made of the numbers in subsequent operations; (4) information about the method of preparation of the master formula records and individual batch records, and a statement about the manner in which the records are used; (5) information about the number of individuals checking weight or volume of each individual ingredient in each batch of the drug, information about whether the total weight or volume of each batch is determined at any stage of the manufacturing process, and information about precautions taken to check actual package yield produced from a batch of a drug with the theoretical yield; (6) information about precautions taken to assure that each lot of the drug is packaged with the proper label and other labeling; and (7) an explanation of the batch control numbers and the methods used to determine the distribution of batches.

The agency proposes to continue to require applications to contain the following information about the drug substance and drug product, and an environmental impact analysis report.

Drug substance. The agency proposes to continue to require applicants to submit the following information about the drug substance: (1) A full description of the drug substance, including its physical and chemical characteristics and stability; (2) the name and address of its manufacturer; (3) the method of synthesis (or isolation) and purification of the drug substance; (4) the process controls used during its manufacture and packaging; and (5) the specifications and analytical methods needed to assure the identity, strength, quality, and purity of the drug substance and bioavailability of the drug products made from the substance. An applicant may reference a current edition of the official compendia to satisfy some of these requirements instead of submitting the information itself.

Drug product. The agency proposes to continue to require applicants to submit the following information about the drug product that is the subject of the application: (1) A statement of the composition of the drug product and a list of all components used in the manufacture of the drug product, regardless of whether they acually appear in the drug product; for example, if they are removed during processing they would nevertheless be listed; (2) a statement of the specifications and analytical methods for each component; (3) the name and address of the drug product manufacturer; (4) a description of the manufacturing and packaging procedures and in-process controls for the drug product; (5) the specifications and analytical methods that are necessary to assure the identity, strength, quality, purity, and bioavailability of the drug product; and (6) stability data necessary to establish an expiration date for the drug product. An applicant may reference a current edition of an official compendium to satisfy some of these requirements

instead of submitting the information itself.

Environmental impact analysis report. The agency proposes to retain the requirement that an application contain an environmental impact analysis report prepared under § 25.1 (21 CFR 25.1) analyzing the environmental impact of the manufacturing process and the ultimate use of the drug product. The report is necessary for FDA to implement the National Environmental Policy Act of 1969.

2. *Nonclinical pharmacology and toxicology section.* The agency does not propose to change the substance of the current requirements for the submission of data and information from nonclinical laboratory studies. These data are usually derived from laboratory animal studies of the drug substance or drug product and are conducted primarily to determine the safety of the substance or product. These studies are subject to FDA's regulations in Part 58, which prescribe good laboratory practices for conducting the studies. Compliance with those regulations is intended to assure the quality and integrity of the data that result from the studies. The agency proposes to include in the regulations a general statement of the kinds of studies in animals or in vitro that ordinarily are submitted by an applicant in support of an application. These include studies of the pharmacological actions and toxicological effects of the drug, studies of the effects of the drug on reproduction and the developing fetus (if appropriate), and studies of the excretion of the drug in animals. In addition, if a study was not conducted in compliance with the agency's good laboratory practice regulations in Part 58, the application must describe how the study fails to comply with those regulations. The agency intends to provide applicants with guidelines for the presentation of data under this section.

3. *Human pharmacokinetics and bioavailability section.* Under this proposal, the agency would retain the current requirements for the submission of human bioavailability data, or information supporting a waiver under Subpart B of Part 320 (21 CFR Part 320). Part 320 provides detailed information about the agency's in vivo bioavailability requirements and methodology for designing and conducting bioavailability studies. Bioavailability data in an application are necessary to define the pharmacokinetic profile of the drug and to evaluate the adequacy of the proposed labeling. The data are also needed to assure that the dosage formulation intended for marketing has the same characteristics as the dosage formulation used in clinical studies, to determine the drug product's safety and effectiveness, and to assure batch-to-batch consistency. In addition, after a product is approved for marketing, bioavailability data submitted in supplemental applications are used in evaluating product reformulations or changes in manufacturing processes.

Although this proposal would not change the agency's substantive requirements for the submission of human bioavailability data, the proposal, and a guideline the agency intends to establish, would state these requirements more clearly. In the past, the less than explicit statement of what is needed for a biopharmaceutics review may have led some applicants to fail to submit key studies, with such failure significantly protracting the review process. A clearer statement of these requirements should help applicants avoid this problem. The proposal would also require the submission of biopharmaceutics information in a separate section of the application that could be more easily reviewed by the agency. Currently, agency reviewers of this data must collect it from several different sections of the application, and from one of the three copies of the application that are assigned to, and reviewed by, other scientific disciplines in the agency. This data collection causes considerable delay in the agency's review of an application and raises a possibility that some data may be overlooked. The agency believes that revising the format for an application to include the submission of biopharmaceutics information in a separate section would provide both the applicant and FDA with an organized, comprehensive, and efficient means of submitting and reviewing the required studies.

4. *Microbiology section.* For anti-infective drugs, the agency proposes to require a separate section containing information, based on microbiology data, about the anti-infective properties of the drug. The agency does not propose to change the nature of the substantive data that is required. The section would include information about the drug's microbial action, including the biochemical basis of the drug's actions, its anti-microbial spectra, and the results of in vitro studies that show the concentrations of the drug needed to affect that spectra. This section of the application would also be required to contain information about mechanisms and prevalence of microbial resistance to the drug. Finally, the section would continue to require a description of clinical laboratory tests (for example, in vitro sensitivity discs) needed for effective clinical use of the drug.

5. *Clinical data section.* Clinical data and information are generally derived from studies of the drug in humans to determine its safety and effectiveness. The proposal would change little of the substance of the current requirements that require an application to contain a description and analysis of the following: each clinical pharmacology study of the drug, each controlled clinical study, each uncontrolled clinical study, other information relevant to an evaluation of the drug's effectiveness, other information about the drug's safety, and information about possible abuse and overdosage from the drug. The application would also contain a description of the statistical annalyses of the controlled studies and the safety data. In addition to the descriptions and individual analyses, the regulations would require the applicant to prepare an analysis of all the clinical information about the drug.

The agency proposes to add one new requirement with respect to the submission of safety information from ongoing animal and clinical studies in the clinical section of the application. Currently, as applicants prepare to submit their applications, they usually choose a "data lock point" for ongoing studies. The application contains and analyzes all safety information obtained up to that point in time, but information obtained later by the applicant may not be systematically complied and submitted to the new drug or antibiotic application. Although important safety data from ongoing studies are now reported to the investigational new drug (IND) application file, they are not required to be reported in any form to the new drug application. Because the IND is not the main focus of review at this stage, whatever new safety data are submitted do not become integrated into the new drug application data base. FDA has taken interim steps to correct this situation by directing medical reviewers to check the IND files for adverse drug experience reports and to seek commitments from applicants to update the new drug application file while the application is pending. The agency believes, however, that a specific requirement to update the new drug application with new safety data should be contained in the regulations in order to assure that approval decisions reflect the most recent safety information available to an applicant.

Accordingly, the proposed change would explicitly require that applicants submit periodic "safety update reports"

describing new safety information learned about the drug. These reports would include the same kind of information (from clinical studies, animal studies, and other sources) and would be submitted in the same format (through case report forms, tabulations, and narrative summaries) as would be required in an original application. Under the proposal, these reports would be required every 4 months and following the receipt of an approvable letter in order to assure that marketing approval is based on the most up-to-date safety information possible. FDA will prepare a guideline to assist applicants further in the format and content details of these reports. Applicants are also encouraged to consult with agency officials prior to the submission of the first safety update report. The 90-day conference, discussed elsewhere in this preamble, would present a timely forum for such consultation.

6. *Statistical section.* The agency proposes to require a separate section in the application that contains copies of the description and analysis of the controlled studies and the summary of safety data that are required in the clinical data section. This section would also contain descriptions and documentation of the statistical analyses used to evaluate both the controlled clinical studies and the safety data. The agency's proposal to require a separate statistical section would not change the substantive requirements for the submission of that data. The proposal would simply require the submission of the information in a separate section of the application so that it can be more easily and quickly reviewed by the agency.

Archival copy

As noted above, the archival copy of the application would contain copies of the technical sections, the application Form FDA-356H, the summary, an index, and the following additional sections:

Samples and labeling. The agency proposes to retain the requirement that the applicant submit samples of the finished drug product, the drug substance used in the manufacture of the drug product, and reference standards and blanks. The agency also proposes to retain the current requirements for the submission of copies of the proposed label and labeling for the drug product—four copies of draft labeling or 12 copies of final printed labeling. The copies of the final printed labeling are distributed among offices within FDA headquarters and district offices and a copy may be sent to the World Health Organization.

The agency proposes to reduce the applicant's obligations to submit labeling and drug samples by revising the regulations to reflect the agency's current practice of requiring the submission of the finished market package only if specifically requested and by eliminating the requirements for the submission of samples of the drug product used in clinical investigations and samples of the drug substance used to manufacture those drug products. As described below, FDA proposes to continue to require drug samples for methods validation purposes.

The agency proposes two new requirements with respect to the submission of samples. First, the agency proposes to require the applicant to include in this section two copies of the analytical methods and descriptive information needed to perform the tests on the samples and validate the applicant's analytical methods. This information is now submitted as part of the chemistry, manufacturing, and controls section of the application, and would also continue to be submitted in that section. Currently, the FDA reviewer of the chemistry section of the application must identify, extract, and compile the necessary information and send it to FDA's laboratories with the samples before the laboratories can evaluate them and validate the analytical methods. This is resource and time consuming and leads to delays in validating some methods. The separate submission of the analytical methods and descriptive information, which could be sent immediately to FDA's laboratories for evaluation, would eliminate that problem.

Second, unlike the current practice under which applicants normally submit samples when they submit their applications, under the proposal applicants would not submit their samples until FDA requested them to do so. Moreover, FDA would ask applicants to send samples directly to the agency's district laboratories where the samples would be tested. This change would resolve current problems for the agency created by lack of sample storage space and the need to repackage samples for shipment to district laboratories. The change would also benefit those applicants who must now submit samples a second time if their original samples become outdated before the application is close enough to approval to permit testing. Because this procedure involves only a change in the timing and location for submitting samples, the agency believes it can implement this on an interim basis pending completion of the notice and comment rulemaking proceeding. Thus, this procedure regarding submission of samples will become effective for applications submitted 60 days after publication of this proposal.

Supporting information for clinical studies. FDA proposes to reduce significantly the amount of supporting information applicants are required to submit in an application. The agency proposes to decrease by as much as 70 percent (depending upon the application) the amount of paperwork applicants are required to submit by no longer requiring the routine submission of copies of most case report forms. Instead, the agency would require the submission of tabulations of the data in those forms. Moreover, the agency proposes to require tabulations only of the most important data from the clinical studies.

This proposal is consistent with a petition to FDA in which the Pharmaceutical Manufacturers Association (PMA) suggested that FDA not require the routine submission of copies of individual case report forms. This change would reduce substantially the cost and time involved in preparing an application. PMA also suggested that because FDA regulates clinical investigations, the applicant should be permitted to submit comprehensive tabulations and summaries of each clinical study and incorporate individual case reports by reference, with the caveat that FDA would have access to case reports, if necessary.

FDA proposes that, although applicants would still be required to summarize and analyze all the information from clinical studies of the drug product, the agency would no longer require them to submit copies of all the case report forms from the studies. These case report forms now contribute most of the bulk to an application. Many applications now contain thousands of case report forms that fill literally hundreds of volumes. To analyze the studies and prepare their applications, applicants generally extract the data from these case report forms and organize these data in tabular form. Many applicants currently submit these tabulations voluntarily in addition to copies of the case report forms. The agency's experience with those applications leads it be believe that the submission of the tabulations alone obviates the need for the routine submission of most case report forms. The tabulations put the data and information derived from clinical studies in a more condensed and more easily

reviewed form. Thus, the submission of tabulations instead of case report forms is expected to reduce the review time needed for the application.

Although FDA proposes to eliminate the routine submission of copies of most case report forms, copies of case report forms would still be required for patients who died during a clinical study or who did not complete the study because of an adverse event, whether drug related or not. The agency's experience suggests that those case report forms are more likely than others to reveal safety problems with the drug. Although the agency would reserve the right to require the submission of copies of other case report forms, it would only require their submission where a legitimate need for them exists in order to conduct an adequate review of the application. Such a need might exist, for example, when discrepancies in the summary or data tabulations suggest the need to review case report forms or when tabulations are not adequate to convey in a scientifically appropriate manner important information contained in the case report forms.

In addition to minimizing the number of case report forms that must be submitted, FDA would also minimize the submission of tabulated data from them. The agency would only require tabulations of the data on patients from (1) the adequate and well-controlled clinical studies, generally the initial (Phase 2) and more general (Phase 3) clinical studies, that are used to determine whether substantial evidence of effectiveness of the drug exists; (2) the initial clinical pharmacology (Phase 1) studies; and (3) the safety data from all other studies (that is, Phase 2 or Phase 3 studies that are not considered adequate and well-controlled). Efficacy data on patients from Phase 2 or 3 studies that are not adequate and well-controlled need not be tabulated because the description and analysis of these data in the clinical section of the application are adequate for FDA review purposes. The agency estimates that this one provision (that is, not requiring tabulations on those efficacy data) would save applicants between 10 and 30 percent of the amount of tabulations that they would need to submit for review. As with case report forms, however, tabulations not otherwise required would be required following an agency request, if a legitimate need for them exists. Finally, the proposal would permit the agency to excuse an applicant from submitting certain routinely required data if the agency concluded that its submission were unnecessary.

The agency intends to prepare guidelines on the presentation of data in tabulations. These guidelines would explain, for example, that tabulations should include for each study the protocol number, condition studied, clinical investigator, study design (for example, double-blind, open, parallel, or crossover), specific formula and dosage studied, reference drug, if any, and the number of patients. As the guidelines would also explain, tabulations should include specific data on each patient in the study (that is, age, sex, dosage administered, duration of therapy, results of laboratory tests, effectiveness parameters, and adverse reactions). Applicants would be encouraged to meet with agency officials before submitting an application to discuss alternative modes of data presentation.

FDA believes these reductions in the submission of case report forms and tabulations can be made without adversely affecting the application review process and, thus, without compromising the agency's patient protection goals. The required tabulations would contain the data FDA needs to review applications critically. Moreover, as stated above, case report forms would still be available to FDA where there exists a legitimate need for them in order to conduct an adequate review of the application.

The agency is committed to requiring the submission of only that information that is truly essential to its review of an application. In preparing this proposal, the agency considered many possible criteria for use in determining the extent to which case report forms and tabulated data could be routinely omitted from applications. Thus, the agency proposes that the type of study (for example, whether it is adequate and well-controlled) and the data elements within the study (for example, whether they relate to safety) are proper criteria for determining what data should be submitted. The benefits of even greater reductions in requirements for supporting information were thought to be outweighed by the disadvantages those reductions would bring to the review process. Nevertheless, FDA welcomes comments that identify additional areas where reductions in requirements for submission of supporting information can be made.

In sum, this proposal would result in the submission of most supporting information in data tabulations instead of case report forms, thereby improving review efficiency and reducing the paperwork burden on applicants. The proposal would also limit the routine submission of tabulations to those studies FDA believes are essential to its review. For data not included in the required tabulations, the agency would rely on the application summary and the descriptions and analyses of the studies in the technical sections of the application, and would rarely request additional data tabulations.

Abbreviated Applications

FDA currently accepts abbreviated new drug applications for many drug products that were first approved for marketing before October 10, 1962, when the act required that a new drug only be tested to show its safety, if FDA has also determined that they meet current statutory effectiveness criteria. The agency also accepts antibiotic Form 6's, which are in effect abbreviated applications, for duplicates of all antibiotics the agency has already approved for marketing, regardless of the initial year of marketing.

In 1962, Congress amended the drug approval provisions of the act to require that a drug be shown to be both safe and effective before marketing. Under the 1962 amendments, the effectiveness requirement was made applicable, after a 2-year transitional period, to drugs approved before 1962. To implement this Congressional mandate, FDA undertook an evaluation of drugs that had been approved before October 10, 1962 to determine whether there was substantial evidence of effectiveness for each drug for each of its indications. This study led to the Drug Efficacy Study Implementation (DESI) program. Under this review program, a manufacturer who had a pre-1962 approved new drug application could, if the manufacturer submitted a supplemental new drug application to conform the indications for use to those FDA determined to be effective, have its application continue to be approved.

There were also drug products on the market, however, that were identical to or very similar to the drug products found effective in the DESI review but for which no new drug application had been filed. These drug products, commonly referred to as "me-too" drug products, were duplicate versions of approved products. In many cases, FDA had allowed these "me-too" drug products to be marketed without the submission of an application. In other cases, they were introduced to the market without any notification to the agency. FDA established the abbreviated application to provide an appropriate procedure for "me-too" products to obtain FDA approval in reliance on the DESI evaluation. Each **Federal Register** notice announcing the

effectiveness conclusion reached in the DESI review included, when appropriate, an FDA finding that an abbreviated application was the suitable mechanism by which manufacturers or suppliers of "me-too" products could obtain FDA approval. Following a finding of effectiveness under the DESI review, manufacturers of "me-too" drug products subject to the finding were required to submit an abbreviated application. Other manufacturers who subsequently decided to market a duplicate drug product were also required to obtain FDA approval of an abbreviated application.

An abbreviated application, unlike a full application, is not required to include basic safety and effectiveness investigations of the drug product. Rather, the abbreviated application, as a general rule, must establish that the drug product covered by the application is equivalent in safety and effectiveness (generally by bioavailability data) to the "pioneer" drug product that has undergone DESI review. The effectiveness of the drug will have already been determined on the basis of the information reviewed as part of the DESI process. The agency's conclusions, which may be relied upon by all marketers, are stated in the DESI notices. The safety of the drug will have been determined on the basis of the approval and marketing experience of the pioneer product. Thus, the information required to be in an abbreviated application is basically limited to information about the applicant's ability to manufacture a product of acceptable quality. As noted, under current agency policy, abbreviated new drug applications have been limited to drug products that are identical or closely related to pre-1962 drug products reviewed under the DESI program.

The agency has applied a different procedure to duplicates of approved antibiotics. Because FDA approves antibiotic drugs and provides for their certification through a licensing procedure that is more public than that for new drugs, all safety and effectiveness data and information are immediately available for public disclosure after an approval letter has been sent to the applicant for the original pending antibiotic Form 5 for the drug. The antibiotic Form 5 is analogous to a full new drug application. An applicant seeking to market a duplicate of an approved antibiotic may rely upon the publicly available safety and effectiveness data in the first applicant's antibiotic Form 5 to obtain approval of its drug under an antibiotic Form 6, which is analogous to an abbreviated new drug application. This procedure for antibiotics would continue under the current proposal.

Under this proposal, FDA would continue to accept an abbreviated application for any drug product if the agency has first made a finding that an abbreviated application is suitable for the product. The agency would list in the regulations classes of drugs for which it has made such a finding and would make publicly available a list of specific drug products for which the agency has made the finding. The archival and review copies of an abbreviated application would generally only be required to contain two technical sections, a chemistry, manufacturing, and controls section and a human pharmacokinetics and bioavailability section. Abbreviated applications would not be required to contain a summary.

The abbreviated application procedures focus on the ability of the manufacturer to produce a drug product of acceptable quality. In first developing those procedures, FDA assumed it could in most cases adequately assess the manufacturer's ability to produce a product on the basis of less manufacturing and controls information than is required of manufacturers of products not subject to the abbreviated application procedures. The agency's current regulation reflects this assumption, as it requires abbreviated applications to contain only an outline of manufacturing and controls information, unless FDA asks for more information. (See 21 CFR 314.1(f).) Following implementation, however, FDA soon found that an outline of manufacturing and controls information was inadequate as a basis for determining a manufacturer's ability to produce a product of acceptable quality. Thus, almost from the outset of the abbreviated application procedures, FDA relied on the provision in the regulations that permitted it to ask for additional information to obtain for abbreviated applications essentially the same information it obtains for applications for duplicates of marketed drugs that are not subject to those procedures. This proposal conforms the regulations to the agency's need for adequate manufacturing and controls information in abbreviated applications by establishing the same requirement for all applications.

The agency also proposed to establish formally a new kind of submission, called an "application development file," that would permit applicants to obtain agency review of, and comments about, information they intend to include in an abbreviated application before actually submitting it. Many applicants now submit incomplete abbreviated applications that contain only formulation data, dissolution data, and bioequivalence protocols. Lacking bioequivalence data, these submissions are on their face insufficient for filing and approval. Nevertheless, applicants make this kind of submission to obtain agency review and comment on their protocols before beginning bioequivalence tests of their drug products. These submissions are currently reflected in agency records as abbreviated applications, even though they are not complete for review purposes until the results of the tests on which FDA previously commented are submitted. Thus, there may be a misperception that the review period for these applications is longer than is really the case, since the review period does not actually begin until applications are complete, with all test results submitted. The application development file is intended clearly to remove preliminary agency protocol review from the 180-day review period that applies to abbreviated applications while still providing a mechanism for continuing the current agency practice of reviewing this information. The agency would continue to try to review application development files and provide comments on them quickly, so that applicants can begin their bioequivalence tests without delay. If an applicant chooses to submit an application development file, it must be in the same form required for an abbreviated application, but the submission would be limited to the formulation data, dissolution data, and bioequivalence protocols the applicant proposes to rely upon to conduct its bioequivalence tests to support an abbreviated application. Only upon submission and filing of the complete abbreviated application, however, would the statutory 180-day review period begin.

Communication Between FDA and Applicants During Review

FDA believes that increased and improved communication between it and applicants can do much to facilitate review of applications. Frank and open discussions between individuals who develop applications and FDA officials who review those applications can bring both good science and common sense to the drug approval process. FDA encourages such communication wherever feasible both before an

application is submitted and while it is under review.

Communication before submission of an application. The agency's experience has been that a presubmission conference, where the applicant sits down with the reviewing team to discuss the best way to present the information in the application, is exceedingly helpful in speeding up its subsequent review. A significant source of delay in FDA's review of applications occurs when reviewers need to ask the applicant to analyze the data in the application differently or to present it differently. Because a presubmission conference can help avoid this time loss, FDA strongly encourages applicants to initiate one, especially for new chemical entities, or if the applicant is relatively inexperienced in new drug development. FDA does not intend, however, to require such conferences and recognizes that in some cases they may not be necessary.

Communication during review of an application. FDA recognizes that more is needed to foster communication with drug sponsors while applications are being reviewed by the agency. The Pharmaceutical Manufacturers Association (PMA) and others have suggested that more communication is needed during this stage so that sponsors can monitor the status of their applications and learn of deficiencies as soon as possible so that those deficiencies may be corrected promptly. FDA agrees with this goal and is taking the following steps to achieve it.

First, as described in a different section of this preamble, FDA will determine within 60 days from receipt of an application if the application is in a form acceptable for filing. All sponsors, under the proposal, will therefore receive feedback from the agency about 60 days from the submission of their applications. For applications which are filed, drug sponsors will be apprised that their applications have passed this preliminary review. For applications which are not filed, this would be an appropriate time for the sponsor to request a conference with reviewing officials.

Second, the agency will direct its reviewing staff to contact sponsors as easily correctable deficiencies are discovered. Although some reviewing officials currently communicate with drug sponsors in this fashion, the practice varies considerably between different reviewing officials and between different reviewing divisions. When sponsors are not notified of deficiencies during the course of the review, they learn of them at the end of the review period in either an approvable letter or a not approvable letter. Drug sponsors have complained that if they had known of these deficiencies earlier, they could have corrected them and submitted an amendment to FDA before the original 180-day period had elapsed. FDA agrees that current practice has permitted this kind of delay in some instances, and the new practice described above is aimed at correcting that problem. For example, chemistry reviewers in particular will try to inform applicants about manufacturing and controls deficiencies upon completion of their reviews, and if possible before the 90th day of the review period, either by telephone or through a letter requesting more information.

Finally, FDA intends to hold an informal meeting with applicants at approximately 90 days into the review cycle. The purpose of the meeting will be to inform the applicant of the general progress and status of its application, and to advise of important deficiencies which have been identified by that time and which have not already been communicated. The agency, however, will rarely be in a position by the 90th day to give its view on the ultimate approvability of an application because that determination requires full supervisory, and sometimes advisory committee, review that will not yet have been accomplished. This meeting will be available on applications for all new chemical entities and major new indications of marketed drugs and will be chaired by the appropriate division director within the Office of New Drug Evaluation. Such meetings will be held at the applicant's option, and may be held by telephone if mutually agreed upon. Further details pertaining to these meetings will be fully described in a Staff Manual Guide that will be publicly available. These meetings will begin for applications received by FDA after publication of this proposal.

Requests for Reconsideration or Clarification

During review of an application, agency reviewers or division management may communicate with the applicant orally or in writing about what they believe are scientific deficiencies in the application. Reviewers may ask for additional data or information, or for changes in the application to facilitate their review. Similarly, during the review of investigational new drug applications, applicants may be informed through letters, or given opinions orally, about what data may be necessary for subsequent approval of an application, or the applicant may be asked to modify proposed or ongoing clinical studies. In some cases, applicants may question the need for an additional submission or a change in the application, or may disagree with the request, and they properly are entitled to seek a compromise or a reversal of the request through informal meetings with the division or through telephone conversations or letters. FDA intends that kind of give and take between applicants and the agency to continue. In some cases, however, applicants believe that a satisfactory informal resolution cannot be obtained.

A procedure currently exists under which an applicant can seek internal agency review of a decision through the agency's established supervisory channels. (See 21 CFR 10.75 of the agency's administrative practices and procedures regulations.) However, many applicants do not find that procedure useful for seeking rapid agency reconsideration of technical issues with respect to specific applications. Applicants have stated that they fear that if they ask the reviewer's supervisor to reconsider the request under that procedure, the reviewer will be offended and neglect or impede the prompt consideration of the application or some future application. In addition, specific time frames do not apply to that procedure. Thus, some applicants believe it is often less burdensome to comply with a reviewer's request than to ask the agency to reconsider it. PMA has addressed this concern in a petition to FDA.

In response to this problem, the agency has created a new review process that would be triggered by the applicant asking the reviewing division with which it disagrees to clarify or reconsider the request or opinion. The applicant would be free to decide whether the reviewer or the division director should first receive the request for clarification or reconsideration. Some applicants believe that taking the matter to a reviewer's division director without working with the reviewer antagonizes the reviewer. Those applicants may, if they wish, submit their requests to the reviewer directly. In other cases, however, the applicant may believe the best course of action is to appeal directly to the division director. The agency would give the applicant discretion in choosing either of those individuals to receive the request for reconsideration. Regardless of who initially receives the request, the division staff would consult with each other, and with persons outside the division as necessary, to reach a division position. The division director would then answer the request within 20

days of receipt. If the division approves the request, it would concurrently take appropriate action implementing the approval.

If the division's response is unfavorable to the applicant, the matter would then proceed automatically to the director of the Office of New Drug Evaluation (ONDE). The director of ONDE will either resolve the matter to the applicant's satisfaction within 10 days or forward it to a new committee to be known as the National Center for Drugs and Biologics Appeals Committee. Chaired by the National Center Director, this committee would be composed of management representatives, including the director of ONDE, two division directors from ONDE (who would rotate periodically as members of the committee), and other agency employees with technical backgrounds appropriate for scientific appeals. The committee would also include, as needed, other agency scientists with relevant expertise (for example, from the Commissioner's office or other FDA Bureaus) or who are outside experts (for example, members of FDA's standing advisory committees). The committee could also consult with other agency employees with technical backgrounds appropriate for scientific appeals (for example, toxicologists, statisticians, and biopharmaceutics scientists) and outside experts. The applicant would be invited to meet with the Appeals Committee and be accompanied by consultants at the meeting. The meeting would provide an opportunity for a free exchange of information and views between the agency and the applicant. Following the meeting, the National Center Director, taking into consideration the advice of the committee, would decide the issue. A good faith effort to decide issues within 30 days of their referral to the committee would be made. A similar system is being developed for disputes related to abbreviated applications, consistent with the management structure of the Office of Drugs.

The agency believes this proposal meets the concerns of applicants for a procedure to obtain review by agency managers of opinions or requests by individual reviewers or reviewing divisions on applications and of differences of opinion with respect to technical requirements. This procedure should also promote consistent treatment of applications throughout the agency's reviewing divisions. This particular procedure would not provide for an appeal of technical decisions on an application beyond the National Center Director. An applicant would, however, retain its right under § 10.75 to ask for further review of the decision.

The agency recognizes that there is no way to eliminate the possibility of personal discomfort between agency employees and industry employees when disagreements arise. The concern that retaliation might occur cannot be solved solely by procedural approaches and is best dealt with by open, honest communication and by scientists in both government and industry recognizing the normality and desirability of frank discussion of controversial matters and the appropriateness of management review of such matters. Agency management has long attempted, and will continue in the future, to foster a mature, cooperative, and trustful atmosphere for the discussion of scientific issues and to seek consensus-formation within the agency on controversial positions. This procedure asks the applicant to deal directly with the involved staff as the first stage of a reconsideration or clarification request. It also makes further appeal automatic for unresolved matters. In these ways the agency believes it will maximize employee participation early in the appeals process and minimize the risk of hostility developing among reviewing staff and applicants in the course of later appeals. The agency believes the procedure can be implemented successfully and receive the support and trust of both applicants and agency staff.

As noted above, this procedure is being implemented 30 days after publication of this proposal. The agency believes this process is a management issue which falls within the agency's discretionary power to implement without notice and comment rulemaking. The proposed regulation merely asserts the existence of that procedure, with only a brief outline of the procedure itself. Details of the procedure, stated above in this preamble, are also contained in a Staff Manual Guide which is publicly available upon request.

In petitions to FDA, PMA suggested that two new systems for resolving scientific disputes be established, one with the help of members of FDA's public advisory committees, and a second procedure relying on agency officials. PMA suggested that use of public advisory committees should be reserved for significant disputes of a scientific or technical nature, but that referral to such advisory committees should be at the appplicant's option.

PMA's internal appeals procedure is similar to the agency's proposal which would apply to all disputes involving applications. Consistent with the PMA petition, the applicant could initiate an appeal by filing a written statement with the individual reviewer assigned to the application. If the matter were not resolved quickly, the issue would be further reviewed by managers in the National Center for Drugs and Biologics.

Although the appeals procedure described in this notice would not permit applicants to determine what issues should be raised before an agency advisory committee, that option would still be available to FDA for matters raising significant scientific issues. The agency, however, does not believe, for the following reasons, that it should establish an appeals procedure that would give an applicant the right to initiate the referral of an issue to an advisory committee. (1) Because of the infrequent meetings of advisory committees, the busy schedules of committee members, and the part-time nature of their committee work, it is unlikely that advisory committees, or even subcommittees, could resolve appeals quickly. (2) Advisory committee meetings should be reserved for the most significant issues facing the agency rather than for disagreements between individual applicants and agency reviewers which, while important, would require a devotion of time and effort by advisory committees that could be better used to consider wider ranging issues. As noted above, however, the agency recognizes that the advice of outside experts can greatly aid in the resolution of scientific disputes and, for this reason, the agency intends to include such experts on its Appeals Committee.

Supplements and Other Changes to Approved Applications

With few exceptions, all changes in the conditions originally approved by FDA in the application must now be approved by the agency in a supplemental application before the change can be made. Some limited exceptions are listed in the regulations. Those changes can be made before agency approval, but the agency must be notified about the change, usually in a supplement. Applicants contend that with respect to some changes, particularly those concerning manufacturing practices, this requirement is unnecessary, takes FDA reviewers away from more important work, and causes costly delays for applicants who must defer making changes in approved products until the supplement is approved.

As a result of these concerns, the Pharmaceutical Manufacturers

Association and Parke-Davis petitioned FDA to expand the kinds of changes an applicant can make under an approved application and place in effect before receiving agency approval of the change. FDA could then be notified about the change either through a supplement when the change is made or in the applicant's annual report.

The agency proposes to eliminate or reduce significantly the problems caused by the current supplement requirements by reducing the number of changes for which applicants must submit a supplement and listing them in the regulations. The agency also proposes to reduce dramatically the changes in antibiotic applications that now require prior agency approval by applying the same requirements to antibiotics that apply to new drugs. Currently, virtually all changes in an approved antibiotic application require FDA approval of the change before it can be made. Under this proposal, changes made to the conditions originally approved by FDA for new drugs or antibiotics would fall into one of four categories: (1) Those requiring no reporting to FDA; (2) those requiring reporting in annual reports instead of supplements; (3) those requiring supplements but on which FDA prior approval is not necessary; and (4) those requiring FDA prior approval through supplements. FDA would retain preclearance requirements for those changes in marketed drugs which could be expected to affect adversely the agency's previous conclusions about safety and effectiveness of the drug. These proposed changes would help concentrate the agency's limited resources more on applications for marketing, and would also permit pharmaceutical manufacturers to institute certain postmarketing changes sooner.

No reporting necessary. As discussed above, the agency proposes to eliminate current requirements for the submission in applications of much information about manufacturing practices. Certain changes that now require prior FDA approval could be made without informing the agency. These include changes in personnel or their qualifications, changes in the lot numbering system for raw materials, and changes in master formula records and procedures for individuals who check ingredient weight, batch weight, yield reconciliation, and packaging and labeling.

The agency also proposes to eliminate the requirement that an applicant submit information about new distributors in the annual report to the application. A distributor is a person or firm whose name appears on the label of a drug product as distributing the drug, but does not include a person or firm who, in addition to distributing the product, repackages or relabels it. In the **Federal Register** of June 19, 1981 (46 FR 32016), FDA eliminated its requirement that applicants submit supplements to provide for new distributors. That action was taken to reduce the number of required supplements to approved applications and is part of FDA's overall plan to rewrite its regulations governing its drug approval process. With that change, the regulations now require that applicants submit information about new distributors in their annual reports. The agency now proposes to eliminate the requirement even for annual reports. Although an applicant would not be required to inform the agency about a new distributor, the distributor's drug product would be subject to regulatory action if its labeling were different from the approved labeling in the application in any respect other than differences in the drug products' brand names and the distributors' names.

Annual reports only. The following list includes some of those changes that now require a supplement, but under the proposal would need to be described only in the next annual report: (1) A change in an ingredient to color the drug product; (2) changes in specifications or analytical methods for a drug substance, unless a change is made because of a change in the method of synthesis (or isolation) and purification of the drug substance; (3) a change in a contract labeler or outside testing laboratory; (4) a change in container size for a non-oral dosage form of a drug product (FDA does not now require a supplement for changes involving changes in containers for oral dosage forms); (5) a change in the batch numbering system; and (6) an extension of the expiration date based on full shelf-life data obtained from an approved protocol.

In addition, under this proposal all changes not specifically falling under one of the categories requiring a supplement would be described by the applicant in the next annual report to the application. Also, any change falling under one of the supplement categories which is made simply to comply with an official compendium would instead be described by the applicant in the next annual report. This would generally arise when revisions are made to the compendia which, in turn, require changes by an applicant.

Supplements not requiring prior FDA approval. Although most changes in labeling would require the applicant to submit a supplement and obtain FDA approval before making a change, the following changes in labeling, which would make available important new information about the safe use of a drug product, could be made if the applicant submits a supplement when the change is made: Changes that add or strengthen a contraindication, warning, precaution, or statement about an adverse reaction, drug abuse, dependence, or overdosage, or any other instruction about dosage and administration that is intended to improve the safe use of the product. A change in the description of the drug product or a change in information about how the product is supplied to wholesalers or retailers that does not involve a change in the dosage strength or dosage form, and editorial or other minor changes in labeling, would not require a supplemental application.

An applicant would also be permitted to make the following changes without FDA approval before the change is made if the applicant submits a supplement when making the change: (1) Adding a new specification, adding a test method, or changing a procedure because one or more batches of the drug product fail to meet specifications; (2) establishing a new procedure for reworking a batch of a drug product that fails to meet specifications; or (3) changing the synthesis of the drug substance. Although these changes present some risks with respect to the safety and effectiveness of the product, FDA believes those risks are minimal because the drug product would still be required to comply with each of the in process and final specifications already approved in the application. In addition, FDA reviews supplements containing these changes promptly, usually before the affected products are marketed. The first two kinds of changes require prompt corrective action by the applicant and, under these circumstances, FDA believes it would be neither necessary nor desirable to insist that an applicant discontinue production of its drug product until it obtains agency approval of the change. The third change will give applicants greater flexibility in purchasing in domestic and international markets bulk drug substances produced by a method of synthesis different from the methods in the approved application.

Supplements requiring prior FDA approval. The agency proposes to retain requirements that the applicant submit a supplemental application and obtain FDA approval before making the following changes in the conditions in an approved application: (1) A change in a specification or analytical method for

the drug substance because of a change in the method of synthesis (or isolation) and purification of the drug substance. (2) A change affecting either the drug substance or drug product that relaxes the limits for a specification, establishes a new regulatory analytical method, or deletes a specification or analytical method. (3) A change in the drug product to delete or add an ingredient (except an ingredient intended only to affect the color of the product). (4) A change in the method of manufacture of the drug product. (5) A change in a facility or establishment for the manufacture, processing, or packing of the drug product. (6) A change in the drug product container and closure system. (7) An extension of the expiration date of the drug product based on data obtained under a new or revised stability testing protocol that has not been approved by FDA. FDA believes these changes needing prior approval are of a type that are more likely than others to affect the conclusions about the safety and effectiveness of drugs.

Change In Ownership Of An Application

The agency proposed to codify its policy on changes in ownership of approved applications. This information is not now codified in any form, but it is the subject of numerous inquiries to the agency. Under the proposal, both the former owner and the new owner of the application would notify the agency about the change when ownership is transferred. The new owner must provide to the agency a signed application form in which the new owner makes a commitment to comply with the regulations and conditions applicable to the application. The new owner also must confirm that it has a complete copy of the application or ask FDA to provide one. A change in ownership of the application, including a change in labeling to reflect a new brand name and the name of the new manufacturer, packer, or distributor, would not require FDA approval if each of the conditions in the regulations is met. FDA approval would be required, however, if the new owner makes a change in the application that requires a supplement.

Records and Reports

The agency proposes to revise significantly applicants' recordkeeping and reporting requirements after FDA approves an application. The recordkeeping and reporting requirements enable FDA to monitor the use of a drug after approval. FDA may withdraw approval of an application for a new drug or rescind certification of an antibiotic if an applicant fails to establish a system for maintaining required records, fails to maintain records or make reports, or refuses to permit access to, or copying or verification of, its records.

The proposed changes would eliminate excessive and duplicative recordkeeping. Current FDA regulations require an applicant to maintain indefinitely records of everything it submits to FDA. In addition, other FDA regulations require persons to maintain records of information concerning nonclinical studies, clinical studies, and manufacturing and control data. For example, record retention requirements are imposed on sponsors of nonclinical laboratory studies under FDA's good laboratory practice (GLP) regulations (21 CFR Part 58) and on manufacturers of drug products under FDA's good manufacturing practice (GMP) regulations (21 CFR Part 211). Because of these other recordkeeping requirements, the agency proposes to reduce the recordkeeping requirements under these new drug and antibiotic application regulations and only require the applicant to keep records of adverse drug experiences with the product, which include the raw data and any correspondence relating to the drug experience. (The term "adverse drug experience" is defined and discussed below.) The agency would require the applicant to maintain those records for only 10 years (as opposed to indefinitely, which is the current practice).

FDA now requires any person whose name appears on the labeling of an approved drug, or who manufactures, processes, packs, or labels it, to keep records and make reports to the agency about the drug. The agency proposes to require only the applicant, who is the person who owns the approved application, to keep records and make reports.

As a major reduction in applicants' reporting burdens, FDA proposes to eliminate the 3-month and 6-month reporting requirements which are now used to monitor a drug's safety in the first 2 years after approval. Because applicants would be required to report adverse drug experiences to FDA within 30 days (as described below), the agency believes it would be able to monitor in a timely way a drug's safety in the postmarketing environment. The agency proposes to retain current reporting requirements for new advertising and promotional material, and current requirements for annual reporting. Current regulations require applicants to submit new advertising and promotional material at the time of initial dissemination or initial publication.

Currently, an applicant must immediately report information about any incident that causes the drug or its labeling to be mistaken for, or applied to, another drug, to report further any bacteriological contamination, any significant change or deterioration in the drug, and the failure of one or more batches of the drug to meet its specifications. Although the agency proposes to continue to require immediate reporting of this information, it would consider the requirement to be met under the proposal if the applicant reports the information to FDA within 3 working days of receipt. Although FDA recognizes that an applicant may not be able to submit a complete report within that time, the agency believes these reports, which can lead to preventing potential safety problems from products already in distribution, are important and must be made whether or not the applicant has obtained all the facts regarding the incident giving rise to the report.

Annual reports would be modified by requiring that they contain a summary providing a brief review by the applicant of significant new information about the drug since the last annual report that might affect the drug's safety, effectiveness, or labeling. The summary would also describe what the applicant has done, or intends to do, as a result of the new information; for example, submit a supplement proposing changes in labeling, add a warning to the labeling, or initiate a new study.

Annual reports would continue to contain information about: (1) The quantity of the drug distributed; (2) copies of labels, professional labeling and patient labeling, if any, and a summary of labeling changes since the last report; (3) manufacturing or controls changes that do not require a supplement; (4) published and unpublished reports on nonclinical laboratory studies; (5) published and unpublished reports about clinical studies (except articles that do not contain original data such as review articles, articles describing the use of the drug in medical practice, promotional articles, and press clippings), including summaries of completed unpublished clinical studies or manuscripts, if available (the agency considers a study completed 1 year after it is concluded); (6) a summary tabulation of reported adverse drug experiences; and (7) a list of the current status of any commitments made by the applicant at the time of approval of the

application, which may include a log of all open regulatory business with FDA about the application; for example, a list of the applicant's unanswered correspondence to the agency and the agency's unanswered correspondence to the applicant.

The proposal retains the current requirements for the submission, in special circumstances, of unscheduled reports, the submission in one report of information common to more than one application, and the exclusion of patients' names and addresses from reports.

Reporting of Adverse Drug Experiences

Applicants are currently required to report as soon as possible, but within at least 15 working days after the applicant obtains the information, unexpected side effects, injuries, toxicities, or sensitivity reactions from their drug, and information about the failure of the drug to exhibit its expected pharmacological activity. These reports are now supplemented by 3-month, 6-month, and annual reports of other adverse drug experiences not falling under the 15-day reporting requirement. In addition to reports by applicants, FDA encourages health care professionals to submit similar reports about adverse drug experiences directly to the agency.

In the past, FDA's adverse drug experience reporting system encountered problems in the quality and usefulness of reports and in processing and analyzing them. The agency has already taken several administrative steps to correct these problems, including the following: (1) Centralizing the collection and dissemination of adverse drug experience information within the Division of Drug Experience; (2) improving communications between that office and the Office of New Drug Evaluation's review staff; (3) establishing and maintaining a comprehensive and current computerized file of adverse drug experiences into which new reports can be processed quickly; and (4) publicizing the agency's adverse drug experience system and encouraging more reporting by hospital and health care professionals. In addition to these administrative improvements, the agency believes changes in its regulations will also improve its adverse drug experience reporting system.

FDA previously proposed to revise its adverse drug experience reporting requirements (see the **Federal Register** of April 3, 1979; 44 FR 19434). Because FDA believes criticisms of that proposal justify a substantial revision in its proposed definitions and other changes, the agency will withdraw the proposal. Although FDA is again proposing revisions in its reporting requirements, applicants are required to continue submitting adverse drug experience reports under the existing regulations until new regulations are finalized. Applicants must report all adverse drug experiences known to them, including foreign experiences.

The agency now proposes to define the term "adverse drug experience" more broadly to mean "any experience associated with the use of a drug in humans, whether or not considered drug related," which would include the following: (1) All suspected adverse drug reactions; (2) reactions occurring from drug overdose, whether accidental or intentional; (3) reactions occurring from drug abuse; (4) reactions occurring from drug withdrawal; and (5) the failure of a drug's expected pharmacological action. FDA believes this definition improves on both the current requirements and the April 3, 1979 proposal by unambiguously identifying the specific groups of drug experiences for which reporting is required. Although some applicants already submit reports on each of these types of adverse drug experiences, this proposal would increase the required reporting burden on applicants. FDA believes this change is justified for the following reasons: (1) Reports of all adverse drug experiences are useful and, in adequate numbers, can provide profiles of a drug's effects; (2) reports of overdoses (accidental or otherwise), abuse, and withdrawal are useful in ascertaining other aspects of a drug's risk; (3) reports of some trivial reactions serve as predictors of more serious problems; and (4) reports that are timely in relation to the market volume of the drug provide a better adverse drug experience data base.

Under the proposal, FDA would require the most important adverse drug experiences to be reported within 15 working days and the remainder within 30 working days. The 15-day report would be called an "alert report" and would apply to fatal and life-threatening adverse drug experiences that are not mentioned in the drug's current labeling. This change would highlight those experiences that have the greatest public health significance and that require early evaluation and close monitoring. These are the types of adverse drug experiences for which waiting 30 working days would not be in the public interest. Applicants should report these experiences as soon as possible, even if they have not obtained complete information about the experience. Complete information should be included in a followup report.

All other adverse experiences, as well as follow-ups to 15-day reports, would be required to be reported within 30 working days of initial receipt by the applicant. The 30-day reporting requirement should result in complete adverse drug experience reports being incorporated in a timely manner into the agency's data base. This is because experiences now contained in annual reports would be submitted earlier so that the monitoring system can be kept current. The agency's experience is that 30 working days is an adequate period of time for applicants to obtain the necessary information to be reported. The 30-day reporting requirement, therefore, should not impose an unreasonable burden on industry and should strengthen significantly the quality of FDA's adverse drug experience data base. All adverse drug experience reports would be required to be submitted on a Form FDA-1639. The agency intends to prepare guidelines on meeting the proposed reporting requirements.

FDA is also proposing the following additional changes in its adverse experience reporting requirements. (1) Applicants would no longer be required to submit duplicate copies of adverse drug experience reports. This change is made possible by the centralization of FDA's processing of drug experience reports in a single office in the National Center for Drugs and Biologics that has exclusive responsibility for ensuring the proper distribution and analysis of all reports. (2) This proposal also introduces flexibility into the rapidly developing area of computer-generated reports. The proposal would permit an applicant to use any format for computer-generated reports, subject to the approval of FDA's Division of Drug Experience (HFD-210), instead of prescribing a specific format. (3) The proposed regulations would also provide that reports of adverse drug experiences reported in the published literature must be reported to FDA only if they involve adverse drug events or clinical toxicity information, and that reports to FDA be accompanied by a copy of the original publication. The information in the publication would become part of the actual file of the adverse drug experience and the submission of a copy would help to prevent duplicate recording of the experience. The agency proposes to require a Form FDA-1639 when reporting these adverse drug experiences.

Waivers

The agency proposes to add a section under which an applicant may obtain a

waiver of requirements for the submission of information in an application. An applicant would submit a request for a waiver with supporting information in an application, or in an amendment or a supplement to an application. The request must either explain why the requirement is unnecessary or cannot be achieved in a particular case, describe an alternative submission that satisfies the purpose of the requirement, or provide other information justifying a waiver. FDA could grant a waiver if it finds the applicant's compliance with a requirement is unnecessary or cannot be achieved, the applicant makes an alternative submission that satisfies the requirement, or the applicant otherwise justifies a waiver. This waiver provision is intended to give applicants flexibility to seek alternative ways of complying with the statutory standards for drug approval. Clearly, however, FDA is unable to waive statutory requirements.

Time Frames for FDA Action On Applications

The agency proposes to revise its regulations regarding agency actions in filing, reviewing, and approving or refusing to approve applications. Under section 505(c) of the act, within 180 days after an application for a new drug is filed, FDA must either approve the application or give the applicant a notice of an opportunity for a hearing (NOOH) on whether the application is approvable, unless FDA and the applicant agree to an extension. The agency proposes to revise its regulations to specify, in accordance with the statute, how long the agency would take to review an application, when FDA would file an application, and how extensions would be given to the review period.

The key to the proposal is a provision under which FDA would be required to send to an applicant an action letter (that is, an "approvable" letter, a "not approvable" letter, or an "approval" letter) within 180 days of receipt of the applications. Although this time period could be extended when amendments are submitted to the application, any extension would be only for the period of time necessary for the additional review of the amendment. Thus, under this proposal, applicants would be assured of a response from the agency within a reasonable period of time on whether their application is approvable.

In addition, the proposal contains several technical features regarding the "filing" of an application and the issuance of an NOOH. Under the proposal, FDA would determine 60 days after receipt of the application whether that application is acceptable for filing, and applicants would receive notification at the 60 day point stating whether their application is indeed "filed." Thus, this provision would give the applicant earlier feedback on whether its application is suitable for filing, but it would not affect FDA's commitment to issue an action letter within 180 days of receipt of the application. The proposal would also reduce the time period between the issuance of a "not approvable" letter and an NOOH to 60 days, including a 10-day period during which the applicant would notify FDA if it wishes an NOOH to be issued. This revision would expedite the commencement of administrative hearing procedures in those instances where applicants wish to invoke them. The FDA actions from date of receipt and from date of filing are shown in a table at the end of this section.

The agency believes that the proposed changes would expedite the new drug review process in the following ways. First, codifying the provision for the 180-day review clock would signify the agency's commitment to review applications quickly. Although the agency now attempts to review applications within this period of time, the agency feels that formalizing the length of this review period would provide clear goals to agency staff as well as signal applicants that their applications are receiving prompt review.

Second, the provision regarding amendments to pending applications would be a substantial departure from current policy. The current rule is that any substantive amendment submitted to an application, whether at FDA's request or on the applicant's own initiative, automatically restarts the 180-day clock, and this begins a new review cycle. Under the proposal, extensions to the review clock for evaluating major amendments would be limited to the time necessary for FDA review of them. An amendment would be major if it would require a substantial amount of time to review; for example, a major amendment might contain significant new data from a previously unreported study or detailed new analyses of previously reported data. The agency would consider a major amendment to constitute an agreement by the applicant to an extension of the review period, but, as noted above, only for the length of time needed to review the submission. The time for which the review period is extended, up to a maximum of 180 days, would be determined by the director of the division that is responsible for the application, who would inform the applicant of the length of extension. An applicant who disputes the extension could request reconsideration of it. Because most applications are amended at some point during the review process, this change should reduce significantly the amount of time the agency would have to review applications.

Third, the proposed date for "filing" an application would also be an important change from current practice. Under the current system, an application is not technically filed until an approvable letter has been issued. If a not approvable letter issues, then, under the current system, the application is not filed at all. In this way, applications may be under review for many months, if not years, before they are actually filed. The proposed change to this practice would make the agency determine, 60 days following receipt of the application, whether the application is acceptable for filing. Under the proposal, the applicant would receive feedback from the agency after 60 days one way or another. This early date for filing is very important because it triggers the statutory time period alloted for agency review of an application. The recent Federal court decision in *Newport Pharmaceuticals International Inc.* v. *Schweiker*, Civil Action No. 81-1283 (D.D.C. December 1, 1982), held that FDA is entitled to a reasonable period of time to make a threshold determination on whether an application is sufficiently complete for filing. The agency believes that 60 days constitutes a reasonable time in these circumstances.

Fourth, the proposal would modify the current mechanism for "filing over protest." Under the current system, upon the issuance of a not approvable letter, the applicant has the option of requesting that its application be filed over protest. This request triggers an expedited review by a separate team of reviewers to be completed within 90 days. If that review also concludes that the application is not approvable, FDA issues an NOOH. Under the proposal, the filing over protest would occur earlier in the process and a second scientific review would not be necessary. The proposal provides that, if an applicant is notified within 60 days of receipt of the application that the application is not suitable for filing, the applicant would at that time be permited to request that its application be filed over protest. In that case, the application would continue to be reviewed, and the 180-day clock would still begin when the application was initially received.

Finally, the proposal would expedite the issuance of an NOOH following a not approvable letter, if the applicant so elects. Under the current system, following a not approvable letter, an applicant may request that its application be filed over protest, as described above. Following that request, FDA has 90 days to issue an NOOH. The second scientific review of the application, referred to above, is conducted during that same 90-day period. No time constraints are now placed on the applicant for requesting that its application be filed over protest. Under this proposal, however, both FDA and the applicant would be subject to tighter time frames. The proposal provides that, following a not approvable letter, the applicant would have 10 days to notify FDA if it wishes an NOOH, and FDA would then have 50 days to issue one. Thus, the process for FDA to issue an NOOH is greatly simplified and the time period is reduced nearly in half. As a result of these proposed changes, there would also be 180 days between the date the application is filed and the issuance of the NOOH, as required by law.

The agency recognizes that one confusing aspect of this proposal is the creation of two overlapping 180-day time periods. However, the agency believes that the proposal meets both the pragmatic concerns of applicants and the legal requirements of the statute. From a pragmatic standpoint, what applicants care about most is how long FDA will take from receipt of the application until reaching an institutional decision on whether the application is approvable. This is the 180-day clock described above at the beginning of this section. The statute, however, speaks in terms of "filing" rather than "receipt," and in terms of issuing an "NOOH" rather than an "action letter," and it is the time between filing and issuance of an NOOH which statutorily must be within 180 days. The proposal meets this legal requirement also. The two overlapping 180-day time periods are illustrated in the following table:

	Days from submission	Days from filing
1. FDA receipt of application	0	
2. Filing	60	0
3. Action letter issues	180	120
4. Applicant requests NOOH	190	130
5. NOOH issues	240	180

Because relatively few applications ever progress to the NOOH stage, FDA believes that the 180-day clock "from receipt to action letter" is the time period that should be emphasized.

Action Letters

After FDA completes its substantive review of an application, the agency sends to the applicant an action letter, which is either an "approval" letter, an "approvable" letter, or a "not approvable" letter. Because these terms have created some confusion, the proposed regulations would clarify their meaning.

First, if FDA finds that none of the grounds in the statute for refusing to approve an application applies, the agency would approve the application and send the applicant an "approval" letter. Only an approval letter permits immediate marketing of the drug. This is the same as current practice. In an important change, an application that requires only editorial changes or contains similar minor deficiencies in the product's draft labeling would be approved before final printed labeling is submitted on the condition that the deficiencies are corrected before the product is marketed. In that case, an approval letter would also be sent, with the specific conditions regarding labeling changes.

If the application contains significant deficiencies, however, the agency provides its conclusion to the applicant in either an approvable letter or a not approvable letter. An "approvable letter" means the agency believes that important, but easily resolved, deficiencies exist in the application, and FDA will approve it if the applicant submits specific additional information or material identified in the letter or agrees to other specific conditions. In contrast, a "not approvable" letter has reflected the agency's conclusion that major deficiencies exist in the application or that the information contained in the application is unable to support approval of the drug for marketing. Unless an applicant has corrected the deficiencies by amendment, submitted new information, or withdrawn the application, the agency would formally refuse to approve it. The proposal would simply codify these practices for purposes of clarity.

Also under the proposal, an applicant would be required to respond within 10 days to either an approvable or a not approvable letter unless FDA and the applicant agree to an extension. The applicant could either (1) withdraw the application, (2) amend the application or notify FDA of its intent to file an amendment, or (3) for a new drug, ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) of the act; or, for of an antibiotic, file a petition or notify FDA of an intent to file a petition proposing the issuance, amendment, or repeal of an antibiotic regulation. FDA would view an applicant's failure to respond within 10 days to be a request by the applicant to withdraw the application. The withdrawal of the application would be without prejudice to refiling. If the applicant receives an approvable letter and then files an amendment or notice of intent to file an amendment, FDA would review it and take appropriate action within 45 days of receipt of the amendment. If the applicant receives a not approvable letter, requiring the applicant to attempt to resolve major deficiencies in the application by amendment, FDA would extend the review period by the time needed to review the amendment.

Refusal To Approve An Application

The agency proposes to retain its regulations governing a refusal to approve an application but to amend them to provide that FDA will prepare and issue a notice of opportunity for hearing on its refusal to approve an application only if the following three conditions are met: (1) The agency sends the applicant an approvable letter or a not approvable letter; (2) the applicant within 10 days of the date of the letter asks the agency to provide it an opportunity for a hearing for a new drug or files a petition for an antibiotic; and (3) the agency concludes that there are grounds for denying approval of the application.

The agency proposes to add the following reasons for refusing to approve an application to those in the current regulations: (1) The applicant refuses to correct a deficiency for which the agency may refuse to file an application (this reason might apply to an application filed over protest); (2) the drug will be manufactured or processed in an establishment that is not registered or exempt from registration under section 510 of the act; (3) the applicant refuses to permit an FDA inspection of the facilities, controls, or records relevant to the application; (4) the applicant does not comply with the agency's current good manufacturing practice regulations; and (5) the drug product's labeling does not comply with the agency's labeling regulations (other than minor deviations easily correctable).

A notice of opportunity for a hearing on a refusal to approve an application would generally provide, as such notices now do, a detailed description and analysis of the specific facts resulting in

the agency's refusal to approve the application and would refer to specific requirements in the act and regulations under which the agency refused to approve the application. An applicant would have, as it does now, 30 days to respond to such a notice. If the applicant requests a hearing on a new drug, the agency would issue a notice granting or denying a hearing within 90 days of the expiration of the 30-day period. In the case of an antibiotic, the current procedure involving formal rulemaking would continue to apply.

Adequate and Well-Controlled Investigations

FDA proposes several minor revisions to the regulation defining the characteristics of adequate and well-controlled investigations. For example, the proposed revisions would clarify the characteristics of a good study and make explicit certain provisions of the regulation that may now only be implicit. This regulation does not establish the requirement that applicants demonstrate the effectiveness of drugs by substantial evidence consisting of adequate and well-controlled studies; that requirement is imposed by statute (section 505(d) of the act). Rather, this regulation simply defines the characteristics, based on principles generally accepted in the scientific community, of what constitutes an adequate and well-controlled clinical study. The agency will explain in a guideline how the requirements in this regulation are to be interpreted and applied in order to meet the statutory substantial evidence test.

For example, the current regulation calls for a method of selection of the subjects in test and control groups that minimizes bias and assures comparability of pertinent variables such as age, sex, severity or duration of disease, and use of drugs other than the test drug. Although no method of assignment can invariably assure comparability, the agency proposes to revise the section to note that a study must have a method of assignment that is intended to assure comparability with respect to significant independent variables. Acknowledging the possibility that, in fact, test and control subjects may not be matched in all respects, the agency proposes to require in the analysis of the results of a study, an assessment of the comparability of test and control subjects with respect to pertinent variables. The agency also proposes to revise this section dealing with selection of subjects to note that ordinarily, in a concurrently controlled study, assignment of both test and control subjects is to be made by randomization.

One problem also exists with respect to the current provision requiring a study protocol and report of results to contain a summary of the methods of analysis and an evaluation of data derived from the study. Apart from the impossibility of submitting in the protocol an evaluation of data not yet obtained, this provision is deficient in failing to require explicitly that the analysis of results of the study adequately assess the effects of the drug under study. The proposed revision corrects this deficiency and also drops the requirement that the plan or protocol, as opposed to the report of the study, contain a summary of the methods of analysis and an evaluation of data derived from the study.

The agency also proposes several revisions to the provisions describing the various kinds of controls that may be incorporated into a study design. The current regulation requires that the study provide a comparison of the results of treatment or diagnosis with a control group in such a fashion as to permit quantitative evaluation, but does not explicitly call for a design that permits a valid comparison between treatment and control. The proposed revision contains an explicit requirement.

The proposed revision retains, with only minor changes, the descriptions of placebo, no treatment, active treatment, and historical controls contained in the current regulation. With respect to active treatment controls, the proposal adds a provision asking, if the intent of a trial using such a control is to show similarity of the test and control drugs, that the report of the study assess the ability of the study to have detected a difference between treatments. The provision is added to overcome the difficulties inherent in a study design that looks for a lack of difference between the control and the drug under study.

Finally, the agency would recognize and describe in the regulations the dose-comparison concurrent control study, a fifth study design in which both the treatment group and the control group receive the drug under study. The proposal notes that a dose-comparison study may include additional groups, such as placebo control or active control, and the dose-comparison trials usually include randomization and blinding of patients or investigators, or both.

Withdrawal of Approval

The agency proposes to retain its current regulations stating the grounds for the withdrawal of approval of applications for new drugs and to apply them as well to rescinding a certification or release for an antibiotic, or amending or repealing a regulation providing for certification. The regulations describe the circumstances under which the agency is obligated to notify and afford an applicant an opportunity for a hearing on a proposal to withdraw approval of an application; for example, if FDA finds that the drug is unsafe or not shown to be safe, that there is a lack of substantial evidence that the drug is effective, or that the application contains an untrue statement of a material fact. The regulations also describe circumstances under which the agency has discretion to withdraw approval of an application; for example, because the applicant fails to keep required records and make required reports or because the facilities or controls used for the manufacture of the drug are inadequate to assure and preserve its identity, strength, quality, and purity, and the applicant fails to make them adequate within a reasonable time after notice from the agency.

The agency proposes to make two substantive changes in these regulations. The changes are consistent with a PMA petition to the agency to provide for withdrawal of approval of an application with the consent of the applicant. PMA urged that the agency also amend its public information regulations to ensure that data and information in an application that may be confidential and have proprietary value not be made available for public disclosure after FDA withdraws approval at the applicant's request. As discussed below, the agency is proposing to revise its public information regulations to ensure that trade secret and confidential commercial information is not disclosed in an application for which approval is withdrawn.

The first change would permit FDA to withdraw approval of an application if the applicant asks that approval be withdrawn because the drug product is no longe marketed. The agency would consider the request for withdrawal to waive the notice and opportunity for a hearing that the agency is otherwise obligated to provide. If the agency withdraws approval of an application at the applicant's request, the applicant may subsequently refile the application. The second substantive change would permit FDA to notify an applicant if the agency believes a potential problem associated with the drug product is sufficiently serious that the product

should be removed from the market. The agency may ask the applicant to remove the product from the market voluntarily and to waive the notice and opportunity for a hearing and permit FDA to withdraw approval of the application. If the applicant agrees to withdrawal of approval of the application, FDA would not make the detailed finding it would otherwise be obligated to make when withdrawing approval. The agency would, however, when publishing a notice to withdraw approval of the application, give a brief summary of the agency's views of the reasons for withdrawing approval of the application together with a summary of the applicant's views on the withdrawal.

A comment to FDA objected to a revision of the regulations to permit the agency to withdraw approval of an application simply on the applicant's request. The comment suggested that before the agency withdraws approval under those circumstances it should determine that the public would not be harmed by the removal of the drug from the market.

FDA disagrees with the comment. The agency does not believe it can require applicants to maintain an active application. Applicants are free to discontinue marketing an approved drug at any time. Experience has shown that generally applicants only ask the agency to withdraw approval of applications for drugs they have already discontinued marketing. Thus, the review the comment contemplates would not keep the drug on the market.

Adulteration and Misbranding

The agency proposes to add a new section to the regulations to clarify the relationship between the premarket approval requirements of the act and its adulteration and misbranding provisions. Holders of approved applications have contended that the agency may not, through informal notice and comment rulemaking, require the holder of an approved application to comply with revisions of the current good manufacturing practice regulations or labeling regulations without first providing the applicant an opportunity for a hearing about whether new information exists that shows that the manufacturing practices or labeling of the approved drug product are inadequate to ensure the safe and effective use of the product. These manufacturers contend that the existence of an approved application for a drug product insulates the product from the adulteration and misbranding provisions of the act and that withdrawal of approval of a drug product is the exclusive method for regulating an approved product.

FDA rejects that contention. The statutory scheme contemplates FDA regulation of all drugs through enforcement actions against drugs that are adulterated or misbranded and against persons who are responsible for the failure of a drug to comply with statutory requirements. Because of the potential for serious dangers from untested products, however, the statute imposes additional requirements on new drugs and antibiotics that they be approved by the agency before maketing on the basis of a showing of safety and effectiveness. Those requirements do not insulate new drugs and antibiotics from the general requirements of the act; instead, they impose additional burdens on these drugs. To make explicit the relationship between the adulteration and misbranding provisions of the act and the new drug and antibiotic provisions, FDA proposes to codify its position that the agency has the authority to regulate approved new drug products and antibiotic drugs under sections 501, 502, and 503 of the act.

Hearing Procedures for New Drugs and Administrative Procedures for Antibiotics

The agency proposes to make editorial, but not substantive, changes in its regulations describing notices of opportunity for hearing on proposals to refuse to approve applications or to withdraw approval of approved applications, notices of participation and requests for hearing, and notices and orders granting and denying hearings with respect to new drugs. It also proposes to recodify in Part 314 its current regulations describing FDA's procedures for issuing, amending, and repealing regulations providing for the certification of antibiotics. The changes in the regulations clarify the responsibility of both FDA and applicants with respect to hearings. For example, the current requirement that "the notice of opportunity for hearing shall be provided to applicants" is revised to state "FDA will provide the notice * * * to applicants," and the current requirement that "a request for hearing shall be supported by a submission * * *" is revised to state "The person requesting a hearing is required to submit * * *." These changes clearly identify the person who is responsible for taking an action.

Miscellaneous Provisions

Imports and exports. FDA proposes to add to the regulations a section that codifies the agency's current policy on imports and exports. Because of different statutory requirements for new drugs and antibiotic drugs, the regulations contain different requirements applying to their export.

The act prohibits interstate commerce of unapproved new drugs and uncertified (or unreleased) antibiotics and section 201(b) of the act defines the term "interstate commerce" to effectively include imports and exports. Thus, a new drug product or an antibiotic drug product may be imported or exported if it is subject to an approved application or is subject to an exemption provided for in Part 312 (21 CFR Part 312) for investigational new drugs. In addition, a bulk drug substance may be imported if it complies with the agency's labeling regulations for domestic shipments. See 21 CFR 201.122.

An antibiotic that is subject to certification, but which has not been certified or released, is misbranded under section 502(1) of the act and its shipment in interstate commerce is prohibited under section 301(a) of the act (21 U.S.C. 331(a)). Under section 801(d)(1) of the act (21 U.S.C. 381(d)(1)), however, an antibiotic drug or any other drug intended for export is not considered misbranded if it meets the specifications of the foreign purchaser, is not in conflict with the laws of the country to which it is intended for export, is labeled on the outside shipping package that it is intended for export, and is not sold or offered for sale in the United States. Thus, an antibiotic that may not be marketed in the United States may be exported under those provisions. Similar provisions do not apply, however, to new drugs. Thus, new drugs may be exported only if they are approved for shipment in domestic commerce.

Although the proposed regulations codify the agency's curent policy on imports and exports, the agency is making two changes in that policy. The first change would permit a supplier of a bulk drug substance used in an approved new drug product to export the bulk drug substance even if the drug substance manufacturer does not hold an application for a drug product containing it. FDA is taking this action to facilitate commerce in bulk drug substances. Because the agency generally does not approve applications for new drug substances, it would consider the approval of the application for a drug product, which contains detailed information about the drug substance, to cover the export of the drug substance. The export shipment would be required to meet the same standards as the substance meets for use in an approved drug product and

include a copy of the labeling for the product with the shipment.

The second change would permit an individual entering the United States (for example, a foreign visitor or an American citizen returning to this country) to bring in a reasonable quantity of an unapproved drug product for personal use. The agency believes that this statement of policy represents a reasonable exercise of its enforcement discretion and that individuals should be allowed to freely bring medicine they obtain abroad for personal use into the United States, without fear of legal sanctions. The agency believes such sanctions should be reserved for manufacturers and distributors who seek to profit financially from the unlawful importation of unapproved drugs. This policy would not apply, however, to drugs controlled by the Drug Enforcement Administration under the Controlled Substances Act, nor would it apply to persons who promote this activity to subvert the restrictions on manufacturers and distributors.

Drug master files. The agency proposes to amend substantially the regulations on drug master files to conform them to current practice. A drug master file is a body of information that a person (the drug master file holder) submits to FDA. The existence of a drug master file permits its holder to incorporate the information by reference in investigational new drug applications, or other applications or submissions to the agency without having to submit repeatedly individual copies of the information. In addition, the holder may authorize other persons to rely upon the information to support their submissions to FDA without the holder or the agency disclosing to the other person information in the master file that may be a trade secret. The proposed amendments describe a master file and clarify that FDA only reviews the content of a master file in the context of its review of an application.

The proposal lists five examples of drug master files that the agency accepts. Although it is not specifically requried, the drug master file holder should review its drug master file annually and keep it up to date. The proposed regulations specify that each incorporation by reference from a drug master file is required to describe the incorporated material by name, reference number, volume, and page number. The regulations would require the holder to (1) submit three copies of the drug master file, (2) maintain a list in the master file of each person authorized to incorporate by reference information in the file and identify the information the person is authorized to incorporate, and (3) notify, in writing, each person authorized to reference information in the file each time the file holder makes a change in the information upon which that person relies. The agency sends one copy of the master file to its district office where the master file holder is located for use by compliance officials who may be required to inspect the drug master file holder's facilities. FDA retains the other two copies in its document rooms; one copy becomes a permanent reference copy and the other may be borrowed temporarily by reviewers.

Finally, the agency proposes to delete the provision in the current regulations under which it may disclose information in a drug master file to a person authorized to reference the file. This provision predates the agency's comprehensive public information regulations and has been superseded by them. It also might be read to suggest that the agency is required to disclose trade secrets, although such disclosure is prohibited under section 301(j) of the act. Thus, the agency proposes to rely solely on its public information regulations for disclosure of information in a drug master file. Persons authorized to rely on a drug master file who desire information from the file that would not be available to them from the agency through a freedom of information request must reach private agreements with the drug master file holder for the disclosure of information in the drug master file.

Other changes. FDA proposes a new section in the regulations that would better identify appropriate agency offices to which applications should be sent. The agency is also proposing a new section that explains the agency's use of guidelines to help persons comply with the regulations. Although this revision of the regulations would establish general requirements for the kind, quantity, and presentation of data needed to obtain marketing approval of a new drug or antibiotic, the proposed regulations would give applicants a great deal of flexibility in putting together an application. For those applicants who desire more guidance, the agency will make available guidelines under § 10.90(b) (21 CFR 10.90(b)) of the agency's administrative practices and procedures regulations. The guidelines will outline procedures and standards of general applicability that are acceptable to the agency for complying with the regulations. As noted in FDA's general procedural requirements (21 CFR 10.90), guidelines do not establish legal requirements, but a person may be assured that by following an agency guideline his or her submission will be in a form acceptable to the agency. A person may also choose to use alternative procedures or standards even though they are not provided for in a guideline. A person who chooses to use alternative procedures or standards may discuss the matter in advance with FDA to prevent an expenditure of money and effort on work that may later be found unacceptable. Final regulations establishing the agency's new drug and antibiotic application regulations will make publicly available a list of guidelines that apply to the regulations. The list will also state how a person can obtain a copy of each guideline.

The proposal retains the current regulations on the public availability of data and information in an application, except that the agency proposes to revise the provision concerning the disclosure of safety and effectiveness information in an application when an application is not approved, approval is withdrawn, or the application is abandoned. That provision now provides for disclosure of the information unless extraordinary circumstances exist. The agency proposes to revise the regulation to provide for disclosure if the data and information no longer represent a trade secret or confidential commercial or financial information under § 20.61 (21 CFR 20.61) of the agency's public information regulations. The agency believes the change reflects better the exemption in the Freedom of Information Act from public disclosure of trade secrets and commercial or financial information and the limitations in section 301(j) of the act on disclosure of trade secrets. It would no longer require applicants to make useless submissions to existing files in the form of annual reports primarily to prevent disclosure of trade secret information in the file.

Foreign Data

Introduction. FDA's acceptance of foreign data has evolved considerably over the past decade, consistent with the increasing quantity and quality of research performed in other countries. As a result, the agency has relied increasingly on foreign data in new drug applications, to the extent that foreign data have sometimes been pivotal in approving new drug applications. The Pharmaceutical Manufacturers Association (PMA) has petitioned the agency to go one step further and approve drugs based solely on foreign data meeting U.S. statutory criteria,

unless the agency can point to something specifically in the studies which prevents the foreign data from being applicable to the U.S. population. FDA agrees with PMA that agency policy should be changed to provide the flexibility for approving drugs based solely on foreign data in scientifically appropriate instances, although the agency believes the requisites for such approval need to be delineated somewhat differently than those suggested by PMA. This new agency policy is set forth below, following a more general discussion on agency criteria for the acceptance of individual foreign studies.

Acceptance of individual foreign studies. FDA's policy is to consider all clinical studies on their merits regardless of the country of origin, providing such studies meet the standards prescribed in FDA's regulations (21 CFR 312.20). To be acceptable as an adequate and well-controlled investigation, a foreign study must meet the standards in FDA's regulation for adequate and well-controlled investigations (21 CFR 314.111) and must be conducted by a well-qualified investigator in a facility adequate for the conduct of such studies; the study must meet the ethical standards described in the Declaration of Helsinki or the laws of the country of origin; the protocol must be reviewed by an independent committee and patients must give their informed consent; and full documentation of the study must be submitted to FDA, including necessary case report forms, data tabulations, and other appropriate raw data. These are the same or analogous requirements that apply to domestic studies. Foreign studies that meet these requirements are acceptable for all decisionmaking purposes by the agency.

The same general policy applies to animal data, chemistry data, and other information such as biopharmaceutical and microbiological data. To be acceptable in support of a new drug application, toxicological studies must be conducted in accordance with the good laboratory practice (GLP) regulations (21 CFR Part 58). Drug products used in clinical trials must be produced in accordance with applicable sections of the good manufacturing practice (GMP) regulations (21 CFR Parts 210 and 211). These are the same requirements that apply to domestic animal studies and to chemistry data obtained in the United States. Animal data and chemistry data from foreign laboratories may be used in full support of a new drug application, providing such data meet all of the applicable requirements in FDA's regulations.

Foreign clinical data as sole basis for approval. The agency proposes to consider, on a case-by-case basis, the scientific appropriateness of approving a given drug based solely on foreign clinical data. The foremost consideration in making this determination would be whether the foreign studies meet U.S. criteria in terms of the quality of scientific research. See § 312.20 (a), (b), and (d) and the discussion above on individual studies. The agency is committed to relying on only those studies—be they foreign or domestic—which meet contemporary scientific standards for demonstrating the safety and efficacy of new drugs. In addition, the agency believes that there are three specific considerations which are important in deciding whether a given new drug should be approvable based solely on foreign clinical data: (1) medical, genetic, and cultual differences between countries; (2) lack of familiarity of FDA with foreign clinical investigators and facilities; and (3) inability of FDA to conduct on-site verification of most foreign studies. These three special considerations may be detailed, as follows:

1. *Medical, genetic, and cultural differences between countries.* It is well recognized that medical, genetic, and cultural differences may affect the domestic applicability of a clinical study conducted in a foreign country. As an example of differences in medical practice, anti-hypertensive drugs are customarily studied in conjunction with thiazide diuretics in the United States but are commonly studied in conjunction with a beta-adrenergic blocking drug in the United Kingdom. As an example of a genetic difference in populations, the metabolism by acetylation of the anti-tuberculosis drug isoniazid is generally rapid in the Japanese population, and slow in Scandinavians; the U.S. population contains a roughly equal proportion of rapid and slow acetylators. As an example of cultural diferences that influence clinical research, psychiatric diagnoses are heavily colored by cultural concepts of behavior and by linguistic nuances; thus terms such as "anxiety" or "depression" may not have clearly identical meanings in different societies. For these reasons, the agency would not accept foreign studies as the sole basis of approval when there is reason to believe that the applicability of the foreign data to the U.S. population or U.S. medical practice is limited by medical, genetic, or cultural differences.

2. *Lack of familiarity of FDA with foreign clinical investigators and facilities.* FDA believes that it should not approve new drugs for marketing where the caliber of the key clinical investigators and facilities is unknown. Although this concern applies implicitly to domestic studies as well, the agency can verify a particular clinical investigator's or institution's qualifications. This is not the case, however, for many foreign investigators. Accordingly, where an application is sought to be approved based solely on foreign data, the agency would need to be satisfied that the key foreign clinical investigators and facilities have a demonstrated competence. Factors considered by the agency in this regard include an investigator's international scientific reputation, experience in the evaluation of drugs, publication in established scientific journals, participation as an expert in scientific meetings, and conduct of research in well-known medical institutions. Personal knowledge of, or familiarity with, a foreign clinical investigator's work by FDA's staff or one or more members of an FDA advisory committee is another such factor. As noted above, this general concern of establishing a foreign investigator's competence is already expressed in § 312.20(b)(1).

3. *Inability of FDA to conduct on-site verification of most foreign studies.* As a practical matter, FDA either is not permitted or lacks the necessary resources to conduct on-site inspections of foreign clinical data. For this reason, the agency strongly encourages drug sponsors to verify the validity of information submitted to the agency through on-site spot check audits of the supporting medical records. In appropriate instances, however, the agency may seek to audit specific foreign studies where good cause exists and will reject such studies if an FDA audit or other appropriate audit is not permitted. Thus, an application would not be approvable based solely on foreign data in those instances where a "for cause" on-site inspection (an inspection triggered by something FDA finds in the review) of essential data would ordinarily be conducted were the study of domestic origin, and such inspection cannot be conducted.

In summary, an application based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved if: (1) The foreign data are applicable to the U.S. population and U.S. medical practice; (2) the studies have been performed by clinical investigators of recognized competence; and (3) the data may be considered

valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate that data through an on-site inspection or other appropriate means. Failure of an application to meet any of these criteria will result in the application not being approvable based on the foreign data alone. FDA will apply this policy in a flexible manner according to the nature of the drug and the data being considered.

Consultation between sponsors and the agency. The question of approving a given drug based solely on foreign data is one which will require close consultation between the drug sponsor and the agency. Applicants are urged to meet with agency officials as early as possible in the drug development process to determine if approval based on foreign data alone looks promising or, alternatively, if domestic confirmatory data are clearly necessary. Such advice may be given as part of an "End-of-Phase II Conference," at a "Presubmission Conference," or at some other time as requested by the manufacturer. FDA reserves the right, however, to determine at any stage of the process the scientific appropriateness of approving a particular drug based solely on foreign data. Where domestic data are found to be necessary, the sponsor should consult with the agency to determine the type of domestic study that is required. The agency would attempt to limit requests for confirmatory domestic data to one adequate and well-controlled trial whenever possible.

Purpose of foreign data policy. The purpose of this provision is to add flexibility to the new drug approval process whereby foreign clinical data demonstrating the safety and effectiveness of a new drug can provide the sole basis for approval in scientifically appropriate instances. Application of this policy should, in certain instances, prevent duplication in this country of competent foreign clinical data, thereby reducing costs on manufacturers and speeding public access to beneficial new therapies.

The whole question of foreign data, however, needs to be placed in perspective. First, the issue of approvability based solely on foreign data is expected to arise only in a minority of cases. This is because, for a variety of reasons, most commercial sponsors plan, and are likely to continue to plan, inclusion of at least some U.S. trials in their drug development programs. These reasons include the high quality of U.S. clinical investigators and the commercial desire, from a marketing standpoint, of having some domestic physicians familiar with and eager to use the drug once it is approved.

Second, when the issue does arise, FDA will apply this policy in a flexible manner according to the nature of the drug and the data being considered. For example, situations in which foreign data are likely to provide the sole basis for approval include major health gains (e.g., Timolol and myocardial infarction), drugs for diseases that are uncommon in the United States (e.g., tropical diseases and orphan drugs), and drugs on which decisionmaking is less difficult from a risk-benefit point of view (e.g., topical products).

At the other end of the spectrum, certain situations make approvability based on foreign data alone less likely, such as when a U.S. sponsor has purchased a complete set of foreign data under a licensing agreement with an overseas firm. Special concern arises here because the original foreign manufacturer has no obligation under U.S. law to supply complete or accurate information to the U.S. licensee, and because the licensee usually has had no direct contact with the clinical investigators. Thus, in this situation, a data audit by the U.S. sponsor and FDA's familiarity with the foreign clinical investigators and their institutions are especially important if approvability based solely on the available foreign data is sought.

In all cases, the key to FDA's policy would be an openness and willingness to consider, on a case-by-case basis, the merits of approving an application based solely on foreign data. The benchmarks of this policy would be flexibility and reasonableness that strike a fair balance between extremes. Although the agency would not require domestic data where the foreign data are sufficient, the agency would review critically requests to approve drugs based solely on foreign data to ensure that such drugs are just as safe and just as effective as drugs tested in this country.

Implementation. The agency proposes to codify its policy on the acceptance of foreign data as the sole basis of a new drug's approval and to modify § 312.20(c) of the investigational new drug regulations to conform to the proposed policy.

Conforming Amendments

FDA's substantial revision of its application regulations necessitates changes in other regulations in Parts 310, 430, 431, and 433.

In Part 310, FDA proposes to remove § 310.9 *Designated journals* (21 CFR 310.9) which lists the medical and scientific journals available in FDA's library, to remove the definition of "designated journal(s)" in § 310.3(m) (21 CFR 310.3(m)), and remove §§ 310.300, 310.301, and 310.302 (21 CFR 310.300, 310.301, and 310.302) concerning records and reports. Applicants have inaccurately perceived that § 310.9 permits them to reference an article from a listed journal in their applications instead of submitting a copy or reprint of it. The agency believes the availability of a journal in FDA's library should not determine whether an applicant should submit a copy of it in an application. If the applicant intends to rely upon an article in a medical or scientific journal to support its application, the article should be provided in full to permit prompt and efficient review of the application. If the article is peripheral, it can be omitted. For example, the agency believes that a copy of virtually every reference available should be submitted in an investigational new drug application for a drug never before studied in the United States, for important and novel laboratory or measurement techniques, and to support an obscure rationale for a study. On the other hand, an application for a new use of a marketed drug would only need copies of articles pertinent to the new use and to safety concerns particularly related to that use. Also in Part 310, FDA proposes to remove the regulations on records and reports because they would be superseded by the new regulations on records and reports proposed in Part 314.

Because the revised regulations in Part 314 would apply to both antibiotics and new drugs, FDA proposes to amend its antibiotic regulations in Parts 430, 431, and 433 by removing those regulations that apply only to applications for antibiotics, which will be superseded by the proposed revisions, and by amending other regulations to conform them to changes in the new drug regulations.

The agency proposes to amend Part 430 in Subpart D to explain better the agency's implementation of the Drug Amendments of 1962 (Pub. L. 87-781) with respect to antibiotics on the market before the effective date of those amendments. The regulations now unnecessarily describe the agency's actions in establishing its procedures to implement the amendments for antibiotics, many of which were regulated as new drugs. The proposed revisions, which contain no substantive changes, would eliminate this extraneous information and briefly

describe how FDA is implementing the Drug Amendments of 1962 with respect to antibiotics.

The agency proposes to remove § 430.20 (21 CFR 430.20) which describes the procedures used for issuing, amending, and repealing regulations providing for the certification of antibiotics. These procedures are being recodified under new § 314.300.

The agency proposes to remove §§ 431.1(b) and 431.16 (21 CFR 431.1(b) and 431.16) concerning the submission of information about facilities and controls in an initial request for certification of antibiotics and concerning subsequent changes in facilities and controls from those described in the initial request for certification. The agency proposes to remove those provisions because they are superseded by the proposed regulations concerning the chemistry, manufacturing, and controls section of the application and the proposed regulations on supplements.

The agency proposes to revise § 431.17 (21 CFR 431.17) to state that a request to provide for certification of antibiotics must comply with procedures and meet the requirements applicable to new drugs. The agency also proposes to remove the references to antibiotic Form's 5 and 6 in § 431.50 (21 CFR 431.50), to remove § 431.60 *Records and reports concerning experience with antibiotic drugs for human use for which a certificate or release has been issued* (21 CFR 431.60), to remove § 431.71 *Confidentiality of data and information in an antibiotic drug file* (21 CFR 431.71), and to remove § 433.25 *Antibiotic drugs intended for export* (21 CFR 433.25), because the agency's proposed changes in Part 314 would cover those issues.

List of Subjects

21 CFR Part 310: Administrative practice and procedure, Drugs, Medical devices, Reporting requirements.
21 CFR Part 312: Drugs, Medical research.
21 CFR Part 314: Administrative practice and procedure, Drugs.
21 CFR Part 430: Administrative practice and procedure, Antibiotics.
21 CFR Part 431: Administrative practice and procedure, Antibiotics.
21 CFR Part 433: Antibiotics, Labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501, 502, 503, 505, 506, 507, 701, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 351, 352, 353, 355, 356, 357, 371)) and the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), it is proposed that Parts 310, 312, 314, 430, 431, and 433 be amended as follows:

PART 310—NEW DRUGS

1. Part 310 is amended:

§ 310.3 [Amended]

a. In § 310.3 *Definitions and interpretations* by removing and reserving paragraph (m).

§ 310.9 [Removed]

b. By removing § 310.9 *Designated journals.*

§ 310.300 [Removed]

c. By removing § 310.300 *Records and reports concerning experience on drugs for which an approval is in effect.*

§ 310.301 [Removed]

d. By removing § 310.301 *Reporting of adverse drug experiences.*

§ 310.302 [Removed]

e. By removing § 310.302 *Records and reports on new drugs and antibiotics for use by man for which applications or certification forms 5 and 6 became effective or were approved prior to June 20, 1963.*

PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

2. Part 312 is amended in § 312.20 by revising paragraph (c), to read as follows:

§312.20 Clinical data generated outside the United States and not subject to a "Notice of Claimed Investigational Exemption for a New Drug."

* * * * *

(c) Data from studies performed outside the United States and conducted in accordance with the requirements of this section may be utilized without duplication of the studies in the United States, as appropriate.

* * * * *

3. By revising Part 314 to read as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

Subpart A—General Provisions

Sec.
314.1 Scope of this part.
314.3 Definitions.

Subpart B—Applications

314.50 Content and format of an application.
314.55 Abbreviated application.
314.56 Drug products for which abbreviated applications are suitable.
314.57 Application development file for an abbreviated application.
314.60 Amendments to an unapproved application.
314.61 Request for reconsideration or clarification of technical requirements or informal opinions.
314.65 Withdrawal by the applicant of an unapproved application.
314.70 Supplements and other changes to an approved application.
314.71 Procedures for submission of a supplement to an approved application.
314.72 Change in ownership of an application.
314.80 Records and reports.
314.81 Reporting of adverse drug experiences.
314.90 Waivers.

Subpart C—FDA Action on Applications

314.100 Time frames for reviewing applications.
314.101 Filing and application.
314.102 Food and Drug Administration communication about deficiencies in an application under review.
314.103 Drugs with potential for abuse.
314.105 Approval of an application.
314.106 Foreign data.
314.110 Approvable letter to the applicant.
314.120 Not approvable letter to the applicant.
314.125 Refusal to approve an application.
314.126 Adequate and well-controlled studies.
314.150 Withdrawal of approval of an application.
314.152 Notice of withdrawal of approval of an application for a new drug.
314.160 Approval of an application for which approval was previously refused, suspended, or withdrawn.
314.170 Adulteration and misbranding of an approved drug.

Subpart D—Hearing Procedures for New Drugs

314.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant of denial of hearing.
314.201 Procedure for hearings.
314.235 Judicial review.

Subpart E—Administrative Procedures for Antibiotics

314.300 Procedure for the issuance, amendment, or repeal of regulations.

Supart F—Miscellaneous Provisions

314.410 Imports and exports of new drugs and antibiotics.
314.420 Drug master files.
314.430 Availability for public disclosure of data and information in an application.
314.440 Addresses for applications.
314.445 Guidelines.

Authority: Secs. 501, 502, 503, 505, 507, 701, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 351, 352, 353, 355, 356, 357, 371); sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262).

Subpart A—General Provisions

§ 314.1 Scope of this part.

(a) This part sets forth procedures and requirements for the submission to, and

the review by, the Food and Drug Administration of applications and abbreviated applications and amendments and supplements to them by persons seeking approval from FDA of the following:

(1) An application under section 505 of the Federal Food, Drug, and Cosmetic Act to market a new drug.

(2) A request under section 507 of the Federal Food, Drug, and Cosmetic Act to provide for certification of an antibiotic drug.

(b) This part does not apply to drug products subject to licensing by FDA under the Public Health Service Act (58 Stat. 632 as amended (42 U.S.C. 201 et seq.)) and Subchapter F of Chapter I of Title 21 of the Code of Federal Regulations.

(c) References in this part to regulations in the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 314.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the act apply to those terms when used in this part.

(b) The following definitions of terms apply to this part:

"Act" means the Federal Food, Drug, and Cosmetic Act (sections 201–901, 52 Stat. 1040 et seq., as amended (21 U.S.C. 301–392)).

"Applicant" means any person who submits an application or abbreviated application or an amendment or supplement to them under this part to obtain Food and Drug Administration approval of a new drug or to request FDA to provide for certification of an antibiotic drug and any person who owns an approved application.

"Application" means both the application described under § 314.50 and the abbreviated application under § 314.55, including all amendments and supplements.

"Approvable letter" means a written communication to an applicant from FDA stating that the agency will approve the application if specific additional information or material is submitted or specific conditions are met. An approvable letter does not constitute approval of any part of an application and does not permit marketing of the drug that is the subject of the application.

"Approval letter" means a written communication to an applicant from FDA approving an application. An approval letter permits marketing of the drug product that is the subject of the application or, in the case of an antibiotic drug, permits the applicant to seek certification or release of batches of the antibiotic drug.

"Drug product" means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

"Drug substance" means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body.

"FDA" means the Food and Drug Administration.

"Not approvable letter" means a written communication to an applicant from FDA stating that the agency does not consider the application approvable because one or more deficiencies in the application preclude the agency from approving it.

Subpart B—Applications

§ 314.50 Content and format of an application.

Applications, including abbreviated applications, and supplements to approved applications are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section. Two copies of the application are required, an archival copy and a review copy. An application for a new chemical entity will generally contain an application Form FDA–356H, an index, a summary, five or six technical sections, case report tabulations of patient data, some case report forms, drug samples, and labeling. An application for a duplicate of a marketed drug product, an abbreviated application, an amendment, and a supplement will generally contain only some of those items, and information will be limited to that needed to support the submission. Each submission is required to contain all information that is received or otherwise obtained by the applicant from any source and that is pertinent to an evaluation of the submission. The Food and Drug Administration will maintain guidelines on the format and content of applications to assist applicants in their preparation.

(a) *Application Form FDA–356H.* The applicant shall submit a completed and signed Form FDA–356H that contains the following:

(1) The name and address of the applicant; the date of the application; the application number if previously issued (for example, if the application is a resubmission, a supplement, or an abbreviated application given a number under an application development file); the name of the drug product, including its established, proprietary, code, and chemical names; the dosage form and strength; the route of administration; the identification numbers of all investigational new drug applications that are referenced in the application; the identification numbers of all drug master files and other applications under this part that are referenced in the application; and the drug product's proposed indications for use.

(2) A statement whether the submission is an orginal submission, a resubmission, an abbreviated application under § 314.55, an application development file under § 314.57, or a supplement to an application under § 314.70.

(3) A statement whether the applicant proposes to market the drug product as a prescription or an over-the-counter product.

(4) A check-list identifying what enclosures required under this section the applicant is submitting.

(5) The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application. If the person signing the application does not reside or have a place of business within the United States, the application is required to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.

(b) *Index.* The archival copy of the application is required to contain a comprehensive index by volume number and page number to the summary under paragraph (c) of this section, the technical sections under paragraph (d) of this section, and the supporting information under paragraph (f) of this section.

(c) *Summary.* (1) An application is required to contain a summary of the application in enough detail that the reader may gain a good general understanding of the data and information in the application. The summary is not required for abbreviated applications under § 314.55 or supplements under § 314.70. Resubmissions of an application should contain an updated summary, as appropriate. The summary should discuss all aspects of the application, and synthesize the information into a well-structured and unified document. The summary should be written in the same detail required for publication in, and meet the editorial standards generally applied by, referred scientific and medical journals. In addition to the agency personnel reviewing the summary in the context of their review

of the application, FDA may furnish the summary to FDA advisory committee members and agency officials whose duties require an understanding of the application. To the extent possible, data in the summary should be presented in tabular and graphic forms. FDA has prepared a guideline under § 10.90(b) that provides information about how to prepare a summary. The summary required under this paragraph my be used by FDA or the applicant to prepare the Summary Basis of Approval document for public disclosure under § 314.430(e)(2)(ii) when the application is approved.

(2) The summary is required to contain the following information:

(i) The proposed text of the labeling for the drug, with annotations to the information in the summary and technical sections of the application that support the inclusion of each statement in the labeling, and, if the application is for a prescription drug, statements describing the reasons for omitting a section or subsection of the labeling format in § 201.57.

(ii) A statement identifying the pharmacologic class of the drug and a discussion of the scientific rationale for the drug, its intended use, and the potential clinical benefits of the drug product.

(iii) A brief description of the marketing history, if any, of the drug outside the United States, including a list of the countries in which the drug has been marketed and a list of any countries in which the drug has been withdrawn from marketing for any reason related to safety or effectiveness. The description is required to describe both marketing by the applicant and, if known, the marketing history of other persons.

(iv) A summary of the chemistry, manufacturing, and controls section of the application.

(v) A summary of the animal pharmacology and animal or in vitro toxicology section of the application.

(vi) A summary of the human pharmacokinetic and bioavailability section of the application.

(vii) A summary of the microbiology section of the application (for anti-infective drugs only).

(viii) A summary of the clinical section of the application, including the results of statistical analyses of the clinical trials.

(ix) A concluding discussion that presents the benefit and risk considerations related to the drug, including a discussion of any proposed additional studies or surveillance the applicant intends to conduct postmarketing.

(d) *Technical sections.* The application is required to contain the technical sections described below. Each technical section is required to contain data and information in sufficient detail to permit the agency to make a knowledgeable judgment about whether to approve the application or whether grounds exist under section 505(d) or 507 of the act to refuse to approve the application. The required technical sections are as follows:

(1) *Chemistry, manufacturing, and controls section.* A section describing the composition, manufacture, and specification of the drug substance and the drug product, including the following:

(i) *Drug substance.* A full description of the drug substance including its physical and chemical characteristics and stability; the name and address of its manufacturer; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and such specifications and analytical methods as are necessary to assure the identity, strength, quality, and purity of the drug substance and the bioavailability of the drug products made from the substance, including where necessary specifications of the drug substance, for example, specifications relating to stability, sterility, particle size, and crystalline form. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary may be made to satisfy relevant requirements in this paragraph.

(ii) *Drug product.* A list of all components used in the manufacture of the drug product regardless of whether they appear in the drug product and a statement of the composition of the drug product; a statement of the specifications and analytical methods for each component; the name and address of the drug product manufacturer(s); a description of the manufacturing and packaging procedure and in-process controls for the drug product; such specifications and analytical methods as are necessary to assure the identity, strength, quality, purity, and bioavailability of the drug product, including where necessary specifications, for example, those relating to sterility, dissolution rate, containers and closure systems; and stability data with proposed expiration dating. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary may be made to satisfy relevant requirements in this paragraph.

(iii) *Environmental impact analysis report.* An environmental impact analysis report under § 25.1 analyzing the environmental impact of the manufacturing process and the ultimate use of the drug product.

(2) *Nonclinical pharmacology and toxicology section.* A section describing the nonclinical laboratory studies with the drug, including the following:

(i) Studies of the pharmacological actions of the drug in relation to its proposed therapeutic indication and to other possible therapeutic indications and adverse effects.

(ii) Studies of the toxicological effects of the drug as they relate to the drug's intended clinical uses, including, as appropriate, studies assessing the drug's acute, subacute, and chronic toxicity; carcinogenicity; and studies of toxicities related to the drug's particular mode of administration or conditions of use.

(iii) Studies, as appropriate, of the effects of the drug on reproduction and on the developing fetus.

(iv) Any studies of the absorption, distribution, metabolism, and excretion of the drug in animals.

(v) For each study that was not conducted in compliance with Part 58 relating to good laboratory practices, a statement that describes each difference between the practices used in the study and those required under the regulations.

(3) *Human pharmacokinetics and bioavailability section.* A section on human bioavailability data, or information supporting a waiver of the submission of in vivo bioavailability data under Subpart B of Part 320, including the following:

(i) A description of each of the bioavailability and pharmacokinetic studies of the drug in humans performed by or on behalf of the applicant.

(ii) A description of the analytical and statistical methods used in each study.

(iii) A summarizing discussion and analysis of the pharmacokinetics and metabolism of the active ingredients and the bioavailability or bioequivalence, or both, of the drug product.

(4) *Microbiology section.* If the drug is an anti-infective drug, a section on microbiology data, including the following:

(i) A description of the biochemical basis of the drug's action on microbial physiology.

(ii) A description of the antimicrobial spectra of the drug, including results of in vitro preclinical studies to demonstrate concentrations of the drug required for effective use.

(iii) A description of any known mechanisms of resistance to the drug including results of any known epidemiologic studies to demonstrate prevalence of resistance factors.

(iv) A description of clinical microbiology laboratory methods (for example, in vitro sensitivity discs) needed for effective use of the drug.

(5) *Clinical data section.* A section on clinical studies containing a description of clinical investigations of the drug, including the following:

(i) A description and analysis of each clinical pharmacology study of the drug, including a brief comparison of the results of the human studies with the animal pharmacology and toxicology data.

(ii) A description and analysis of each controlled clinical study, including the protocol and a description of the statistical analyses used to evaluate the study.

(iii) A description of each uncontrolled clinical study and a summary of the results.

(iv) A description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product received or otherwise obtained by the applicant from any source, foreign or domestic, including information derived from other investigations, commercial marketing experience, and reports in the scientific literature.

(v) A summary and updates of safety information, as follows:

(*a*) The applicant is required to submit an integrated summary of all available information about the safety of the drug product including potential human risks based on animal data, demonstrated or potential adverse effects of the drug, clinically significant drug/drug interactions, and other safety considerations such as data from epidemiological studies of related drugs. A description of any statistical analyses performed in analyzing safety data should also be included, unless already included under paragraph (a)(5)(ii) of this section.

(*b*) The applicant is required under section 505(i) of the act to update periodically its pending application with new safety information learned about the drug. These "safety update reports" shall include the same kinds of information (from clinical studies, animal studies, and other sources) and shall be submitted in the same format (through case report forms, tabulations, and narrative summaries) as are required for an original application. The applicant shall submit these reports every 4 months and following receipt of an approvable letter. Prior to the submission of the first such report, applicants are encouraged to consult with agency officials regarding further details on its form and content.

(vi) A description and analysis of studies or information related to abuse of the drug, including a proposal for scheduling under the Controlled Substances Act, if the drug is subject to abuse. A description of any studies related to overdosage, including information on dialysis, antidotes, or other treatments, if known.

(vii) An integrated summary of the benefits and risks of the drug, including a discussion of why the benefits exceed the risks under the conditions stated in the labeling.

(6) *Statistical section.* A section on statistical evaluation of clinical data that includes the following:

(i) A copy of the information submitted under paragraph (d)(5)(ii) of this section concerning the description and analysis of each controlled clinical study plus the documentation and supporting statistical analyses used in evaluating the controlled clinical studies.

(ii) A copy of the information submitted under paragraph (d)(5)(ii) of this section concerning a summary of information about the safety of the drug product plus any documentation and new supporting statistical analyses used in evaluating the safety information.

(e) *Samples and labeling.* Upon request from FDA, the applicant shall submit the samples described below to the places identified in the agency's request. FDA will generally ask applicants to submit samples directly to two or more agency laboratories that will perform all necessary tests on the samples and validate the applicant's analytical methods.

(1) Four representative samples of the following, each sample in sufficient quantity to permit FDA to perform three times each test described in the application to determine whether the drug substance and the drug product meet the specifications given in the application:

(i) The drug product proposed for marketing;

(ii) The drug substance used in the drug product from which the samples in paragraph (e)(1)(i) of this section were taken;

(iii) Reference standards and blanks (except that reference standards recognized in an official compendium need not be submitted); and

(iv) The finished market package, if requested by FDA.

(2) Two copies of the analytical methods and related descriptive information contained in the chemistry, manufacturing, and controls section under paragraph (d)(1) of this section for the drug substance and the drug product that are necessary for FDA's laboratories to perform all necessary tests on the samples and to validate the applicant's analytical methods.

(3) Copies of the label and all labeling proposed for the drug product (4 copies of draft labeling or 12 copies of final printed labeling).

(f) *Supporting information.* The archival copy of the application is required to contain the following case report tabulations and case report forms:

(1) *Case report tabulations.* The application is required to contain tabulations of the data from each adequate and well-controlled study under § 314.126 (Phase 2 and Phase 3 studies as described in § 312.1 (a)(2), Form FDA-1571), tabulations of the data from the earliest clinical pharmacology studies (Phase 1 studies as described in § 312.1(a)(2), Form FDA-1571), and tabulations of the safety data from other clinical studies. Routine submission of other patient data from uncontrolled studies is not required. The tabulations are required to include the data on each patient in each study. Before submitting an application, an applicant may discuss with the Food and Drug Administration the presentation of the data in the tabulations. FDA will waive the submission of tabulations when appropriate, for example, if an application is supported only by published papers.

(2) *Case report forms.* The routine submission of copies of all case report forms for each clinical study is not required, but the applicant shall submit copies of individual case report forms for each patient who died during a clinical study or who did not complete the study because of an adverse event, whether believed to be drug related or not. This requirement may be waived by FDA for specific studies if the case report forms are unnecessary for adequately reviewing the study.

(3) Applicants are invited to meet with FDA before submitting an application to discuss the extent to which tabulations of patient data in clinical studies, data elements within tables, and case report forms can be minimized in selected cases, or to discuss the need for special supporting information in selected cases. If the applicant and FDA agree, the applicant may submit tabulations of patient data and case report forms in a form other than hard copy, for example, on microfiche or computer tapes.

(4) The applicant shall submit copies of additional case report forms, additional case report tabulations, or other data for any study if requested by the agency during the review of the application. FDA will limit its requests

to situations in which a legitimate need to examine the records exists, for example: (i) for case report forms, if discrepancies in the summary or data tabulations suggest the need to review case report forms or if tabulations are not adequate to convey in a scientifically appropriate manner important information contained in case report forms; (ii) for tabulations, if tabulations of patient data from uncontrolled studies are needed to evaluate a claim or statement in the proposed labeling for the drug (for example, with respect to effectiveness parameters). The applicant's failure to submit information requested by FDA within 30 days after receipt for the request may result in the agency viewing any eventual submission as a major amendment under § 314.60 and extending the review period as necessary.

(g) *Other information.* (1) The applicant ordinarily is not required to resubmit information previously submitted, but may incorporate the information by reference. A reference to information submitted previously is required to identify the file by name, reference number, volume, and page number in the agency's records where the information can be found. A reference to information submitted to the agency by a person other than the applicant is required to contain a written statement that authorizes the reference and that is signed by the person who submitted the information.

(2) The applicant shall submit an accurate and complete English translation of each part of the application that is not in English. The applicant shall submit a copy of each original literature publication for which an English translation is submitted.

(h) *Format of an original application.* (1) The applicant shall submit a complete archival copy of the application that contains the information required under paragraphs (a) through (g) of this section. FDA will maintain the archival copy during the review of the application to permit individual reviewers to refer to information that is not contained in their particular technical sections of the application, to give other agency personnel access to the application for official business, and to maintain in one place a complete copy of the application. An applicant may submit the archival copy of the application on microfiche, but tabulations of patient data and case report forms may be submitted on microfiche only if the applicant and FDA agree.

(2) The applicant shall submit a review copy of the application. Each of the technical sections (described in paragraph (d)(1) through (6) of this section) in the review copy is required to be separately bound with a copy of Form FDA-356H required under paragraph (a) of this section and a copy of the summary required under paragraph (c) of this section. The applicant may obtain from FDA sufficient folders to bind the archival and review copies of the application.

§ 314.55 Abbreviated application.

(a) An abbreviated application is an application in which reports of nonclinical laboratory studies and reports of clinical investigations (except those pertaining to in vivo bioavailability of the drug product) may be omitted. The information may be omitted when the Food and Drug Administration has determined that the information already available to it is adequate to establish that a particular dosage form of a drug meets the statutory standards for safety and effectiveness. An abbreviated application will usually be reseved for duplicates of drug products previously approved under a full application under § 314.50 An abbreviated application is not required to comply with the requirements in § 314.50(c), (d)(2), (4), (5), (6), and (f).

(b) FDA will file an abbreviated application only if it has made a finding that an abbreviated application is suitable for a drug product. If FDA finds that a drug product may be approved for marketing on the basis of an abbrevieated application, it will make that finding publicly available, as follows:

(1) If the finding applies to a class of drug products, the agency will amend § 314.56 to identify the class in that section.

(3) If the finding applies to a drug product because it is so closely related to a product for which an abbreviated application is suitable that the same conclusions about safety and effectiveness apply to it, the agency will make the finding public by updating its list of drug products for which abbreviated applications are suitable. The list will be available from the National Technical Information Service, Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22151.

(3) If the finding applies to duplicates of a drug product that is subject to FDA's drug efficacy study (a review of drug products approved as safe between 1938 and 1962), the agency will make the finding public through a notice published in the **Federal Register.**

(c)(1) A finding by FDA that an abbreviated application is suitable for a drug product applies only to a product that is the same in active ingredient, dosage form and strength, route of administration, and conditions of use as the drug product that was the subject of the finding. For a drug product that is similar but different in one or more of these characteristics, an abbreviated application will be accepted only if FDA has made a separate finding suitability.

(2) A finding that a drug product is a new drug because it is similar to a product that is a new durg, and is therefore subject to an application, does not include a finding that an abbreviated application is suitable for the similar product.

(d)(1) A prospective applicant may seek a determination of the suitability of an abbreviated application for a product that the applicant believes similar or related to a drug product that has been declared to be suitable for an abbreviated application. Extension of the finding that a drug product is safe and effective to another product will ordinarily be limited to other dosage forms for the same route of administration or to closely related ingredients. If preclinical or clinical evidence is needed to support the safety, or if clinical evidence is needed to support the effectiveness, of the proposed product, then an abbreviated application is not appropriate for the similar or related drug product.

(2) A person seeking a determination that an abbreviated application is suitable for a similar or related drug product shall use the procedures established in § 10.30. The petitioner shall set forth the reasons that justify extending the finding that an abbreviated application is suitable for one product to the similar or related product proposed to be marketed.

(3) An application submitted in the form of an abbreviated application for a drug product that has not been the subject of a finding that allows an abbreviated application for the product will be considered to be a petition under § 10.30 and will be processed as such.

(e) Each abbreviated application is required to contain a reference to FDA's finding that an abbreviated application is suitable for the specific product that is the subject of the application and to contain both an archival and a review copy of the application.

(1) The applicant shall submit a complete archival copy of the application that contains the information required under § 314.50(a), (b), (d)(1) and (3), (e), and (g). An applicant may submit the archival copy of the application on microfiche.

(2) The applicant shall submit a review copy that contains the technical

sections described in § 314.50(d)(1) and (3). Each of the technical sections in the review copy is required to be separately bound with a copy of Form FDA-365H required under § 314.50(a).

(3) The applicant may obtain from FDA sufficent folders to bind the archival and the review copies of the application.

§ 314.56 Drug products for which abbreviated applications are suitable.

Abbreviated applications are suitable for the following drugs within the limits set forth in § 314.55(c):

(a) Duplicates of drug products that were first approved before October 10, 1962, and reformulations of these products, if the original or reformulated product has been evaluated as part of the drug efficacy study and announced by notice in the **Federal Register** as effective for one or more indications, and if the Food and Drug Administration has made a finding that an abbreviated application is suitable.

(b) [Reserved]

(c) Drug products that are very closely related to a product described in paragraph (a) of this section and that are subject to a separate finding of suitability for marketing under an abbreviated application.

(d) Drug products that contain a chlorofluorocarbon determined to be an essential use and identified in § 2.125(h)(2) as suitable for an abbreviated application.

(e) Duplicates of an antibiotic drug for which FDA has approved a request to provide for certification or which FDA releases under § 430.10.

§ 314.57 Application development file for an abbreviated application.

A person who intends to submit an abbreviated application for a drug for which the Food and Drug Administration has found that form of application acceptable, but who does not have all information needed to support a complete application, may first submit an application development file for the drug product. An application development file is intended to provide a mechanism for potential applicants to obtain agency comment on formulation data, dissolution data, the bioequivalence protocols and pilot studies before conducting bioequivalence tests. An application development file should be in the form required for an application under § 314.50 and it may contain any item or items of information required in an abbreviated application under § 314.55; however, it will not be filed under § 314.100. Within the limits of available resources, the agency will review and comment to the person submitting an application development file on protocols or any deficiencies in the submission.

§ 314.60 Amendments to an unapproved application.

The applicant may submit an amendment to an application that is filed under § 314.100, but not yet approved. The submission of a major amendment (for example, an amendment that contains significant new data from a previously unreported study or detailed new analyses of previously submitted data), whether on the applicant's own initiative or at the invitation of the agency, constitutes an agreement by the applicant under section 505(c) of the act to extend the date by which the agency is required to reach a decision on the application. Ordinarily, the agency will extend the review period for a major amendment but only for the time necessary to review the new information. The director of the division responsible for reviewing the application will notify the applicant if the agency has extended the review period for the application. The applicant may request reconsideration of the extension under the procedure outlined in § 314.61. The submission of an amendment that is not a major amendment will not extend the review period.

§ 314.61 Request for reconsideration or clarification of technical requirements or informal opinions.

The Food and Drug Administration is committed to resolving differences between applicants and FDA reviewing divisions with respect to technical requirements for applications as quickly and amicably as possible through the cooperative exchange of information and views. That exchange may take place through written correspondence, telephone conversations, or informal meetings. In addition, FDA has established administratively a specific procedure under which an applicant may ask the agency to reconsider or clarify a technical requirement imposed by FDA or an informal opinion expressed to an applicant by an agency employee with respect to an application. Examples of issues contemplated for resolution under that procedure include requests by FDA for specific studies or information and unfavorable responses by FDA to requests from applicants for waivers or special technical approaches to a scientific problem. The procedure will be marked by the applicant's submission of a written request for reconsideration or clarification to the division that is responsible for reviewing the application, the division's prompt response to the applicant, and, if the division's response is not acceptable to the applicant, automatic review of the issue by management of the National Center for Drugs and Biologics. FDA will attempt to issue a final decision within 60 days of the applicant's request. This procedure is described more full in a Staff Manual Guide that is publicly available under FDA's public information regulations in Part 20.

§ 314.65 Withdrawal by the applicant of an unapproved application.

An applicant may at any time withdraw an application that is not yet approved by notifying the Food and Drug Administration in writing. The agency will consider an applicant's failure to respond within 10 days to an approvable letter under § 314.110 or a not approvable letter under § 314.120 to be a request by the applicant to withdraw the application. A decision to withdraw the application is without prejudice to refiling. The agency will retain the application and will provide a copy to the applicant on request under the fee schedule in § 20.42 of FDA's public information regulations.

§ 314.70 Supplements and other changes to an approved application.

(a) *Changes to an approved application.* The applicant shall notify the Food and Drug Administration about each change in each condition established in an approved application beyond the variations already provided for in the application. The notice is required to describe the change fully. Depending on the type of change, the applicant shall notify FDA about it in a supplemental application under paragraph (b) or (c) of this section or by inclusion of the information in the annual report to the application under paragraph (d) of this section. Notwithstanding the requirements of paragraphs (b) and (c) of this section, an applicant shall make a change provided for in those paragraphs (for example, the deletion of an ingredient common to many drug products) in accordance with a guideline, notice, or regulation published in the **Federal Register** that provides for a less burdensome notification of the change (for example, by notification at the time a supplement is submitted or in the next annual report).

(b) *Supplements requiring FDA approval before the change is made.* An applicant shall submit a supplement, and obtain FDA approval of it, before making the changes listed below in the conditions in an approved application,

unless the change is made to comply with an official compendium.

(1) *Drug substance.* A change affecting the drug substance to accomplish any of the following:

(i) To relax the limits for a specification;

(ii) To establish a new regulatory analytical method;

(iii) To delete a specification or analytical method;

(iv) To change a specification or analytical method for the drug substance because of a change in the method of synthesis (or isolation) and purification of the drug substance.

(2) *Drug product.* A change affecting the drug product to accomplish any of the following:

(i) To add or delete an ingredient, or otherwise to change the composition of the drug product, other than an ingredient intended only to affect the color of the drug product;

(ii) To relax the limits for a specification;

(iii) To establish a new regulatory analytical method;

(iv) To delete a specification or analytical method;

(v) To change the method of manufacture of the drug product, including changing or relaxing an in-process control;

(vi) To use a different facility or establishment to manufacture, process, or pack the drug product;

(vii) To change the container and closure system for the drug product or change a specification or analytical method for the container and closure system;

(viii) To extend the expiration date of the drug product based on data obtained under a new or revised stability testing protocol that has not been approved by FDA.

(3) *Labeling.* Any change in labeling, except one described in paragraph (c)(4) or (d) of this section.

(c) *Supplements for changes that may be made before FDA approval.* An applicant shall submit a supplement at the time the applicant makes any kind of change listed below in the conditions in an approved application, unless the change is made to comply with an official compendium. A supplement under this paragraph is required to give a full explanation of the basis for the change, identify the date on which the change is made, and, if the change concerns labeling, include 12 copies of final printed labeling. The applicant shall promptly revise all promotional labeling and drug advertising to make it consistent with any change in the labeling. The supplement and its mailing cover are requested to be plainly marked: "Special Supplement-Changes Being Effected."

(1) Adds a new specification or test method or changes a procedure because one or more batches of the drug product fail to meet specifications;

(2) Establishes a new procedure for reworking a batch of the drug product that fails to meet specifications;

(3) Changes the synthesis of the drug substance, including a change in solvents and a change in the route of synthesis; or

(4) Changes labeling to accomplish any of the following:

(i) To add or strengthen a contraindication, warning, precaution or adverse reaction;

(ii) To add or strengthen a statement about drug abuse, dependence, or overdosage; or

(iii) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the product.

(d) *Changes described in the annual report.* An applicant shall not submit a supplement to make any change in the conditions in an approved application, including the following, unless otherwise required under paragraph (b) or (c) of this section, but shall describe the change in the next annual report required under § 314.80:

(1) Any change made to comply with an official compendium.

(2) A change in the description of the drug product or a change in information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form.

(3) An editorial or similar minor change in labeling.

§ 314.71 Procedures for submission of a supplement to an approved application.

(a) Only the applicant may submit a supplement to an application.

(b) all procedures and actions that apply to an application under § 314.50 also apply to supplements, except that the information in the supplement is limited to that needed to support the change. A supplement is required to contain an archival copy that includes a Form FDA-356H and appropriate technical sections, samples, and labeling. The supplement is also required to contain a review copy as described under § 314.50 (except the summary may be omitted from the working copies).

(c) All procedures and actions the Food and Drug Administration takes under §§ 314.100 through 314.170 apply to supplements.

§ 314.72 Change in ownership of an application.

(a) An applicant may transfer ownership of its application. At the time of transfer the new and former owners are required to submit information to the Food and Drug Administration as follows:

(1) The former owner shall submit a letter or other document that states that all rights to the application have been transferred to the new owner.

(2) The new owner shall submit an application Form FDA-356H signed by the new owner and a letter or other document containing the following:

(i) The new owner's commitment to agreements, promises, and conditions made by the former owner and contained in the application;

(ii) The date that the change in ownership is effective; and

(iii) Either a statement that the new owner has a complete copy of the approved application, including supplements and records that are required to be kept under § 314.80(b), or a request for a copy of the application from FDA's files. FDA will provide a copy of the application to the new owner under the fee schedule in § 20.42 of FDA's public information regulations.

(b) The new owner shall advise FDA about any change in the conditions in the approved application under § 314.70, except the new owner may advise FDA in the next annual report about a change in the drug product's label or labeling to adopt a new brand name or a change in the name of the manufacturer, packer, or distributor.

§ 314.80 Records and reports.

(a) *Applicability.* Each applicant shall establish and maintain records and make reports for each of its approved applications and abbreviated applications under this section as required under sections 505(j) and 507(g) of the act to facilitate a determination by the Food and Drug Administration whether there may be grounds for invoking section 505(e) of the act to suspend or withdraw approval of the application for a new drug, or whether a certification or release for an antibiotic drug should be rescinded, or a regulation issued for an antibiotic drug under section 507 of the act should be amended or repealed.

(b) *Records to be maintained.* The applicant shall maintain for a period of 10 years records of all adverse drug experiences, as defined in § 314.81, with the drug product subject to the application, including raw data and any correspondence relating to adverse drug experiences.

(c) *Reporting requirements.* The applicant shall submit to the Food and Drug Administration at the specified times two copies of the following reports:

(1) *Immediate report.* The applicant shall submit information of the following kinds within 3 working days of receipt by the applicant:

(i) Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article.

(ii) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specifications established for it in the application.

(2) *Fifteen-day alert report.* The applicant shall submit reports under § 314.81(c)(1)(i) of fatal and life-threatening adverse drug experiences not mentioned in the current labeling as soon as the essental information has been obtained, but in any case within 15 working days of receipt by the applicant.

3) *Thirty-day report.* The applicant shall submit reports under § 314.81(c)(1)(ii) of adverse drug experiences and followups to 15-day alert reports, within 30 working days of receipt by the applicant.

(4) *Annual report.* The applicant shall submit the following information in the order listed each year within 30 days of the anniversary date of approval of the application. Each annual report is required to be accompanied by a completed transmittal Form FDA-2252 (Transmittal of periodic Reports for Drugs for Human Use) which may be obtained from the PHS Forms and Publications Distribution Center, 12100 Parklawn Dr., Rockville, MD 20857, and is required to include all the information required under this section that the applicant received or otherwise obtained during the annual reporting interval which ends on the anniversary date. The report is required to contain the following:

(i) *Summary.* A brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

(ii) *Distribution data.* Information about the quantity of the drug product distributed under the approved application, including that distributed to distributors. The information is required to include the National Drug Code (NDC) number, the total number of dosage units of each strength or potency distributed (e.g., 100,000/5 milligram tablets, 50,000/10 milliliter vials), and the quantities distributed for domestic use and foreign use. Disclosure of financial or pricing data is not required.

(iii) *Labeling.* Currently used professional labeling, patient brochures or package inserts (if any), a representative sample of the package labels, and a summary of any changes in labeling that have been made since the last report listed chronologically, or if no changes, a statement of that fact.

(iv) *Manufacturing or controls changes.* A description of the manufacturing or controls changes not requiring a supplemental application under § 314.70(b) and (c), listed by date in the order in which they were implemented.

(v) *Nonclinical laboratory studies.* Published or unpublished reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the applicant concerning the ingredients in the drug product.

(vi) *Clinical date.* (a) Published clinical trials of the drug (or abstracts of them), including clinical trials on safety and effectiveness, clinical trials on new uses; and biopharmaceutic, pharmacokinetic, and clinical pharmacology studies conducted by or otherwise obtained by the applicant. Review articles, papers, and abstracts in which the drug is used as a research tool, papers describing the use of the drug product in medical practice, promotional articles, press clippings, and papers that do not contain tabulations or summaries of original data should not be reported.

(*b*) Summaries of completed unpublished clinical trials, or prepublication manuscripts if available, conducted by, or otherwise obtained by, the applicant. Supporting information should not be reported. (A study is considered completed 1 year after it is concluded.)

(vii) *Adverse drug experiences.* A tabulation, by adverse drug experience, of the adverse drug experiences reported under § 314.81 during the reporting interval. The tabulation should include, but need not be limited to, the adverse drug experience, the patient's age and sex, and the applicant's internal patient identification number used in reporting the drug experience under § 314.81. The applicant may not submit copies of the drug experience Form FDA-1639 to satisfy this requirement. A statement of the significance of these adverse drug experiences with respect to the safety and effectiveness of the drug product should be included in the summary required under paragraph (c)(3)(i) of this section.

(viii) *Status reports.* A statement on the current status of any postmarketing studies performed by, or on behalf of, the applicant. To facilitate communications between FDA and the applicant, the report may, at the applicant's discretion, also contain a list of any open regulatory business with FDA concerning the drug product subject to the application.

(5) *Other reporting*—(i) *Advertisements and promotional labeling.* The applicant shall submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisment for a prescription drug product. Mailing pieces and labeling that are designed to contain samples of a drug product are required to be complete, except the sample of the drug product may be omitted. Each submission is required to be accompanied by a completed transmittal Form FDA-2253 (Transmittal of Advertisments and Promotional Labeling for Drugs for Human Use) and is required to include a copy of the product's current professional labeling. Form FDA-2253 may be obtained from the PHS Forms and Publications Distribution Center, 12100 Parklawn Dr., Rockville, MD 20857.

(ii) *Special reports.* Upon written request the agency may require that the applicant submit the reports under this section at different times than those stated.

(d) *General requirements*—(1) *Multiple applications.* For all reports required by this section, the applicant shall submit the information common to more than one application only to the application first approved, and shall not report separately on each application. The submission is required to identify all the applications to which the report applies.

(2) *Patient identification.* Applicants should not include in reports under this section the names and addresses of individual patients; instead, the applicant should code the patient names whenever possible and retain the code in the applicant's files. Upon written request by FDA, the applicant shall submit individual patient identification information from designated reports; this will ordinarily occur when the agency needs to investigate the reports

further or when there is reason to believe that the reports do not represent actual results obtained.

(3) *Access to records and reports.* The applicant shall upon written request from any properly authorized officer or employee of the Department of Health and Human Services, at reasonable times, permit such officer or employee to have access to and copy and verify any records and reports established and maintained under this section.

(e) *Withdrawal of approval.* An applicant's failure to establish a system for maintaining required records, or failure to maintain records or to make required reports under this section, or the applicant's refusal to permit access to, or copying of verification of such records or reports, may be grounds for withdrawal of approval of the application for a new drug under §§ 314.150 and 314.200, or for rescinding a certification or release for an antibiotic drug or for amending or repealing under §§ 314.150 and 314.300 a regulation issued for an antibiotic drug under section 507 of the act.

§ 314.81 Reporting of adverse drug experiences.

(a) *Definitions.* As used in this section:

(1) The term "adverse drug experience" means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following:

(i) An adverse event occurring in the course of the use of a drug product in professional practice.

(ii) An adverse event occurring from drug overdose, whether accidental or intentional.

(iii) An adverse event occurring from drug abuse.

(iv) An adverse event occurring from drug withdrawal.

(v) Failure of a drug product to produce its expected pharmacological action.

(2) [Reserved]

(b) *Reporting form.* (1) Except as provided in paragraph (b)(2) and (3) of this section, the applicant shall report all adverse drug experiences on Form FDA-1639 (Drug Experience Report). Sample copies of Form FDA-1639 may be obtained from the Division of Drug Experience (HFN-730), National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Supplies of Form FDA-1639 may be obtained from the PHS Forms and Publications Distribution Center, 12100 Parklawn Dr., Rockville, MD 20857. Each form should refer only to an individual patient or a single attached publication.

(2) Instead of a Form FDA-1639, the applicant may submit a computer-generated report or tape if the Division of Drug Experience (HFD-210) has approved the format proposed for this use.

(3) Form FDA-1639 may not be used to report adverse drug experience information obtained in phase 1 and phase 2 of an investigation (phases 1 and 2 are described in paragraph 10a of Form FDA-1571 set forth in § 312.1(a)(2)).

(c) *Report requirements.* (1) Each applicant having an approved application under § 314.50 or § 314.55 shall submit the following reports on Form FDA-1639 to the Division of Drug Experience (HFD-210):

(i) *Fifteen-day alert reports.* The applicant shall submit a report about any fatal or life-threatening adverse drug experience not mentioned in the current labeling as soon as the essential information has been obtained, but in any case within 15 working days of initial receipt of the information. The applicant shall prominently identify the report as a 15-day alert report.

(ii) *Thirty-day reports.* The applicant shall submit a report about any other adverse drug experience, and a followup to a 15-day alert report under paragraph (c)(1)(i) of this section, within 30 working days of initial receipt of the information. The applicant shall prominently identify those reports which are followups to 15-day alert reports.

(2) Reports of adverse drug experiences in the published literature are required to be accompanied by a copy of the published article.

(3) The Food and Drug Administration has prepared under § 10.90(b) a guideline for the submission of reports of adverse drug experiences and suggested followup investigation of such reports.

(4) An applicant should not include in reports under this section the names and addresses of individual patients; instead, the applicant should include some other identifier, such as initials or a code number. The reporting person should include the name of the physician from whom the information was received to allow followup, if necessary. Names of patients, practitioners, hospitals, or any geographic identifier are not releasable to the public under FDA's public information regulations in Part 20.

(5) An applicant should not include in reports under this section any adverse drug experiences that occurred in clinical trials if they were previously submitted as part of the application.

(6) The applicant should separate and clearly mark reports of adverse drug experiences that occur during a postmarketing study from those experiences that are spontaneously reported to the applicant.

(d) *Withdrawal of approval.* If an applicant fails to make required reports under this section, FDA may withdraw approval under §§ 314.150 and 314.200 of an application for a new drug or rescind a certification or release for an antibiotic drug, or amend or repeal under §§ 314.150 and 314.300 a regulation issued for an antibiotic drug under section 507 of the act.

§ 314.90 Waivers.

(a) An applicant may ask the Food and Drug Administration to waive under this section any requirement that applies to the applicant under §§ 314.50 through 314.80. An applicant may ask FDA to waive under § 314.126(c) any criteria of an adequate and well-controlled study described in § 314.126(b). A waiver request under this section is required to be submitted with supporting documentation in an application, or in an amendment or supplement to an application. The waiver request is required to contain one of the following:

(1) An explanation why the applicant's compliance with the requirement is unnecessary or cannot be achieved;

(2) A description of an alternative submission that satisfies the purpose of the requirement; or

(3) Other information justifying a waiver.

(b) FDA may grant a waiver if it finds one of the following:

(1) The applicant's compliance with the requirement is unnecessary for the agency to evaluate the application or compliance cannot be achieved;

(2) The applicant's alternative submission satisfies the requirement; or

(3) The applicant's submission otherwise justifies a waiver.

Subpart C—FDA Action on Applications

§ 314.100 Time frames for reviewing applications.

(a) Within 180 days of receipt of an application, the Food and Drug Administration will review it and send the applicant either an approval letter under § 314.105, an approvable letter under § 314.110, or a not approvable letter under § 314.120. The approvable letter and the not approvable letter will invite the applicant to amend the application, withdraw it, or request a notice of opportunity for a hearing under § 314.200.

(b) During the review period an applicant may withdraw an application under § 314.65 and later resubmit it. FDA will then follow the same procedure as if a new application were submitted.

(c) The time period may be extended by mutual agreement between FDA and an applicant or, as provided in § 314.60, as the result of submitting a major amendment.

§ 314.101 Filing an application.

(a) Within 60 days after the Food and Drug Administration receives an application, the agency will determine whether the application may be filed. The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review.

(b) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for refusing to file the application apply, the agency will file the application and notify the applicant in writing. The date of filing will be the date 60 days after the date FDA received the application. The statutory 180-day review period for a new drug begins to run on the date the application is filed.

(c) If FDA refuses to file the application, the agency will notify the applicant in writing and state the reason under paragraph (d) or (e) of this section for the refusal. If FDA refuses to file the application under paragraph (d) of this section, the applicant may request in writing within 10 days of the date of the agency's notification an informal conference with the agency about whether the agency should file the application or the applicant may request that the application be filed over protest. If following the informal conference the applicant resubmits the application (with or without amendments to correct the deficiencies), the agency will file the application under paragraph (b) of this section, notify the applicant in writing, and review it as filed. If the application is filed over protest, the date of filing will be the date 60 days after the date FDA originally received the application. If FDA refuses to file the application under paragraph (e) of this section the applicant may amend the application and resubmit it and the agency will make a determination under this section whether it may be filed.

(d) FDA may refuse to file an application if any of the following applies. An application that FDA has once refused to file under this paragraph will be automatically filed if resubmitted by the applicant under paragraph (c) of this section.

(1) The application does not contain a completed Form FDA-356H.

(2) The application is not submitted in the form required under § 314.50 or § 314.55.

(3) The application is incomplete because it does not on its face contain information required under section 505(b)(1), (2), (3), (4), (5), and (6) or section 507 of the act and § 314.50 or § 314.55.

(4) The application does not contain an environmental impact analysis report analyzing under § 25.1 the environmental impact of the manufacturing process and the ultimate use or consumption of the drug.

(5) The application does not contain an accurate and complete English translation of each part of the application that is not in English.

(6) The application does not contain a statement that each nonclinical laboratory study was conducted in compliance with the requirements set forth in Part 58, or, for each study not conducted in compliance with Part 58, a statement that describes the differences between the practices used in the study and those required in the regulations.

(e) The agency will refuse to file an application if any of the following applies:

(1) The drug product that is the subject of the submission is already covered by an approved application.

(2) The submission purports to be an abbreviated application under § 314.55, but the drug product is not one for which FDA has made a finding that an abbreviated application is acceptable under § 314.55(b). FDA will file a copy of the application Form FDA-356H as a citizen petition under § 10.30 seeking a finding under § 314.55 that an abbreviated application is acceptable for the drug product, and so notify the applicant in writing.

(3) The drug product is subject to licensing by FDA under the Public Health Service Act (58 Stat. 632 as amended (42 U.S.C. 201 et seq.)) and Subchapter F of Chapter I of Title 21 of the Code of Federal Regulations.

(f)(1) Within 180 days after the date of filing, plus the period of time the review period was extended (if any), FDA will either (i) approve the application or (ii) issue a notice of opportunity for hearing if the applicant asked FDA to provide it an opportunity for a hearing on an application in response to an approvable letter or a not approvable letter.

(2) This paragraph does not apply to applications that have been withdrawn from FDA review by the applicant.

§ 314.102 Food and Drug Administration communication about deficiencies in an application under review.

(a) The Food and Drug Administration may communicate with the applicant orally or in writing during FDA's review of an application about deficiencies in the application or about the agency's need for more data or information or for changes in the application to facilitate the agency's review. FDA will consider a written response from an applicant to any communication under this section to be an amendment to the application under § 314.60.

(b) Approximately 90 days into the review cycle, FDA will provide applicants with an opportunity to have an informal meeting with agency reviewing officials. The purpose of the meeting will be to inform applicants of the general progress and status of their applications, and to advise applicants of important deficiencies which have been identified by that time and which have not already been communicated. This meeting will be available on applications for all new chemical entities and major new indications of marketed drugs. Such meetings will be held at the applicant's option, and may be held by telephone if mutually agreed upon.

§ 314.103 Drugs with potential for abuse.

The Food and Drug Administration will inform the Drug Enforcement Administration under section 201(f) of the Controlled Substances Act (21 U.S.C. 801) when an application is submitted for a drug that appears to have an abuse potential.

§ 314.105 Approval of an application.

(a) The Food and Drug Administration will approve an application and send the applicant an approval letter if none of the reasons in § 314.125 for refusing to approve the application apply. The date of the agency's approval letter is the date of approval of the application. When FDA sends an applicant an approval letter for an antibiotic, it will promulgate a regulation under § 314.300 providing for certification of the drug, if necessary. A new drug product or antibiotic may not be marketed until an approval letter is issued. Marketing of an antibiotic need await the promulgation of a regulation under § 314.300, if FDA issues a release for the drug.

(b) FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling. While the statutory standards apply to all drugs,

the many kinds of drugs that are subject to them and the wide range of uses for those drugs demand flexibility in applying the standards. Thus FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet them. FDA makes its views on drug products and classes of drugs available through guidelines, recommendations, and other statements of policy.

§ 314.106 Foreign data.

(a) *General.* The acceptance of foreign data in an application generally is governed by § 312.20.

(b) *As sole basis for marketing approval.* An application based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved if: (i) the foreign data are applicable to the U.S. population and U.S. medical practice; (ii) the studies have been performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means. Failure of an application to meet any of these criteria will result in the application not being approvable based on the foreign data alone. FDA will apply this policy in a flexible manner according to the nature of the drug and the data being considered.

(c) *Consultation between FDA and applicants.* Applicants are encouraged to meet with agency officials in a "presubmission" meeting when approval based solely on foreign data will be sought.

§ 314.110 Approvable letter to the applicant.

In selected circumstances it is useful at the end of the review period for the Food and Drug Administration to indicate to the applicant that the application is basically approvable providing certain issues are resolved. An approvable letter may be issued in such circumstances. FDA will send the applicant an approvable letter if the application substantially meets the requirements of this part and the agency believes that it can approve the application if specific additional information or material is submitted or specific conditions (for example, certain changes in labeling) are agreed to by the applicant. The approvable letter will describe the information or material FDA requires or the conditions the applicant is asked to meet. As a practical matter, the approvable letter will serve in most instances as a mechanism for resolving outstanding issues on drugs that are about to be approved and marketed. Within 10 days after the date of the approvable letter, the applicant shall either:

(a) Amend the application or notify FDA of an intent to file an amendment. The filing of an amendment or notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period for 45 days after the date FDA receives the amendment. The extension is to permit the agency to review the amendment.

(b) Withdraw the application. FDA will consider the applicant's failure to respond within 10 days to an approvable letter to be a request by the applicant to withdraw the application under § 314.65. A decision to withdraw an application is without prejudice to a refiling.

(c) For a new drug, ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) of the act. The applicant shall submit the request to the Assistant Director for Regulatory Affairs (HFN-7), National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Within 60 days of the date of the approvable letter, or within a different time period to which FDA and the applicant agree, the agency will either approve the application under § 314.105 or refuse to approve the application under § 314.125 and give the applicant written notice of an opportunity for a hearing under § 314.200 and section 505(c)(2) of the act on the question of whether there are grounds for denying approval of the application under section 505(d) of the act.

(d) For an antibiotic, file a petition or notify FDA of an intent to file a petition proposing the issuance, amendment, or repeal of a regulation under § 314.300 and section 507(f) of the act.

§ 314.120 Not approvable letter to the applicant.

The Food and Drug Administration will send the applicant a not approvable letter if the agency believes that the application may not be approved for one of the reasons given in § 314.125. The not approvable letter will describe the deficiencies in the application. Within 10 days after the date of the not approvable letter, the applicant shall either:

(a) Amend the application or notify FDA of an intent to file an amendment. The filing of an amendment or a notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period under §314.60.

(b) Withdraw the application. FDA will consider the applicant's failure to respond within 10 days to a not approvable letter to be a request by the appliant to withdraw the application under § 314.65. A decision to withdraw the application is without prejudice to refiling.

(c) For a new drug, ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) of the act. The applicant shall submit the request to the Assistant Director for Regulatory Affairs (HFN-7), National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Within 60 days of the date of the not approvable letter, or within a different time period to which FDA and the applicant agree, the agency will either approve the application under § 314.105 or refuse to approve the application under § 314.125 and give the applicant written notice of an opportunity for a hearing under § 314.200 and section 505(c)(2) of the act on the question of whether there are grounds for denying approval of the application under section 505(d) of the act.

(d) For an antibiotic, file a petition or notify FDA of an intent to file a petition proposing the issuance, amendment, or repeal of a regulation under § 314.300 and section 507(f) of the act.

§ 314.125 Refusal to approve an application.

(a) The Food and Drug Administration will refuse to approve the application and for a new drug give the applicant written notice of an opportunity for a hearing under § 314.200 on the question of whether there are grounds for denying approval of the application under section 505(d) of the act, or for an antibiotic publish a proposed regulation based on an acceptable petition under § 314.300, if:

(1) FDA sends the applicant an approvable or a not approvable letter under § 314.110 or § 314.120;

(2) The applicant requests an opportunity for hearing for a new drug on the question of whether the application is approvable or files a petition for an antibiotic proposing the issuance, amendment, or repeal of a regulation; and

(3) FDA finds that any of the reasons given in paragraph (b) of this section apply.

(b) FDA may refuse to approve an application for any of the following reasons:

(1) The methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the drug substance or the drug product are inadequate to preserve its identity, strength, quality, purity, stability, and bioavailability.

(2) The investigations required under section 505(b) or 507 of the act do not include adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling.

(3) The results of the tests show that the drug is unsafe for use under the conditions prescribed, recommended, or suggested in its proposed labeling or the results do not show that the drug product is safe for use under those conditions.

(4) There is insufficient information about the drug to determine whether the product is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling.

(5) There is a lack of substantial evidence consisting of adequate and well-controlled investigations, as defined in § 314.126, that the drug product will have the effect it purports or is represented to have the conditions of use prescribed, recommended, or suggested in its proposed labeling.

(6) The proposed labeling is false or misleading in any particular.

(7) The application contains an untrue statement of a material fact.

(8) The drug product's proposed labeling does not comply with the requirements for labels and labeling in Part 201.

(9) The bioavailability or bioequivalence data in the application do not show whether the drug product is safe or effective for use under the conditions prescribed, recommended, or suggested in its proposed labeling.

(10) A reason given in a letter refusing to file the application under § 314.101(d), if the deficiency is not corrected.

(11) The drug will be manufactured or processed in whole or in part in an establishment that is not registered and not exempt from registration under sectin 510 of the act and Part 207.

(12) The applicant does not permit a properly authorized officer or employee of the Department of Health and Human Services an adequate opportunity to inspect the facilities, controls, and any records relevant to the application.

(13) The methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the drug substance or the drug product do not comply with the current good manufacturing practice regulations in Parts 210 and 211.

(14) A nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations as set forth in Part 58 and no explanation of the differences is provided or, if it is, described differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

§ 314.126 Adequate and well-controlled studies.

(a) The purpose of conducting clinical investigations of a drug is to distinguish the effect of a drug from other influences, such as spontaneous change in the course of the disease, placebo effect, or biased observation. The characteristics described in paragraph (b) of this section have been developed over a period of years and are recognized by the scientific community as the essentials of an adequate and well-controlled clinical investigation. The Food and Drug Administration considers these characteristics in determining whether an investigation is adequate and well-controlled for purposes of sections 505 and 507 of the act. Reports of adequate and well-controlled investigations provide the primary basis for determining whether there is "substantial evidence" to support the claims of effectiveness for new drugs and antibiotics. Therefore, the study report should provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present.

(b) An adequate and well-controlled study has the following characteristics:

(1) There is a clear statement of the objectives of the investigation in the protocol for the study and in the report of its results.

(2) The study uses a design that permits a valid comparison with a control to provide a quantitative assessment of drug effect. The protocol for the study and report of results should describe the study design precisely; for example, duration of treatment periods, whether treatments are parallel, sequential, or crossover. Generally, the following types of control are recognized:

(i) *Placebo concurrent control.* The test drug is compared with an inactive preparation designed to resemble the test drug as far a possible. A placebo-controlled study may include additional treatment groups, such as an active treatment control or a dose-comparison control, and usually includes randomization and blinding of patients or investigators, or both.

(ii) *No treatment concurrent control.* Where objective measurements of effectiveness are available and placebo effect is negligible, the test drug is compared with no treatment. No treatment concurrent control trails usually include randomization.

(iii) *Active treatment concurrent control.* The test drug is compared with known effective therapy; for example, where the condition treated is such that administration of placebo or no treatment would be contrary to the interest of the patient. An active treatment study may include additional treatment groups, however, such as a placebo control or a dose-comparison control. Active treatment trails usually include randomization and blinding of patients or investigators, or both. If the intent of the trial is to show similarity of the test and control drugs, the report of the study should assess the ability of the study to have detected a difference between treatments.

(iv) *Dose-comparison concurrent control.* At least two doses of the drug are compared. A dose-comparison study may include additional treatment groups, such as placebo control or active control. Dose-comparison trails usually include randomization and blinding of patients or investigators, or both.

(v) *Historical control.* The results of treatment with the test drug are compared with experience historically derived from the adequately documented natural history of the disease or condition, or from the results of active treatment, in comparable patients or populations. Because historical control populations usually cannot be as well assessed with respect to pertinent variables as can concurrent control populations, historical control designs are usually reserved for special circumstances. Examples include studies of diseases with high and predictable mortality (for example, certain malignancies) and studies in which the effect of the drug is self-evident (general anesthetics, drug metabolism).

(3) The method of selection of subjects provides adequate assurance that they have the disease or condition being studied, or evidence of susceptibility and exposure to the condition against which prophylaxis is directed.

(4) The method of assigning patients to treatment and control groups minimizes bias and is intended to assure comparability of the groups with respect to pertinent variables such as age, sex, severity of disease, duration of disease, and use of drugs or therapy other than the test drug. The protocol for the study and the report of its results should describe how subjects were assigned to groups. Ordinarily, in a concurrently controlled study, assignment is by randomization, with or without stratification.

(5) Adequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data. The protocol and report of the study should describe the procedures used to accomplish this, such as blinding.

(6) The methods of assessment of subjects' response are well-defined and reliable. The protocol for the study and the report of results should explain the variables measured, the methods of observation, and criteria used to assess response.

(7) There is an analysis of the results of the study adequate to assess the effects of the drug. The report of the study should describe the results and the analytic methods used to evaluate them, including any appropriate statistical methods. The analysis should assess, among other things, the comparability of test and control groups with respect to pertinent variables.

(c) The Director of the National Center for Drugs and Biologics may, on the Director's own initiative or on the petition of an interested person, waive in whole or in part any of the criteria in paragraph (b) of this section with respect to a specific clinical investigation, either prior to the investigation or in the evaluation of a completed study. A petition for a waiver is required to set forth clearly and concisely the specific criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular clinical investigation, what alternative procedures, if any, are to be, or have been employed, and what results have been obtained. The petition is also required to state why the clinical investigations so conducted will yield, or have yielded, substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(d) For an investigation to be considered adequate for approval of a new drug, it is required that the test drug be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

(e) Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies carefully conducted and documented, may provide corroborative support of well-controlled studies regarding efficacy and may yield valuable data regarding safety of the test drug. Such studies will be considered on their merits in the light of the principles listed here, with the exception of the requirement for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

§ 314.150 Withdrawal of approval of an application.

(a) The Food and Drug Administration will notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6, and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application under section 505(e) of the act and under the procedure in § 314.200, or, for an antibiotic, rescind a certification or release, or amend or repeal a regulation providing for certification under section 507 of the act and under the procedure in § 314.300, if any of the following applies:

(1) The Secretary of Health and Human Services has suspended the approval of the application for a new drug on a finding that there is an imminent hazard to the public health. FDA will promptly afford the applicant an expedited hearing following summary suspension on a finding of imminent hazard to health.

(2) FDA finds:

(i) That clinical or other experience, tests, or other scientific data show that the drug is unsafe for use under the conditions of use upon the basis of which the application was approved; or

(ii) That new evidence of clinical experience, not contained in the application or not available to FDA until after the application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available when the application was approved, reveal that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or

(iii) Upon the basis of new information before FDA with respect to the drug, evaluated together with the evidence available when the application was approved, that there is a lack of substantial evidence from adequate and well-controlled investigations as defined in § 314.126, that the drug will have the effect it is purported or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling; or

(iv) That the application contains any untrue statement of a material fact.

(b) FDA may notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6, and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application under section 505(e) of the act and under the procedure in § 314.200, or, for an antibiotic, rescind a certification or release, or amend or repeal a regulation providing for certification under section 507 of the act and the procedure in § 314.300, if the agency finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has reportedly or deliberately failed to maintain required records or to make required reports under section 505(j) or 507(g) of the act and § 314.80, or that the applicant has refused to permit access to, or copying or verification of, its records as required under § 314.80.

(2) That on the basis of new information before FDA, evaluated together with the evidence available when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the agency.

(3) That on the basis of new information before FDA, evaluated together with the evidence available when the application was approved, the labeling of the drug, based on a fair evaluation of all material facts, is false or misleading in any particular; and the labeling was not corrected by the applicant within a reasonable time after receipt of written notice from the agency.

(4) That the applicant has failed to comply with the notice requirements of section 510(j)(2) of the act.

(5) That the applicant has failed to submit bioavailability or bioequivalence data required under Part 320.

(c) FDA will withdraw approval of an application if the applicant requests its

withdrawal because the drug subject to the application is no longer being marketed, provided none of the conditions listed in paragraphs (a) and (b) of this section apply to the drug. FDA will consider a written request for withdrawal under this paragraph to be a waiver of an opportunity for hearing otherwise provided for in this section. Withdrawal of approval of an application under this paragraph is without prejudice to refiling.

(d) FDA may notify an applicant that it believes a potential problem associated with a drug is sufficiently serious that the drug should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided for under this section, to permit FDA to withdraw approval of the application for the product, and to remove voluntarily the product from the market. If the applicant agrees, the agency will not make a finding under paragraph (b) of this section, but will withdraw approval of the application in a notice published in the **Federal Register** that contains a brief summary of the agency's and the applicant's views of the reasons for withdrawal.

§ 314.152 Notice of withdrawal of approval of an application for a new drug.

If the Food and Drug Administration withdraws approval of an application for a new drug, FDA will publish a notice in the **Federal Register** announcing the withdrawal of approval.

§ 314.160 Approval of an application for which approval was previously refused, suspended, or withdrawn.

Upon the Food and Drug Administration's own initiative or upon request of an applicant, FDA may, on the basis of new data, approve an application which it had previously refused, suspended, or withdrawn approval. FDA will publish a notice in the **Federal Register** announcing the approval.

§ 314.170 Adulteration and misbranding of an approved drug.

All drugs, including those the Food and Drug Administration approves, or provides for certification of, under sections 505, 506, and 507 of the act and this part, are subject to the adulteration and misbranding provisions in sections 501, 502, and 503 of the act. FDA is authorized to regulate approved new drugs and approved antibiotic drugs by regulations issued through informal rulemaking under section 501, 502, and 503 of the act.

Subpart D—Hearing Procedures for New Drugs

§ 314.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.

(a) *Notice of opportunity for hearing.* The Director of the National Center for Drugs and Biologics, Food and Drug Administration will give the applicant, and all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6, notice and an opportunity for a hearing on the National Center's proposal to refuse to approve an application or to withdraw the approval of an application. The notice will state the reasons for the action and the proposed grounds for the order.

(1) The notice may be general (that is, simply summarizing in a general way the information resulting in the notice) or specific (that is, either referring to specific requirements in the statute and regulations with which there is a lack of compliance, or providing a detailed description and analysis of the specific facts resulting in the notice).

(2) FDA will publish the notice in the **Federal Register** and will state that the applicant, and other persons subject to the notice under § 310.6, who wishes to participate in a hearing, has 30 days after the date of publication of the notice to file a written notice of participation and request for hearing. The applicant, or other persons subject to the notice under § 310.6, who fails to file a written notice of participation and request for hearing within 30 days, waives the opportunity for a hearing.

(3) It is the responsibility of every manufacturer or distributor of a drug product to review every notice of opportunity for a hearing published in the **Federal Register** to determine whether it covers any drug product that person manufacturers or distributes. Any person may request an opinion of the applicability of a notice to a specific product that may be identical, related, or similar to a product listed in a notice by writing to the Division of Drug Labeling Compliance (HFN-310), National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. A person shall request an opinion within 30 days of the date of publication of the notice to be eligible for an opportunity for hearing under the notice. If a person requests an opinion, that person's time for filing an appearance and request for hearing and supporting studies and analyses begins on the date the persons receives the opinion from FDA.

(b) FDA will provide the notice of opportunity for hearing to applicants and to other persons subject to the notice under § 310.6, as follows:

(1) To any person who has submitted an application, by delivering the notice in person or by sending it by registered or certified mail to the last address shown in the application.

(2) To any person who has not submitted an application but who is subject to the notice under § 310.6, by publication of the notice in the **Federal Register.**

(c)(1) *Notice of participation and request for hearing, and submission of studies and comments.* The applicant, or any other person subject to the notice under § 310.6, who wishes to participate in a hearing, shall file with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, Rockville, MD 20857, (i) within 30 days after the date of the publication of the notice (or of the date of receipt of an opinion requested under paragraph (a)(3) of this section) a written notice of participation and request for hearing and (ii) within 60 days after the date of publication of the notice, unless a different period of time is specified in the notice of opportunity for hearing, the studies on which the person relies to justify a hearing as specified in paragraph (d) of this section. The applicant, or other person, may incorporate by reference the raw data underlying a study if the data were previously submitted to FDA as part of an application or other report.

(2) FDA will not consider data or analyses submitted after 60 days in determining whether a hearing is warranted unless they are derived from well-controlled studies begun before the date of the notice of opportunity for hearing and the results of the studies were not available within 60 days after the date of publication of the notice. Nevertheless, FDA may consider other studies on the basis of a showing by the person requesting a hearing of inadvertent omission and hardship. The person requesting a hearing shall list in the request for hearing all studies in progress, the results of which the person intends later to submit in support of the request for hearing. That list is required to include a copy of the complete protocol, a list of the participating investigatiors, and a brief status report of the studies under paragraph (c)(1(ii) of this section.

(3) Any other interested person who is not subject to the notice of opportunity for hearing may also submit comments on the proposal to withdraw approval of the application. The comments are required to be submitted within the time

and under the conditions specified in this section.

(d) The person requesting a hearing is required to submit under paragraph (c)(1)(ii) of this section the studies (including all protocols and underlying raw data) on which the person relies to justify a hearing with respect to the drug product. Except, a person who requests a hearing on the refusal to approve an application is not required to submit additional studies and analyses if the studies upon which the person relies have been submitted in the application and in the format and containing the summaries required under § 314.50.

(1) If the grounds for FDA proposed action concern the effectiveness of the drug, each request for hearing is required to be supported only by adequate and well-controlled clinical studies meeting all of the precise requirements of § 314.126 and, for combination drug products, § 300.50, or by other studies not meeting those requirements for which a waiver has been previously granted by FDA under § 314.126. Each person requesting a hearing shall submit all adequate and well-controlled clinical studies on the drug product, including any unfavorable analyses, views, or judgments with respect to the studies. No other data, information, or studies shall be submitted.

(2) The submission is required to include a factual analysis of all the studies submitted. If the grounds for FDA proposed action concern the effectiveness of the drug, the analysis is required to specify how each study accords, on a point-by-point basis, with each criterion required for an adequate well-controlled clinical investigation established under § 314.126 and, if the product is a combination drug product, with each of the requirements for a combination drug established in § 300.50, or the study is required to be accompanied by an appropriate waiver previously granted by FDA. If a study deals with a drug or dosage form or condition of use or mode of administration other than the one(s) in question that fact(s) is required to be clearly stated. Any study conducted on the final marketed form of the drug product is required to be clearly stated.

(3) Each person requesting a hearing shall submit an analysis of the data upon which the person relies, except that the required information relating either to safety or to effectiveness may be omitted if the notice of opportunity for hearing does not raise any issue with respect to that aspect of the drug; information on compliance with § 300.50 may be omitted if the drug product is not a combination drug product. FDA finds that it can most efficiently consider submissions made in the following format.

I. Safety data.
A. Animal safety data.
1. Individual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
2. Combinations of the individual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
B. Human safety data.
1. Individual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
c. Documented case reports.
d. Pertinent marketing experiences that may influence a determination about the safety of each individual active component(s).
2. Combinations of the individual active components.
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
c. Documented case reports.
d. Pertinent marketing experiences that may influence a determination about the safety of each individual active component(s).
II. Effectiveness data.
A. Individual active components: Controlled studies, with an analysis showing clearly how study satisfies, on a point-by-point basis, each of the criteria required by § 314.126.
B. Combinations of individual active components.
1. Controlled studies with an analysis showing clearly how each study satisfies on a point-by-point basis, each of the criteria required by § 314.126.
2. An analysis showing clearly how each requirement of § 300.50 has been satisfied.
III. A summary of the data and views setting forth the medical rationale and purpose for the drug and its ingredients and the scientific basis for the conclusion that the drug and its ingredients have been proven safe and/or effective for the intended use. If there is an absence of controlled studies in the material submitted or the requirements of any element of § 300.50 or § 314.126 have not been fully met, the fact(s) is required to be stated clearly and a waiver obtained under § 314.126 is required to be submitted.
IV. A statement signed by the person responsible for such submission that it includes in full (or incorporates by reference as permitted in § 314.200(c)(2)) all studies and information specified in § 314.200(d). (Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001.)

(e) *Contentions that a drug product is not subject to the new drug requirements.* A notice of opportunity for hearing encompasses all issues relating to the legal status of the drug product(s) subject to it, including indentical, related, and similar drug products as defined in § 310.6. A notice of appearance and request for hearing under paragraph (c)(1)(i) of this section is required to contain any contention that the product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act, or because it is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, contained in section 201(p) of the act or under section 107(c) of the Drug Amendments of 1962, or for any other reason. Each contention is required to be supported by a submission under paragraph (c)(1)(ii) of this section and the Commissioner of Food and Drugs will make an administrative determination on each contention. The failure of any person subject to a notice of opportunity for a hearing, including any person who manufactures or distributes an identical related, or similar drug product as defined in § 310.6, to submit a notice of participation and request for hearing or to raise all such contentions constitutes a waiver of any contentions not raised.

(1) A contention that a drug product is generally recoginized as safe and effective within the meaning of section 201(p) of the act is required to be supported by submission of the same quantity and quality of scientific evidence that is required to obtain approval of an application for the product, unless FDA has waived a requirement for effectiveness (under § 314.126) or safety, or both. The submission should be in the format and with the analyses required under paragraph (d) of this section. A person who fails to submit the required scientific evidence required under paragraph (d) waives the contention. General recognition of safety and effectiveness shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.

(2) A contention that a drug product is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, contained in section 201(p) of the act, or under section 107(c) of the Drug Amendments of 1962, is required to be supported by evidence of past and present quantitative formulas, labeling, and evidence of marketing. FDA asks a person who makes such a contention to submit the formulas, labeling, and evidence of marketing in the following format.

I. Formulation.
A. A copy of each pertinent document or record to establish the exact quantitative

formulation of the drug (both active and inactive ingredients on the date of inital marketing of the drug).

B. A statement whether such formulation has at any subsequent time been changed in any manner. If any such change has been made, the exact date, nature, and rationale for each change in formulation, including any deletion or change in the concentration of any active ingredient and/or inactive ingredient, should be stated, together with a copy of each pertinent document or record to establish the date and nature of each such change including but not limited to the formula which resulted from each such change. If no such change has been made, a copy of representative documents or records showing the formula at representative points in time should be submitted to support the statement.

II. Labeling.

A. A copy of each pertinent document or record to establish the identity of each item of written, printed, or graphic matter used as labeling on the date the drug was initially marketed.

B. A statement whether such labeling has at any subsequent time been discontinued or changed in any manner. If such discontinuance or change has been made, the exact date, nature, and rationale for each discontinuance or change and a copy of each pertinent document or record to establish each such discontinuance or change should be submitted, including but not limited to the labeling which resulted from each such discontinuance or change. If no such discontinuance or change has been made, a copy of representative documents or records showing labeling at representative points in time should be submitted to support the statement.

III. Marketing.

A. A copy of each pertinent document or record to establish the exact date the drug was initially marketed.

B. A statement whether such marketing has at any subsequent time been discontinued. If such marketing has been discontinued, the exact date of each such discontinuance should be submitted, together with a copy of each pertinent document or record to establish each such date.

IV. Verification.

A statement signed by the person responsible for such submission, that all appropriate records have been searched and to the best of that person's knowledge and belief it includes a true and accurate presentation of the facts. (Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001.)

(3) The Food and Drug Administration will not find a drug product, including any active ingredient, which is identical, related, or similar, as described in § 310.6, to a drug product, including any active ingredient for which an application is or at any time has been effective or deemed approved, or approved under section 505 of the act, to be exempt from part or all of the new drug provisions of the act.

(4) A contention that a drug product is not a new drug for any other reason is required to be supported by submission of the factual records, data, and information that are necessary and appropriate to support the contention.

(5) It is the responsibility of every person who manufactures or distributes a drug product in reliance upon a "grandfather" provision(s) of the act to maintain files that contain the data and information necessary fully to document and support that status.

(f) *Separation of functions.* Separation of functions commences upon receipt of a request for hearing. The Director of the National Center for Drugs and Biologics, Food and Drug Administration, will prepare an analysis of the request and a proposed order ruling on the matter. The analysis and proposed order, the request for hearing, and any proposed order denying a hearing and response under paragraph (g) (2) or (3) of this section will be submitted to the Office of the Commissioner of Food and Drugs for review and decision. When the National Center for Drugs and Biologics recommends denial of a hearing on all issues on which a hearing is requested, no representative of the National Center will participate or advise in the review and decision by the Commissioner. When the National Center for Drugs and Biologics recommends that a hearing be granted on one or more issues on which a hearing is requested, separation of functions terminates as to those issues, and representatives of the National Center may participate or advise in the review and decision by the Commissioner on those issues. The Commissioner may modify the text of the issues, but may not deny a hearing on those issues. Separation of functions continues with respect to issues on which the National Center for Drugs and Biologics has recommended denial of a hearing. The Commissioner will neither evaluate nor rule on the National Center's recommendation on such issues and such issues will not be included in the notice of hearing. Participants in the hearing may make a motion to the presiding officer for the inclusion of any such issue in the hearing. The ruling on such a motion is subject to review in accordance with § 12.35(b). Failure to so move constitutes a waiver of the right to a hearing on such an issue. Separation of functions on all issues resumes upon issuance of a notice of hearing. The Office of the General Counsel, Department of Health and Human Services, will observe the same separation of functions.

(g) *Summary judgment.* A person who requests a hearing may not rely upon allegations or denials but is required to set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing with respect to the particular drug product(s) specified in the request for hearing.

(1) Where a specific notice of opportunity for hearing (as defined in paragraph (a)(1) of this section) is used, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing, if it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the refusal to approve the application or the withdrawal of approval of the application; for example, no adequate and well-controlled clinical investigations meeting each of the precise elements of § 314.126 and, for a combination drug product, § 300.50, showing effectiveness have been identified. Any order entering summary judgment is required to set forth the Commissioner's findings and conclusions in detail and is required to specify why each study submitted fails to meet the requirements of the statute and regulations or why the request for hearing does not raise a genuine and substantial issue of fact.

(2) When following a general notice of opportunity for hearing (as defined in paragraph (a)(1) of this section) the Director of the National Center for Drugs and Biologics concludes that summary judgment against the person(s) requesting a hearing should be considered, the Director will serve upon the person requesting a hearing by registered mail a proposed order denying a hearing. This person has 60 days after receipt of the proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(3) When following a general or specific notice of opportunity for hearing the person(s) requesting a hearing submits data or information of a type required by the statute and regulations, and the Director of the National Center for Drugs and Biologics concludes that summary judgment against the person(s) should be considered, the Director may serve upon the person(s) by registered mail a proposed order denying a hearing. The person has 60 days after receipt of the proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(4) If review of the data, information, and analyses submitted show that the

ground(s) cited in the notice are not valid, for example, that substantial evidence of effectiveness exists, the Commissioner will enter summary judgment for the person(s) requesting the hearing, and rescind the notice of opportunity for hearing.

(5) If the Commissioner grants a hearing, it will begin within 90 days after the expiration of the time for requesting the hearing unless the parties otherwise agree in the case of denial of approval, and as soon as practicable in the case of withdrawal of approval.

(6) The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be in the public interest.

(7) If the manufacturer or distributor of an identical, related, or similar drug product requests and is granted a hearing, the hearing may consider whether the product is in fact identical, related, or similar to the drug product named in the notice of opportunity for hearing.

(8) A request for hearing, and any subsequent grant or denial of a hearing, applies only to the drug product(s) named in such documents.

(h) FDA will issue a notice withdrawing approval and declaring all products unlawful for drug products subject to a notice of opportunity for hearing, including any identical, related, or similar drug product under § 310.6, for which an opportunity for a hearing is waived or for which a hearing is denied. The Commissioner may defer or stay the action pending a ruling on any related request for a hearing or pending any related hearing or other administrative or judicial proceeding.

§ 314.201 Procedure for hearings.

Parts 10 through 16 apply to hearings relating to new drugs under section 505 (d) and (e) of the act.

§ 314.235 Judicial review.

(a) The Commissioner of Food and Drugs will certify the transcript and record. In any case in which the Commissioner enters an order without a hearing under § 314.200(g), the record certified by the Commissioner is required to include the requests for hearing together with the data and information submitted and the Commissioner's findings and conclusion.

(b) A manufacturer or distributor of an identical, related, or similar drug product under § 310.6 may seek judicial review of an order withdrawing approval of a new drug application, whether or not a hearing has been held, in a United States court of appeals under section 505(h) of the act.

Subpart E—Administrative Procedures for Antibiotics

§ 314.300 Procedure for the issuance, amendment, or repeal of regulations.

(a) The procedures in Part 10 apply to the issuance, amendment, or repeal of regulations under section 507 of the act.

(b)(1) The Commissioner of Food and Drugs, on his or her own initiative or on the application or request of any interested person, may publish in the **Federal Register** a notice of proposed rulemaking and order to issue, amend, or repeal any regulation contemplated by section 507 of the act.

The notice and order may be general (that is, simply summarizing in a general way the information resulting in the notice and order) or specific (that is, either referring to specific requirements in the statute and regulations with which there is a lack of compliance, or providing a detailed description and analysis of the specific facts resulting in the notice and order).

(2) The Food and Drug Administration will give interested persons an opportunity to submit written comments and to request an informal conference on the proposal, unless the notice and opportunity for comment and informal conference have already been provided in connection with the announcement of the reports of the National Academy of Sciences/National Research Council, Drug Efficacy Study Group, to persons who will be adversely affected, or as provided in §§ 10.40(e) and 12.20(c)(2). The time for requesting an informal conference shall be 30 days unless otherwise specified in the notice of proposed rulemaking. If an informal conference is requested and granted, those persons participating in the conference shall be provided an additional 30 days for comment, beginning the date of the conference, unless otherwise specified in the proposal.

(3) It is the responsibility of every manufacturer or distributor of an antibiotic drug product to review every proposal published in the **Federal Register** to determine whether it covers any drug product that person manufacturers or distributes.

(4) After considering the written comments, the results of any conference, and the data available, the Commissioner will publish an order in the **Federal Register** acting on the proposal, with opportunity for any person who will be adversely affected to file objections, to request a hearing, and to show reasonable grounds for the hearing. Any person who wishes to participate in a hearing, shall file with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, (i) within 30 days after the date of the publication of the order a written notice of participation and request for hearing and (ii) within 60 days after the date of publication of the order, unless a different period of time is specified in the order, the studies on which the person relies to justify a hearing as specified in paragraph (b)(6) of this section. The person may incorporate by reference the raw data underlying a study if the data were previously submitted to FDA as part of an application or other report.

(5) FDA will not consider data or analysis submitted after 60 days in determining whether a hearing is warranted unless they are derived from well-controlled studies begun before the date of the order and the results of the studies were not available within 60 days after the dae of publication of the order. Nevertheless, FDA may consider other studies on the basis of a showing by the person requesting a hearing of inadvertent omission and hardship. The person requesting a hearing shall list in the request for hearing all studies in progress, the results of which the person intends later to submit in support of the request for hearing. That list is required to include a copy of the complete protocol, a list of the participating investigators, and a brief status report of the studies under paragraph (b)(4)(ii) of this section.

(6) The person requesting a hearing is required to submit as required under § 314.200(c)(1)(ii) the studies (including all protocols and underlying raw data) on which the person relies to justify a hearing with respect to the drug product. Except, a person who requests a hearing on a proposal is not required to submit additional studies and analyses if the studies upon which the person relies have been submitted in an application and in the format and containing the summaries required under § 314.50.

(i) If the grounds for FDA proposed action concern the effectiveness of the drug, each request for hearing is required to be supported only by adequate and well-controlled clinical studies meeting all of the precise requirements of § 314.126 and, for combination drug products, § 300.50, or by other studies not meeting those requirements for which a waiver has been previously granted by FDA under § 314.126. Each person requesting a hearing shall submit all adequate and well-controlled clinical studies on the

drug product, any unfavorable analyses, views, or judgments with respect to the studies. No other data, information, or studies shall be submitted.

(ii) The submission is required to include a factual analysis of all the studies submitted. If the grounds for FDA proposed action concern the effectiveness of the drug, the analysis is required to specify how each study accords, on a point-by-point basis, with each criterion required for an adequate well-controlled clinical investigation established under § 314.126 and, if the product is a combination drug product, with each of the requirements for a combination drug established in § 300.50, or the study is required to be accompanied by an appropriate waiver previously granted by FDA. If a study deals with drug entity or dosage form or condition of use or mode of administration other than the one(s) is question that fact(s) is required to be clearly stated. Any study conducted on the final marketed form of the drug product is required to be clearly stated.

(iii) Each person requesting hearing shall submit an analysis of the data upon which the person relies, except that the required information relating either to safety or to effectiveness may be omitted if the notice of opportunity for hearing does not raise any issue with respect to that aspect of the drug; information on compliance with § 300.50 may be omitted if the drug product is not a combination drug product. FDA finds that it can most efficiently consider submissions made in the following format.

I. Safety data.
A. Animal safety data.
1. Induvidual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
2. Combinations of the individual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
B. Human safety data.
1. Individual active component(s).
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
c. Documented case reports.
d. Pertinent marketing experiences that may influence a determination about the safety of each individual active component(s).
2. Combinations of the individual active components.
a. Controlled studies.
b. Partially controlled or uncontrolled studies.
c.Documented case reports.
d. Pertinent marketing experiences that may influence a determination about the safety of each individual active component(s).
II. Effectiveness data.
A. Individual active components: Controlled studies, with an analysis showing clearly how each study satisfies, on a point-by-point basis, each of the criteria required by § 314.126.
B. Combinations of individual active components.
1. Controlled studies with analysis showing clearly how each study satisfies on a point-by-point basis, each of the criteria required by § 314.126.
2. An analysis showing clearly how each requirement of § 300.50 has been satisfied.
III. A summary of the data and views setting forth the medical rational and purpose for the drug and its ingredients and the scientific basis for the conclusion that the drug and its ingredients have been proven safe and/or effective for the intended use. If there is an absence of controlled studies in the material submitted or the requirements of any element of § 300.50 or § 314.126 have not been fully met, the fact(s) is required to be stated clearly and a waiver obtained under § 314.126 is required to be submitted.
IV. A statement signed by the person responsible for such submission that it includes in full (or incorporates by references as permitted in § 314.200(c)(2)) all studies and information specified in § 314.200(d). (Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001.)

(7) *Separation of functions.* Separation of functions commences upon receipt of a request for hearing. The Director of the National Center for Drugs and Biologics will prepare an analysis of the request and a proposed order ruling on the matter. The analysis and proposed order, the request for hearing, and any proposed order denying a hearing and response under paragraph (b)(8) (ii) or (iii) of this section will be submitted to the Office of the Commissioner for review and decision. When the National Center for Drugs and Biologics recommends denial of a hearing on all issues on which a hearing is requested, no representative of the National Center will participate or advise in the review and decision by the Commissioner. When the National Center for Drugs and Biologics recommends that a hearing be granted on one or more issues on which a hearing is requested, separation of functions terminates as to those issues, and representatives of the National Center may participate or advise in the review and decision by the Commissioner on those issues. The Commissioner may modify the text of the issues, but may not deny a hearing on those issues. Separation of functions continues with respect to issues on which the National Center for Drugs and Biologics has recommended denial of a hearing. The Commissioner will neither evaluate nor rule on the National Center's recommendation on such issues and such issues will not be included in the notice of hearing. Participants in the hearing may make a motion to the presiding officer for the inclusion of any such issue in the hearing. The ruling on such a motion is subject to review in accordance with § 12.35(b). Failure to so move constitutes a waiver of the right to a hearing on such an issue. Separation of functions on all issues resumes upon issuance of a notice of hearing. The Office of the General Counsel, Department of Health and Human Services, will observe the same separation of functions.

(8) *Summary judgment.* A person who requests a hearing may not rely upon allegations or denials but is required to set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing with respect to the particular drug product(s) specified in the request for hearing.

(i) Where a specific notice of opportunity for hearing (as defined in paragraph (b)(1) of this section) is used, the Commissioner will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing, if it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the refusal to approve the application or the withdrawal of approval of the application; for example, no adequate and well-controlled clinical investigations meeting each of the precise elements of § 314.126 and, for a combination drug product, § 300.50, showing effectiveness have been identified. Any order entering summary judgment is required to set forth the Commissioner's findings and conclusions in detail and is required to specify why each study submitted fails to meet the requirements of the statute and regulations or why the request for hearing does not raise a genuine and substantial issue of fact.

(ii) When following a general notice of opportunity for hearing (as defined in paragraph (b)(1) of this section) the Director of the National Center for Drugs and Biologics concludes that summary judgment against the person(s) requesting a hearing should be considered, the Director will serve upon the person requesting a hearing by registered mail a proposed order denying a hearing. This person has 60 days after receipt of the proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(iii) When following a general or specific notice of opportunity for hearing the person(s) requesting a hearing submits data or information of a type required by the statute and regulations, and the Director of the National Center for Drugs and Biologics concludes that summary judgment against the person(s) should be considered, the Director may serve upon the person(s) by registered mail a proposed order denying a hearing. The person has 60 days after receipt of the proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(iv) If review of the data, information, and analyses submitted show that the basis for the order is not valid, for example, that substantial evidence of effectiveness exists, the Commissioner will enter summary judgment for the person(s) requesting the hearing, and revoke the order. If a hearing is not requested, the order will become effective as published.

(v) If the Commissioner grants a hearing, it will be conducted under Part 12.

(vi) The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be in the public interest.

(9) The repeal of any regulation constitutes a revocation of all outstanding certificates based upon such regulation. However, the Commissioner may, in his discretion, defer or stay such action pending a ruling on any related request for a hearing or pending any related hearing or other administrative or judicial proceeding.

(c) Whenever any interested person submits an application or request under section 507 of the act and Part 314 and FDA sends the person an approvable letter under § 314.110 or a not approvable letter under § 314.120, the person may file a petition proposing the issuance, amendment, or repeal of the regulation under the provisions of section 507(f) of the act and Part 10. The Commissioner shall cause the regulation proposed in the petition to be published in the **Federal Register** within 60 days of the receipt of an acceptable petition and further proceedings shall be in accord with the provisions of sections 507(f) and 701(f) and (g) of the the act and Part 10.

(d)(1) No regulation providing for the certrification of any batch of any drug composed wholly or in part of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivation thereof, intended for use by man shall be promulgated and no existing regulation will be continued in effect unless it is established by substantial evidence that the drug will have such characteristics of identity, strength, quality, and purity necessary to adequately ensure safety and efficacy of use. "Substantial evidence" has been defined by Congress to mean "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific traning and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effectiveness it purports and is represented to have under the conditions prescribed, recommended, or suggested in the labeling thereof." This definition is made applicable to a number of antibiotic drugs by section 507(h) of the act and it is the test of efficacy that will be applied in promulgating, amending, or repealing regulations for the certification of all antibiotics under section 507(a) of the act as well.

(2) The scientific essentials of an adequate and well-controlled clinical investigation are described in § 314.126.

(e) No regulation providing for the certification of an antibiotic drug for human use shall be issued or amended unless each nonclinical laboratory study on which the issuance or amendment of the regulation is based was conducted in compliance with the good laboratory practice regulations as set forth in Part 58, or, if any such study has not been conducted in compliance with such regulations, differences between the practices used in conducting the study and the good laboratory practice regulations shall be described in detial.

(f) [Reserved]

(g) No regulation providing for the certification of an antibiotic drug for human use shall be issued or amended unless each clinical investigation involving human subjects on which the issuance or amendment of the regulation is based was conducted in compliance with the requirements for institutional review set forth in Part 56 or was not subject to those requirements in accordance with §§ 56.104 or 56.105, and for informed consent set forth in Part 50.

Subpart F—Miscellaneous Provisions

§ 314.410 Imports and exports of new drugs and antibiotics.

(a) *Imports.* (1) A new drug or an antibiotic may be imported into the United States if it is the subject of either an approved application under this part, and, in the case of an antibiotic, it is certified or released, or it complies with the regulations pertaining to investigational new drugs under Part 312, and it complies with the general regulations pertaining to imports under Subpart E of Part 1.

(2) A drug substance intended for use in the manufacture, processing, or repacking of a new drug may be imported into the United States if it complies with § 201.122 pertaining to shipments of drug substances in domestic commerce.

(3) An individual may bring into the United States a reasonable quantity of an unapproved new drug product or an uncertified antibiotic drug product (except a substance controlled under the Controlled Substances Act (21 U.S.C. 801)) that is intended only for personal use.

(b) *Exports.* (1) A new drug or an antibiotic may be exported if it is the subject of an approved application under this part, and, in the case of an antibiotic, it is certified or released, or it complies with the regulations pertaining to investigational new drugs under Part 312.

(2) A drug substance may be exported if it is used in the manufacture of a drug product approved under this part and the drug substance intended for export meets the specifications of, and is shipped with a copy of the labeling required for, an approved drug product.

(3) An antibiotic drug product or drug substance that is subject to certification under section 507 of the act, but which has not been certified or released, may be exported under section 801(d) of the act if it meets the following conditions:

(i) It meets the specifications of the foreign purchaser;

(ii) It is not in conflict with the laws of the country to which it is intended for export;

(iii) It is labeled on the outside of the shipping package that it is intended for export; and

(iv) It is not sold or offered for sale in the United States.

§ 314.420 Drug master files.

(a) A drug master file is a submission of information to the Food and Drug Administration by a person (the drug master file holder) who intends it to be used for one of the following purposes: to permit the holder to incorporate the information by reference when the holder submits an investigational new drug application under Part 312 or submits an application or an abbreviated application or an amendment or supplement to them or an application development file under this

part, or to permit the holder to authorize other persons to rely on the information to support a submission to FDA without the holder having to disclose the information to the person. FDA ordinarily neither independently reviews drug master files not approves or disapproves submissions to a drug master file. Instead, the agency customarily reviews the information only in the context of an application under Part 312 or this part. A drug master file may contain information of the kind required for any submission to the agency, including information about the following:

(1) Facilities and operating procedures used to manufacture a drug substance or drug product;

(2) Drug substances or components used in the manufacture of a drug product, or drug products;

(3) Packaging materials;

(4) Components used in drug products, including colors, flavors, and essences; or

(5) preclinical or clinical data.

(b) An investigational new drug application or an application, abbreviated application, application development file, amendment, or supplement may incorporate by reference all or part of the contents of any drug master file in support of the submission if the holder authorizes the incorporation in writing. Each incorporation by reference is required to describe the incorporated material by name, reference number, volume, and page number of the drug master file.

(c) A drug master file is required to be submitted in three copies. The agency has prepared under § 10.90(b) a guideline that provides information about how to prepare a well-organized drug master file. If the drug master file holder adds, changes, or deletes any information in the file, the holder shall notify in writing, each person authorized to reference that information. Any addition, change, or deletion of information in a drug master file (except the list required under paragraph (d) of this section) is required to be submitted in three copies and to describe by name, reference number, volume, and page number the information affected in the drug master file.

(d) The drug master file is required to contain a complete list of each person currently authorized to incorporate by reference any information in the file, identifying by name, reference number, volume, and page number the information that each person is authorized to incorporate. If the holder restricts the authorization to particular drug products, the list is required to include the name of each drug product and the application number, if known, to which the authorization applies.

(e) The public availability of data and information in a drug master file, including the availability of data and information in the file to a person authorized to reference the file, is determined under Part 20 and § 314.430.

§ 314.430 Availability for public disclosure of data and information in an application.

(a) The Food and Drug Administration will determine the public availability of any part of an application under this section and Part 20. For purposes of this section, the application includes all data and information submitted with or incorporated by reference in the application, including investigational new drug applications, drug master files under § 314.420, supplements submitted under § 314.70, reports under § 314.80, and other submissions. For purposes of this section, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests of the drug for identity, stability, purity, potency, and bioavailability.

(b) FDA will not publicly disclosure the existence of an application before an approvable letter is sent to the applicant under § 314.110, unless the existence of the application has been previously publicly disclosed or acknowledged. The National Center for Drugs and Biologics will maintain and make available for public disclosure a list of applications for which the agency has sent an approvable letter to the applicant.

(c) If the existence of an unapproved application has not been publicly disclosed or acknowledged, no data or information in the application is available for public disclosure.

(d) If the existence of an application has been publicly disclosed or acknowledged before the agency sends an approval letter to the applicant, no data or information contained in the application is available for public disclosure before the agency sends an approval letter, but the Commissioner may, in his or her discretion, disclose a summary of selected portions of the safety and effectiveness data that are appropriate for public consideration of a specific pending issue, for example, for consideration of an issue at an open session of an FDA advisory committee.

(e) After FDA sends an approval letter to the applicant, the following data and information in the application are immediately available for public disclosure, unless the applicant shows that extraordinary circumstances exist. A list of approved applications is publicly available from the National Technical Information Service, Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22151. The list is updated monthly.

(1) If the application applies to an antibiotic, all safety and effectiveness data.

(2) If the application applies to a new drug, all safety and effectiveness data previously disclosed to the public as set forth in § 20.81 and a summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the application. The summaries do not constitute the full reports of investigations under section 505(b)(1) of the act (21 U.S.C. 355(b)(1)) on which the safety or effectiveness of the drug may be approved. The summaries consist of the following:

(i) For an application approved before July 1, 1975, internal agency records that describe safety and effectiveness data and information, for example, a summary of the basis for approval or internal reviews of the data and information, after deletion of the following:

(*a*) Names and any information that would identify patients or test subjects or investigators.

(*b*) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(ii) For an application approved on or after July 1, 1975, a Summary Basis of Approval (SBA) document that contains a summary of the safety and effectiveness data and information evaluated by FDA during the drug approval process. The SBA is prepared in one of the following ways:

(*a*) Before approval of the application, the applicant may prepare a draft SBA which the National Center for Drugs and Biologics will review and may revise. The draft may be submitted with the application or as an amendment.

(*b*) The National Center for Drugs and Biologics may prepare the SBA.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information after deletion of the following:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as set forth in § 20.81.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established for trade secrets and confidential commerical information in § 20.61.

(7) All correspondence and written summaries of oral discussions between FDA and the applicant relating to the application, under the provisions of Part 20.

(8) All records showing the testing of and action on a particular lot of a certifiable antibiotic by FDA.

(f) All safety and effectiveness data and information on a new drug not previously disclosed to the public are available for public disclosure, if any one of the following events occurs and the data and information no longer represent trade secret or confidential commercial or financial information under § 20.61:

(1) The application has been abandoned and no further work is being undertaken with respect to it.

(2) A final determination is made that the application is not approvable, and all legal appeals have been exhausted.

(3) Approval of the application is withdrawn and, if contested, all legal appeals have been exhausted.

(4) A final determination has been made that the drug is not a new drug.

(5) A final determination has been made that the drug may be marketed without submission of data and information on safety, or effectiveness, or both.

(g) The following data and information in an application are not available for public disclosure unless they have been previously disclosed to the public as set forth in § 20.81 or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information under § 20.61:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales distribution, and similar data and information, except that any compilation of that data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(h) The compilations of information specified in § 20.117 are available for public disclosure.

§ 314.440 Addresses for applications.

(a) Applicants shall send applications and other correspondence relating to matters covered by this part, except for products listed in paragraph (b) of this section, to the National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and directed to the appropriate office identified below:

(1) An application under § 314.50 submitted for filing should be directed to the Product Coordination Staff (HFN-105). Applicants may obtain folders for binding applications from that office. After FDA has filed the application, the agency will inform the applicant which one of the divisions in the Office of New Drug Evaluation is responsible for the application. Amendments, supplements, resubmissions, requests for waivers, and other correspondence about an application that has been filed should be directed to the appropriate division.

(2) An abbreviated application under § 314.55, and amendments, supplements, resubmissions, and other correspondence about an abbreviated application and application development files under § 314.57 should be directed to the Division of Generic Drug Monographs (HFN-530). Applicants may obtain folders for binding abbreviated applications from that office.

(3) A request for an opportunity for a hearing under § 314.110 or §314.120 on the question of whether there are grounds for denying approval of an application, except an application under paragraph (b) of this section, should be directed to the Assistant Director for Regulatory Affairs (HFN-7).

(b) Applicants shall send applications and other correspondence relating to matters covered by this part for the drug products listed below to the Office of Biologics (HFN-820), National Center for Drugs and Biologics, Food and Drug Administration, 880 Rockville Pike, Bethesda, MD 20205, except applicants shall send a request for an opportunity for a hearing under § 314.110 or § 314.120 on the question of whether these are grounds for denying approval of an application to the Director, Office of Biologics (HFN-800), at the same address.

(1) Ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood componsents.

(2) Urokinase products.

(3) Plasma volume expanders and hydroxyethyl starch for leukapheresis.

§ 314.445 Guidelines.

(a) The Food and Drug Administration prepares guidelines under § 10.90(b) to help persons comply with requirements in this part.

(b) The National Center for Drugs and Biologics will maintain and make publicly available a list of guidelines that apply to the National Center's regulations. The list states how a person can obtain a copy of each guideline. A request for a copy of the list should be directed to the Assistant Director for Regulatory Affairs (HFN-7), National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

PART 430—ANTIBIOTIC DRUGS: GENERAL

4. Part 430 is amended:

a. By revising Subpart B to read as follows:

Subpart B—Antibiotic Drugs Affected by the Drug Amendments of 1962

§ 430.10 Certification or release of antibiotic drugs affected by the drug amendments of 1962.

(a) Before the 1962 amendments to it, the Federal Food, Drug, and Cosmetic Act only permitted the Food and Drug Administration to provide for the certification of batches of antibiotic drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative of them. FDA certified those drugs under regulations promulgated on the basis of scientific proof of the drugs' safety and effectiveness. Most drugs containing an antibiotic other than one of those listed were subject to the new drug provisions of the act, which required that an applicant show that the drug was safe and obtain FDA approval of a new drug application before marketing it. An affirmative showing of effectiveness was not then required to obtain approval. Some antibiotic drugs that were not subject to certification, however, were also not subject to the new drug provisions of the act under informal FDA opinions that the drug was "not a new drug" or "no longer a new drug." FDA revoked those opinions under § 310.100 of this chapter.

(b) The 1962 amendments amended section 507 of the act to require the certification, release without certification, or exemption from certification, of all antibiotic drugs on the basis of scientific proof of safety and effectiveness. The amendments provided that FDA implement them for antibiotic drugs that were marketed on April 30, 1963 and were not subject to

the certification provisions on that date. FDA is implementing the amendments with respect to antibiotic drugs formerly subject to the new drug provisions of the act through its Drug Efficacy Study Implementation (DESI) program under which the agency is evaluating those antibiotic drugs for efficacy. Until FDA completes that evaluation it will permit continued marketing of those antibiotic drugs under paragraph (c) of this section. The agency is also implementing the 1962 amendments with respect to antibiotic drugs formerly not subject to either the certification or new drug provisions of the act and the agency is evaluating those antibiotic drugs for both safety and efficacy. Until FDA completes that evaluation, it will permit continued marketing of those antibiotic drugs under paragraph (d) of this section.

(c) Unless exempted from certification, FDA will certify or release antibiotic drugs which on April 30, 1963 were the subject of an approved new drug application under section 505 of the act, under regulations providing for certification of the drugs. Although the initial regulation for each of these drugs established under section 507(h) of the act was not conditioned upon an affirmative finding of the effectiveness of the drug, FDA is proceeding under its DESI program to amend or repeal those regulations to provide for certification of those drugs only if they had been shown to be both safe and effective.

(d) Unless exempted from certification, FDA will release without certification an antibiotic drug that was marketed on April 30, 1963, but not subject to certification, and not subject to an approved new drug application on that date, unless FDA has made a determination that the drug has not been shown to be safe or lacks substantial evidence of effectiveness under the Drug Efficacy Study. FDA is proceeding under its DESI program to establish regulations under section 507 to provide for certification of those drugs only if they have been shown to be safe and effective.

§ 430.20 [Removed]

b. By removing § 430.20 *Procedure for the issuance, amendment, or repeal of regulations.*

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

5. Part 431 is amended:

§ 431.1 [Amended]

a. In § 431.1 *Request for certification, check tests and assays, and working standards; information and samples required* by removing and reserving paragraph (b).

§ 431.16 [Removed]

b. By removing §431.16 *Changes in facilities or controls; changes in mailing or promotionsl pieces.*

c. By revising §431.17, to read as follows:

§ 431.17 Request to provide for certification of an antibiotic drug.

A request under section 507 of the Federal Food, Drug, and Cosmetic Act to provide for certification of an antibiotic drug is required to comply with the procedures and meet the requirements applicable to the submission to the Food an Drug Administration and review by the agency of applications and abbreviated applications, and amendments and supplements to them, under Part 314 of this chapter.

§ 431.50 [Amended]

d. In §431.50 *Forms for certification or exemption of antibiotic drugs* by removing the entries for Form 5 and Form 6.

§ 431.60 [Removed]

e. By removing § 431.60 *Records and reports concerning experience with antibiotic drugs for human use for which a certificate or release has been issued.*

§ 431.70 [Amended]

f. In § 431.70 *Confidentiality of data and information in an investigational new drug notice for an antibiotic drug,* paragraphs (b) and (c) are amended by changing the references "§ 431.71" to "§ 314.430 of this chapter".

§ 431.71 [Removed]

g. By removing § 431.71 *Confidentiality of data and information in an antibiotic drug file.*

PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

§ 433.25 [Removed]

6. Part 433 is amended by removing § 433.25 *Antibiotic drugs intended for export.*

Interested persons may, on or before December 20, 1982 submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, 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.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: June 23, 1982

Richard S. Schweiker,

Secretary of Health and Human Services.

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Tuesday
October 19, 1982

Part III

Environmental Protection Agency

Water Quality Planning and Management; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 35 and 130

[WH-FRL 2143-5]

Water Quality Planning and Management

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: As part of the Administration's regulatory reform effort, the Environmental Protection Agency (EPA) intends to revise the regulation governing the water quality planning and management activities outlined in sections 106, 205(g), 205(j), 208, 303 and 305 of the Clean Water Act. These are the activities that set State goals and standards and which lead to regulatory and construction programs that will meet the goals. In response to criticisms that the existing regulation and resultant planning efforts are too complex and broad, EPA's intent is to simplify and shorten the regulation and to provide States and local governments with increased flexibility to operate their programs and to assure that the basic requirements of the Clean Water Act are satisfied.

DATE: Comments must be submitted on or before November 18, 1982.

ADDRESS: Comments may be mailed to Carl Myers, Environmental Protection Agency, WH-554, Room 811E, Washington, D.C. 20460. Today's proposal may be obtained by writing Mr. Myers at the above address or telephoning him at (202) 382-7080. Comments will be available for public inspection and copying in the Environmental Protection Agency, Room 811E, 401 M Street, S.W., Washington, D.C. 20460, (202) 382-7080.

FOR FURTHER INFORMATION CONTACT: Carl Myers (202) 382-7080.

SUPPLEMENTARY INFORMATION: Today's action proposes to streamline and consolidate the 40 CFR Part 35, Subpart G regulation, currently called Grants for Water Quality Planning, Management and Implementation. It emphasizes the basic planning and management requirements of the Clean Water Act (CWA) while minimizing guidance on meeting these requirements. We have developed this regulation concurrently with the following related regulations: Part 35, Subpart A, "Financial Assistance for Continuing Environmental Programs"; Part 35, Subpart I, "Construction Grants"; Part 35, Subpart J, "Construction Management Assistance Grants (205(g))"; and Part 131, "Water Quality Standards."

We are aware of various problems with the existing program, including the criticism that existing regulations and resultant planning efforts are sometimes too complex and too broad. These criticisms are reflected in duplicative reporting requirements and Water Quality Management (WQM) plans which are not always focused on priority problems.

In revising the existing regulation, EPA's intent is to simplify procedures and requirements to provide States and local governments with more flexibility to define and operate their programs, while assuring that the basic requirements of the CWA are met. The basic thrust of the CWA is to manage water quality, and our revisions assure that management activities are prescribed by those directly responsible for implementing most of the needed control programs, i.e., State and local governments.

Approach: Sections 106, 205(g), 205(j), 208, 303 and 305 of the CWA set out the planning and management activities to be undertaken by States and local governments to establish their water quality goals and standards and to develop programs which will meet those goals. This proposal addresses these activities including: (1) The setting and revision of standards for all water bodies (this process is addressed in more detail in Part 131, Water Quality Standards). Standards, which consist of designated uses and water quality criteria to meet the uses, are the goal or basis for all other activities. (2) The development of water monitoring activities. Monitoring provides the data upon which water quality based decisions are made and evaluates progress in meeting State goals and the effectiveness of water quality planning and management efforts. (3) The calculation of total maximum daily loads and waste load allocations. These calculations are necessary for each water body that cannot meet water quality standards after point sources are controlled by national municipal and industrial technology based controls. (4) The development of WQM plans. The plan is certified by the Governor and approved by EPA and lists the standards and prescribes the regulatory and construction activities necessary to meet the standards. The plan guides the implementation of water pollution control programs. (5) The establishment of a Continuing Planning Process. The CPP document outlines the process by which the State will undertake each of these planning and management activities. (6) The submission of 305(b) reports. These reports document the status of State water quality programs.

Much has been accomplished during the decade that these activities were undertaken. With the completion of effluent guidelines and the application of technology-based controls, EPA is now emphasizing the implementation of the water quality based approach to pollution control. The water quality based approach will allow States to focus on their priority water bodies and, when necessary, to provide adequate water quality protection beyond what will be achieved through technology-based control. In implementing a water quality approach the following basic questions must be considered:

1. *What is the use to be protected?* How is it characterized in physical, chemical and biological terms, and in terms of its social and economic value?

2. *To what extent does pollution contribute to the impairment of the use?* Which pollutants are significant in terms of impairing the use? To what extent does water quality affect the use relative to other non-water quality factors such as flow, and the physical habitat? What level of in-stream water quality must be maintained to provide adequate protection for the use, given the characteristics of the use?

3. *What is the level of point source pollution control necessary to restore or enhance the use?* What are the pollutants of significance that are present in the point source discharges? What is the contribution of point source discharges relative to background levels (pollutants in the stream from upstream sources) and relative to nonpoint sources generated in the water body? What is the allowable pollution load from point sources under specified in-stream flow conditions in the water body and how does that translate to permit requirements? What is the plan?

4. *What is the level of nonpoint source pollution control necessary to restore or enhance the use?* What are the nonpoint source pollutants of significance that are present? What is the contribution of nonpoint sources relative to background levels and point sources? Does the occurrence of nonpoint sources contribute to the impairment of the use? Is it significant? What is the "feasible" level of control of nonpoint sources? What is the plan?

States should focus on analyzing and answering these four questions for priority water bodies. The degree of attention and analysis given to these questions should depend on the resource value of the particular water body and

the complexity of its physical, chemical, and biological characteristics.

Answering these questions is critical to defining what is meant by the term "water quality problem" and to developing plans to resolve problems. Experience indicates that defining the problem is neither an easy process nor, in all cases, a simple scientific exercise. Rather, problem definition requires debate and consensus building among all interested and affected organizations and individuals.

Today's proposal revises the current regulation to:

- Simplify regulatory language and eliminate unnecessary requirements;
- Incorporate new section 205(j) requirements stemming from the Municipal Wastewater Treatment Construction Grant Amendments of 1981;
- Shift emphasis from initial water quality planning and WOM plan adoption to a focus on continuing planning priorities and plan updates;
- Re-emphasize the importance of establishing priority segment lists and the use of the section 305(b) report; and
- Encourage coordination of all program activities funded with sections 106, 205(j) and non-construction management 205(g) while not repeating the grant and administrative requirements contained in the "Financial Assistance for Continuing Environmental Programs" regulation.

The specific features of this proposal are as follows:

1. *Water Quality Standards (WQS).* Water quality standards are the water quality goals for waters of each State. All water quality planning and management activities should be targeted at attaining and protecting these goals. We are also proposing to revise the water quality standards regulation, redesignated as Part 131, to stress the need for each State to make sure its WQS are attainable and to re-evaluate WQS on high priority stream segments. [Additional information on new policy directions on WQS will be available in the preamble and body of proposed revisions to Part 131.]

2. *Water Monitoring.* Water quality monitoring information (including chemical, physical and biological data) enables States and EPA to assure that environmental control decisions and priorities are based on sound scientific data.

Experience in past water quality planning indicates that reasonable water-quality based controls require site-specific information, usually including information on biological conditions.

EPA encourages States to improve the quality of information available for water quality decisions and encourages the active involvement of State, local governments and discharges in developing cooperative monitoring efforts. Monitoring data will provide information for adopting site-specific water quality standards; developing abatement and control requirements, including wasteload allocations/total maximum daily loads (WLAs/TMDLs); measuring water quality trends at the local, State and national level; and assessing program performance.

EPA will work with States to assure that they have strategies to make the best use of monitoring resources and to collect the information needed for developing realistic site-specific controls. Since much of the data generated by the monitoring program is needed to meet the requirements of sections 303(d) and 303(e) of the Act, EPA believes that State updates of the CPP under section 303(e) should contain a description of the State's process for development of the water monitoring program. This description should explain the State's approach for focusing monitoring resources on priority waters to provide data upon which regulatory decisions are based and for reviewing and approving local monitoring efforts performed as a part of the WLA/TMDL planning process. The State's annual monitoring program activities should be discussed in the annual work program under section 106.

3. *Total Maximum Daily loads (Section 303(d) and (e)).* Section 303(d) of the CWA requires each State to develop TMDLs for each water body that cannot meet water quality standards after point sources are controlled to prescribed technology-based levels. Once a TMDL has been completed, a WLA forms the basis for permit limitations for individual dischargers. This process assigns margins of safety, distributes treatment burdens and considers nonpoint source controls. Total maximum daily loads may be established using a pollutant by pollutant approach, e.g., using mathematical modeling. A bio-monitoring approach using bio-assays or bio-surveys may also be utilized. In many cases, EPA feels that the biological approach is needed, in addition to chemical monitoring. EPA has detemined that under proper technical conditions, all pollutants are suitable for the calculation of TMDLs (see 43 FR 60662, December 28, 1978).

EPA expects States to assign priorities under section 303(d) to water bodies that need new or updated TMDLs and to develop TMDLs and WLAs according to CWA requirements and individual water quality goals. Such priorities must consider uses or waters and the severity of the pollution. Priorities could be influenced by such factors as the need to refine NPDES permit limits and the need to make construction grant decisions.

In the past, the affected public often has not had an opportunity to become involved in the early stages of water quality-based effluent limit development and discussions of draft effluent limitations have often been unnecessarily adversarial in nature.

Involving the regulated community in the WLA/TMDL process will ensure that States have access to additional existing data and, in addition, allows cooperative data collection and analysis efforts, leading to more data and better decisions. An open process attracts relevant information and promotes review of the technical background and policy assumptions made. the State or areawide agency responsible for the planning may experience substantial cost savings since its is often in the interest of the regulated parties to provide data. Also, open public review of the process will lead to a wider appreciation of its validity.

The paramount advantage, perhaps, is that by placing the debate in the planning context, the assumptions on which WLAs/TMDLs are developed can be examind and the public can examine the costs and other consequences of meeting the original goals. For example, is the use for which the water body is protected worth the cost that will be requried to attain the use? EPA expects that conducting TMDLs and WLAs in the planning process will result in fewer legal challenges than calculations completed without public debate.

It is recognized that some States may need to phase in the involvement of the affected discharges and the public in developing WLAs/ TMDLs. EPA strongly encourages States to fully implement the WLA/TMDL public planning process for all water quality limited waters. If this process cannot be carried out for all WLAs/TMDLs, States should attempt to implement it for major regulatory decisions.

At a minimum, however, all members of the regulated community discharging on a stream segment should be provided with an opportunity to meet with the regulatory agency to discuss the basis of any proposed water quality-based effluent limitation well in advance of any final permit issuance. Such information should include a description of the techniques used in developing the WLA/TMDL, the assumptions and

estimates involved, and the nature of the supporting monitoring data.

EPA does not intend to review every TMDL calculation for every stream for every pollutant. EPA is considering several alternative methods for meeting the statutory requirement of EPA review and approval of TMDLs including closer scrutiny of each State's CPP and is seeking comment from all affected parties as to the proper approach. The following is a range of proposed options:

1. If a State has described its approach for conducting TMDLs and WLAs in its CPP and EPA has approved the process, then EPA would generally not review all TMDLs. Instead, the agency would examine a sample a of WLAs/TMDLs to evaluate the success of the approved process. EPA may review certain critical individual WLAs/TMDLs, e.g., those for major construction grants projects.

2. Each State would outline its TMDL and WLA process in the CPP and EPA would review the individual TMDLs and WLAs as they accompany permit decisions and construction grant decisions.

3. EPA would review all TMDLs and WLAs prior to use in permits and construction grants.

EPA requests comments on these options.

Under section 303(e) of the Act, States are required to submit to EPA a CPP which will result in water quality management plans which include TMDLs. EPA believes that the CPP is the most appropriate place for a State to describe its approach for developing TMDLs and WLAs. This description must include the steps prior to the actual calculation, i.e., the process for identifying water quality limited waters and setting priorities for these waters. The CPP must also describe the public process and how regulated parties will be informed and involved. The technical approach for completing TMDLs and WLAs described in the CPP should include: (a) Monitoring program requirements, (b) a list of the pollutants to be regulated and (c) calculation methods.

4. *Water Quality Management (WQM) Plans.* WQM plans satisfy the water quality planning requirements of sections 208 and 303 of the CWA. These plans are essential in the documentation of water quality planning and management activities that will lead to the attainment and maintenance of State water quality standards. EPA will continue to emphasize the requirement that decisions regarding NPDES permits and construction grants be consistent with WQM plans.

5. *The Continuing Planning Process (CPP).* Section 303(e) requires each State to have a CPP. The CPP describes the processses the State undertakes in making water quality decisions and must include a process for updating WQM plans. EPA encourages each State to review and update, as necessary, its CPP to meet its needs.

6. *The 305(b) Report.* Section 305(b) requires States to report to EPA on the status of the quality of their waters and the programs underway or needed to attain water quality goals. This report should be based on State and areawide agency activities which identify the nature and location of water quality problems. The latest completed water quality report under section 305(b) of the Act will serve as the State's water quality assessment. As required by section 305(b), this report must include recommendations on current and future program activities needed to address identified problems in priority areas. This proposal affords States the option of utilizing the section 305(b) report as the vehicle for meeting other reporting requirements.

7. *Required Documents.* The Act and this regulation require that States produce specific information (e.g., standards, assessments of water quality conditions, TMDLs) and specified documents (WQM plans, 305(b) reports, annual work programs). The current regulation requires that particular information be contained in each document. In some cases, these requirements overlapped and resulted in duplication and wasted efforts.

The majority of the documents that are required under the CWA need not be submitted every year. The documents articulating a States CPP, the States WQS, the determination of water quality limited segments, TMDLs, WQM plans, and the States monitoring program should be submitted once, and then updated, as necessary. The Act requires that the following be submitted by the States to EPA on a regular basis: a water quality assessment under section 305(b) and 205(j), an annual State program (work program) for the prevention, reduction and elimination of pollution under sections 106 and 205(j) and the annual Governor's certification of the WQM plans. Today's proposal provides States with flexibility to decide the most useful way to organize and present the required informmation. For example, the State's assessment of its water quality conditions and problems is contained in its 305(b) Report. The State may summarize this assessment in its annual work program and WQM plans or may simply reference the document which contains the assessment.

EPA believes that a description of the manner, form, and substance of submittals to EPA should be part of the State's CPP document. The States are requested to provide EPA with such a desciription.

EPA's oversight responsibility with regard to information required in the Act and today's proposal will be to determine that a State has met such requirements and to allow the State to organize this material in the manner it believes to be most useful.

8. *Funding.* Funding to States for water quality planning and management activities is available under sections 106, 205(j) and 205(g) of the Act. Statutory eligibilities are described in the proposed "Financial Assistance for Continuing Environmental Programs," 40 CFR Part 35, Subpart A. Section 106 funding is available for a broad range of activities, while eligibilities under 205(j) and non-construction management eligibilities under 205(g) are more restricted.

Under 40 CFR 35, Subpart A, States are provided with flexibility in organizing their work programs which accompany applications for 106, 205(j), and 205(g) funds. States may write one work program describing their prospective activities and outputs for program elements (e.g., permitting, planning, monitoring) and indicate which funds will be used for which activities.

Alternatively, individual work programs may be submitted with each grant application. An essential feature of either alternative is the coordination of all funding in an effective approach to resolve the State's priority water quality problems.

We will assure that coordination and a clear delineation of uses for all funds are incorporated in the work program so that it can serve as the basic document for purposes of program management, accountability, evaluation of results, and auditing.

9. *Grant-Related Program Requirements; Relationship to Subpart A.* Today's proposal covers all water quality planning and management program activities. Grant related and administrative requirements for all continuing State program grants, including grants under sections 106, 205(j) and 205(g) for non-construction management, are covered in 40 CFR Part 35, Subpart A. The two regulations should be read together to understand the substantive and administrative program requirements.

10. *Future Guidance.* EPA will publish more specific programmatic guidance on 305(b) reports, State monitoring programs, TMDLs, priority segment identification, and use attainability analyses.

While such guidance should be useful in carrying out these regulations, it will not place any additional requirements on State or local governments. They are responsible for meeting the basic CWA requirements, and may use this additional guidance as they see fit.

Comments Received

A draft of proposed revisions was distributed to EPA Regional Offices, the Association of State and Interstate Water Pollution Control Administrators (ASIWPCA) and the National Association of Regional Councils (NARC) on February 24, 1982. Many commenters were concerned about the lack of procedures for assuring effective participaiton of areawide and local agencies as State work programs for anticipated section 205(j) funds are developed. Finally, many commenters remarked on the provisions concerning TDMLs/WLAs and the section 305(b) report. All of these comments will be considered as the final regulation is developed.

Requests for Comments

Comments are solicited on ways to improve the proposed regulations. All comments will be carefully considered in the development of the final regulation.

Regulation Development

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a regulatory impact analysis. This regulation is not major, because it will not have an adverse effect on the economy of large numbers of individuals or businesses. This proposed rulemaking was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

In accordance with the Paperwork Reduction Act of 1980, EPA has submitted the paperwork requirements of this regulation for OMB approval. The reporting and recordkeeping provisions that are included in this proposed rule will be submitted for approval to the Office of Management and Budget under section 3504(h) of the Paperwork Reduction Act. The final rule will include an explanation of how reporting or recordkeeping provisions reflect comments from OMB and the public.

Regulatory Flexibility Act

EPA has determined that the proposed revisions to 40 CFR Part 35, Subpart G, if promulgated, will not have a significant impact on a substantial number of small entities. These revisions will reduce administrative burdens on Federal, State and local governments. Since EPA's water quality planning and management program deals primarily with State water quality agencies, it does not have a direct effect on small entities.

List of Subjects

Part 35

Air pollution control, grant programs—environmental protection, Indians, Pesticids and pests, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

Part 130

Water pollution control, Environmental Protection.

Dated: October 8, 1982.

Anne M. Gorsuch,

Administrator.

For the reasons set out in the preamble, Part 35 of Chapter I of Title 40 of the Code of Federal regulations is proposed to be amended as follows:

PART 35—[AMENDED]

1. The authority cite for Part 35 reads as follows:

Authority: Sec. 501(a), Clean Water Act, as amended. 33 U.S.C. 1251 et seq.

§§ 35.1500, 35.1502, 35.1503, 35.1505, 35.1507, 35.1509—35.1509-3, 35.1511—35.1511-2, 35.1519—35.1519-3, 35.1521—35.1521-6, 35.1523—35.1523-6, 35.1525, 35.1527, 35.1529, 35.1531—35.1531-3 and 35.1533—35.1533-4 [Removed]

2. Part 35 is amended by removing 35.1500, 35.1502, 35.1503, 35.1505, 35.1507, 35.1509—35.1509-3, 35.1511—35.1511-2, 35.1519—35.1519-3, 35.1521—35.1521-6, 35.1523—35.1523-6, 35.1525, 35.1527, 35.1529, 35.1531—35.1531-3 and 35.1533—35.1533-4.

3. 40 CFR Chapter I is further amended by adding a new Part 130, reading as follows:

PART 130—WATER QUALITY PLANNING AND MANAGEMENT

Sec.
130.0 Purpose and scope.
130.1 Applicability.
130.2 Definitions.
130.3 Water quality standards.
130.4 Water quality monitoring.
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Authority: 33 U.S.C. 1251 *et seq.*

§ 130.0 Purpose and scope.

This subpart establishes policies and program requirements for water quality planning and management under the Clean Water Act (CWA) for sections 106, 205(j), 208, 303 and 305. This subpart supplements the general grant regulations set forth in Part 30 of this chapter and the specific grant administration requirements set forth in 40 CFR Part 35, Subpart A of this chapter for funding under sections 106, 205(j) and 205(g).

§ 130.1 Applicability.

(a) This subpart applies to all State, interstate, areawide and local CWA water quality planning and management activities.

(b) This subpart applies to all updates and continuing certifications for approved Water Quality Management (WQM) plans developed under sections 208 and 303 of the Act.

(c) This subpart applies to all planning and management activities undertaken after adoption of the final regulation.

(d) Planning and management activities are governed by the requirements of the regulations in effect at the time of the last grant award.

§ 130.2 Definitions.

The Act—The Clean Water Act, as amended, 33 U.S.C. 1251 *et seq.*

Areawide agency—An agency designated under section 208 of the Act, which has responsibilities for WQM planning within a specified area of a State.

Best Management Practice (BMP)—Methods, measures or practices to prevent or reduce water pollution from nonpoint sources, including structural and nonstructural controls and operation and maintenance procedures.

Designated management agency (DMA)—An agency identified by a WQM plan and designated by the Governor to implement specific control recommendations.

Total maximum daily load (TMDL)—The total loadings of pollutants and natural background for a receiving water which will meet all applicable water quality standards.

Water quality management (WQM) plan—A State or areawide waste treatment management plan developed and updated in accordance with the

provisions of sections 208 and 303 of the act and this regulation.

§ 130.3 Water quality standards.

Water quality standards (WQS) provide the basis for pollution control decisions. They are developed under sections 303(b) and (c) of the Act and consist of designated uses and water quality criteria based upon such uses. States shall review and revise WQS in accordance with part 131 of this chapter and, as appropriate, update their WQM plans to reflect such revisions.

§ 130.4 Water quality monitoring.

(a) In accordance with section 106(e)(1), States must establish and operate appropriate devices, methods and procedures necessary to monitor, and to compile and analyze data on the quality of navigable waters and to the extent practicable, ground waters including biological monitoring. State or interstate agencies shall update this data annually and include it in the report required by section 305(b) of the Act.

(b) The State's water monitoring program includes the use of monitoring data in the identification of water quality limited waters, setting control priorities, and developing water quality standards and total maximum daily loads and wasteload allocations; the State strategy for focusing monitoring resources on priority waters and for reviewing and approving local monitoring efforts performed as a part of the public WLA/TMDL planning process; the performance of compliance monitoring; the assessment of ambient water quality conditions and trends; procedures for data quality assurance/quality control; data handling and storage practices; and the reporting of monitoring results in the report required by section 305(b).

§ 130.5 Total maximum daily loads and individual water quality based effluent limitations.

(a) *General.* The process for identifying water quality limited waters, setting priorities and developing TMDLs and individual water quality based effluent limitations shall be discussed in the State CPP (section 130.7 of this part) which shall also describe how the State will involve the public, affected dischargers, designated areawide agencies and local governments in the process. The technical approach for completing TMDLs and WLAs described in the CPP should include monitoring program requirements, a list of pollutants to be regulated and methods of calculation.

(b) *Identification and priority setting for water quality limited waters.* (1) Where appropriate, each State shall identify those waters within its boundaries for which effluent limitations required by:

(i) Section 301(b) (other than more stringent limitations necessary to meet water quality standards under 301(b)(1)(C)), 306, 307 or other sections of the Act; or

(ii) Existing State or local effluent limitations or other pollution control requirements, e.g., best management practices.

are not stringent enough to implement any water quality standard applicable to such waters. Such waters shall be designated as water quality limited in accordance with the State's adopted CPP. The State shall establish a priority ranking for such waters, taking into account the severity of the pollution and the uses to be made of such waters and shall identify the pollutants causing or expected to cause violations of the water quality standards.

(2) Where appropriate, each State shall identify those waters or parts thereof within its boundaries for which controls on thermal discharges under section 301, or State or local requirements are not stringent enough to meet or attain water quality standards.

(c) *Development of total maximum daily loads and individual water quality based effluent limitations.* (1) Each State shall establish for the waters identified in paragraph (b)(1) of this section, and in accordance with the priority ranking, the total maximum daily load. Such load shall be established at a level necessary to attain and maintain the applicable use classification defined in the water quality standards for these water quality limited segments and shall include a margin of safety which takes into account any lack of knowledge concerning the relationship between effluent limitations and water quality.

(i) Total maximum daily loads may be established using a pollutant by pollutant approach. A bio-monitoring approach may also be utilized. In some cases, use of both techniques may be needed. Site-specific information should be used wherever possible.

(ii) Total maximum daily loads will be established for all pollutants preventing or expected to prevent attainment of water quality standards as identified pursuant to paragraph (b)(1) of this section. TMDLs must be established or determined for all pollutants which will be limited in NPDES permits in order to meet the water quality standards, including numerical or narrative criteria. Such calculations shall be subject to public review as defined in the State CPP.

(2) Each State shall estimate for the waters identified in paragraph (b)(2) of this section, the total maximum daily thermal load which cannot be exceeded if the water quality standards are to be achieved. Such estimates shall take into account the normal water temperatures, flow rates, seasonal variations, existing sources of heat input, and the dissipative capacity of the identified waters or parts thereof. Such estimates shall include a calculation of the maximum heat input that can be made into each such part and shall include a margin of safety which takes into account any lack of knowledge concerning the development of thermal water quality criteria for protection and propagation of a balanced, indigenous population of shellfish, fish and wildlife in the identified waters or parts thereof.

(3) In carrying out WQM planning under sections 205(j), 208 and 303(e) of the Act, including establishing and estimating TMDLs under paragraphs (b)(1) and (2) of this section, States shall allocate loads to individual point and nonpoint sources of pollution so as to specify individual effluent limitations needed to achieve the use classifications.

(d) *Submission and EPA approval.* Each State shall submit to the Regional Administrator from time to time for approval a listing of the waters identified and the loads established under paragraphs (b) and (c) of this section. The Regional Administrator shall either approve or disapprove such listing and loadings not later than thirty days after the date of submission. If the Regional Administrator approves such listing and loadings, the State shall incorporate them into its current WQM plan. If the Regional Administrator disapproves such listing and loadings, he shall not later than thirty days after the date of such disapproval, identify such waters in such State and establish such loads for such waters as determined necessary to implement applicable water quality standards. Upon such identification and establishment the State shall incorporate them into its current WQM plan.

(e) For the specific purpose of developing information and as resources allow, each State shall identify all waters within its boundaries which it has not identified under paragraph (b) of this section and estimate for such waters the total maximum daily loads with seasonal variations and margins of safety, for all pollutants for which numeric standards are adopted, or may

be applied in the NPDES permit process, including thermal discharges.

§ 130.6 Water quality management plans.

(a) *General.* WQM planning shall be conducted by States, designated areawide agencies and other local planning organizations as required by sections 205(j), 208 and 303(e) of the Act. WQM planning should concentrate on removing plan conditions and updating plan elements.

(b) *Plan elements.* Sections 205(j), 208 and 303 of the Act specify water quality planning requirements. The following plan elements shall be included in the WQM plan where they are needed to address water quality problems.

(1) TMDLs—TMDLs in accordance with section 303(e)(3)(C) and 303(d) of the Act and § 130.5 of this part.

(2) Effluent limitations—Effluent limitations and schedules of compliance in accordance with section 303(e)(3)(A) of the Act and § 130.5 of this part.

(3) Municipal and industrial waste treatment—Identification of anticipated municipal and industrial waste treatment works, including urban stormwater needs; programs to provide necessary financial arrangements for such works; establishment of construction priorities and schedules for initiation and completion of such treatment works in accordance with section 208(b)(2)(A) and (B) of the Act.

(4) Residual waste—Identification of a process to control the disposition of all residual waste in the area which could affect water quality in accordance with section 208(b)(2)(J) of the Act.

(5) Land disposal—Identification of a process to control the disposal of pollutants on land or in subsurface excavations to protect ground and surface water quality in accordance with section 208(b)(2)(K) of the Act.

(6) Management agencies—Identification of agencies necessary to carry out the plan and provision for adequate authority for intergovernmental cooperation in accordance with sections 208(b)(2)(D) and 303(e) (3)(E) of the Act. Management agencies must demonstrate the legal, institutional, managerial and financial capability to carry out their responsibilities in accordance with section 208(c)(2)(A–I) of the Act.

(7) Financial measures—Identification of measures, including financing necessary to carry out the plan, the time needed to carry out the plan, and the economic, social and environmental impact of carrying out the plan in accordance with section 208(b)(2)(E).

(8) Nonpoint source control—Identification of best management practices to achieve water quality goals for surface and ground water quality problems in accordance with section 208(b)(2)(F–I) and programs to control, to the extent feasible, pollution from nonpoint sources.

(9) Dredged or fill program—Identification and development of programs for the control of dredged or fill material in accordance with section 208(b)(4)(B) of the Act.

(10) Basin plans—Identification of any relationship to applicable basin plans developed under section 209 of the Act.

(c) *Planning on Indian lands.* (1) To the maximum extent feasible, States and areawide agencies shall coordinate with Indian tribal organizations within and adjacent to their planning areas in the development of WQM plans. Where appropriate, the Regional Administrator shall work with the State and Indian tribal organization to ensure development of WQM planning on Indian lands. The WQM planning area must include all lands within the reservation regardless of ownership.

(2) Where the Regional Administrator, after consultation with the State, determines that a State lacks authority to carry out effective WQM planning and implementation on Indian lands, the Regional Administrator may approve a self-designation application by an Indian tribal organization under section 208(a)(4) of the Act if the Indian tribal organization has the authority and capability to undertake effective WQM planning. After receipt of such a designation, the Indian tribal organization becomes responsible for developing and maintaining a WQM plan in accordance with sections 208 and 303 of the Act and section 130.6 of this Part.

(3) Where the Regional Administrator approves a tribal organization under section 208(a)(4), he or she may enter into a cooperative agreement with the Indian organization for WQM planning on Indian land. The cooperative agreement must identify WQM planning responsibilities for the Federal Government and Indian tribal organizations.

(d) *WQM plan update, certification and approval.* (1) State and/or areawide agency WQM plans shall be updated as needed to reflect changing water quality conditions, new requirements or to remove conditions imposed in prior conditional or partial plan approvals. The State shall ensure that State and areawide WQM plans together include all necessary plan elements and that such plans are consistent with one another.

(2) Annual certification—The Governor shall certify annually by letter to the Regional Administrator that WQM plans are current. This certification shall describe any revisions made during the past year and their expected water quality improvements for specific WQM plan elements.

(3) EPA approval—Updated plans shall be deemed approved by EPA unless the Regional Administrator notifies the State of disapproval within 60 days of receiving the State submittal.

(4) Construction grant and permit decisions must be made in accordance with certified and approved WQM plans as described in § 130.12 (a) and (b) of this part.

§ 130.7 Continuing planning process.

(a) *General.* Each State shall have a continuing planning process (CPP) as described under section 303(e)(3)(A–H) of the Act. The CPP describes the State processes for establishing water quality standards, developing total maximum daily loads and wasteload allocations, developing solutions to control water quality problems, implementing solutions and evaluating whether control programs are improving water quality.

(b) *Content.* The State may determine the format and scope of its continuing planning process. The following items must be addressed in each State continuing planning process:

(1) The processes necessary to determine current water quality conditions, review water quality standards and develop total maximum daily loads. In addressing these issues, States shall include processes for the development, review and adoption of water quality standards; the process for the development of total maximum daily loads and wasteload allocations to meet designated uses in priority water quality limited segments; and the process used in the development of an improved monitoring program.

(2) An identification of State and areawide planning areas.

(3) The process for integrating WQM planning in State planning areas and designated areawide planning areas, and the process for intergovernmental coordination of WQM planning with related federal, State, interstate, and local comprehensive planning activities.

(4) The process for updating WQM plans.

(5) The process for determining the priority of needs for construction of waste treatment works required to meet the applicable requirements of section 301 and 302 of the CWA in accordance with 40 CFR 35.2015.

(6) The process for public participation in the development and revision of planning and management

programs in accordance with section 101(e) of the CWA.

(7) Additional processes deemed appropriate by the State.

(c) *Regional Administrator review.* The Regional Administrator shall review approved State continuing planning processes from time to time to ensure that the planning process is consistent with the Act and this regulation. The Regional Administrator shall not approve any permit program under Title IV of the Act for any State which does not have an approved continuing planning process.

§ 130.8 Water quality report.

(a) Each State shall prepare and submit biennially to the Regional Administrator a water quality report in accordance with section 305(b) of the Act.

(b) Each such report shall include but is not limited to the following:

(1) A description of the water quality of all navigable waters and the extent to which the quality of waters provides for the protection and propagation of a balanced population of shellfish, fish, and wildlife and allows recreational activities in and on the water.

(2) An estimate of the extent to which CWA control programs have improved water quality or will improve water quality for the purposes of section 1 above and recommendation for future activities.

(3) An estimate of the environmental, economic and social costs and benefits needed to achieve the objectives of the Act and an estimate of the date of such achievement.

(4) A description of the nature and extent of nonpoint source pollution and recommendations of programs needed to control each category of nonpoint sources, including an estimate of implementation costs.

(c) The biennial section 305(b) report satisfies the requirement for the annual water quality report under section 205(j). In years when the 305(b) report is not required, the State shall either certify that its current 305(b) report is up to date or supply an annual update.

§ 130.9 Designation and de-designation.

(a) *Designation.* Areawide planning agencies may be designated by the governor in accordance with section 208(a) (2) and (3) of the Act and shall be approved by EPA in accordance with section 208(a)(7) of the Act.

(b) *De-designation.* The Governor may modify or withdraw the planning designation of a designated planning agency if:

(1) The areawide agency requests such cancellation; or

(2) The areawide agency fails to meet its continuing planning requirements as specified in grant agreements, contracts or memoranda of understanding; or

(3) The areawide agency no longer has the resources or the commitment to continue water quality planning activities within the designated boundaries.

(c) *Impact of de-designation.* Once an areawide planning agency's designation has been withdrawn the State agency shall assume direct responsibility for continued WOM planning and oversight of implementation within the area.

(d) *Designated management agencies (DMA).* In accordance with section 208(c)(1) of the Act, management agencies shall be designated by the Governor in consultation with the designated planning agency. EPA shall approve such designations unless the DMA lacks the legal, financial and managerial authority required under section 208(c)(2) of the Act. Designated management agencies shall continue to carry out responsibilities specified in WOM plans. Areawide planning agencies shall monitor DMA activities in their area and recommend necessary plan changes during the annual WOM plan update. Where there is no designated areawide agency, States shall monitor DMA activies and make any necessary changes to the WOM plan during the annual update.

§ 130.10 State submittals to EPA.

(a) The following must be submitted regularly by the States to EPA:

(1) The biennial section 305(b) report and section 205(j) water quality report

(2) The annual State work program(s) under sections 106 and 205(j) of the Act

(3) The annual certification of the WQM plans

(b) The Act also requires that each State initially submit to EPA and revise as necessary the following:

(1) A CPP (303(e))

(2) WQS (303(c))

(3) Identification and a ranking by priority of water quality limited segments (303(d))

(4) TMDLs (303(d))

(5) WQM plans (208, 303(e))

(c) The form and content of required State submittals to EPA may be tailored to reflect the organization and needs of the State, as long as the requirements and purposes of the Act and this regulation are met.

§ 130.11 Planning and management coordination.

(a) State and interstate agencies may apply for grants under section 106 to carry out water quality planning and management activities. State agencies may also apply for grants under sections 205(j) and 205(g) of the Act to support and carry out certain activities. All grant administrative requirements for these funds appear in 40 CFR Parts 30 and 35, Subpart A.

(b) States, areawide agencies, local governments, and designated management agencies are partners in the water pollution control program. To more clearly define roles and responsibilities, States may enter into contractual arrangements or intergovernmental agreements with other agencies concerning the performance of water quality planning and management tasks. Such arrangements should reflect the capabilities of the respective agencies and should efficiently utilize available funds and funding eligibilities to meet Federal requirements commensurate with State and local priorities.

§ 130.12 Coordination with other programs.

(a) *Relationship to the NPDES program.* In accordance with section 208(e) of the Act, no NPDES permit may be issued which is in conflict with an approved WQM plan. Where a State has assumed responsibility for the administration of the permit program under section 402, it shall assure consistency with the WQM plan.

(b) *Relationship to the municipal construction grants program.* In accordance with sections 205(j), 216 and 303(e)(3)(H) of the Act, each State shall develop a system for setting priorities for funding construction of municipal wastewater treatment facilities under section 201 of the Act. The State, or the agency to which the State has delegated WQM planning functions, shall review each facilities plan in its area for consistency with the approved WQM plan. Under section 208(d) of the Act, after a waste treatment management agency has been designated and a WQM plan approved, section 201 construction grant funds may be awarded only to those agencies for construction of treatment works in conformity with the approved WQM plan.

(c) In accordance with section 205(g)(2) of the Act, 205(g) funds not used for construction management may be used to fund program activities under sections 402, 404, and 208(b)(4). These activities should be determined by the State and Regional Administrator.

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday). Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday. This is a voluntary program. (See OFR NOTICE 41 FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
DOT/SECRETARY	USDA/ASCS		DOT/SECRETARY	USDA/ASCS
DOT/COAST GUARD	USDA/FNS		DOT/COAST GUARD	USDA/FNS
DOT/FAA	USDA/REA		DOT/FAA	USDA/REA
DOT/FHWA	USDA/SCS		DOT/FHWA	USDA/SCS
DOT/FRA	MSPB/OPM		DOT/FRA	MSPB/OPM
DOT/MA	LABOR		DOT/MA	LABOR
DOT/NHTSA	HHS/FDA		DOT/NHTSA	HHS/FDA
DOT/RSPA			DOT/RSPA	
DOT/SLSDC			DOT/SLSDC	
DOT/UMTA			DOT/UMTA	

List of Public Laws

Last Listing October 18, 1982

This is a continuing list of public bills from the current session of Congress which have become Federal laws. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (telephone 202-275-3030).

S. 188 / Pub. L. 97-305 To authorize the Secretary of Agriculture to convey certain lands in the Gallatin National Forest, and for other purposes. (Oct. 14, 1982; 96 Stat. 1428) Price: $1.75.

H.R. 6782 / Pub. L. 97-306 Veterans Compensation, Education, and Employment Amendments of 1982. (Oct. 14, 1982; 96 Stat. 1429) Price: $3.00.

S. 2874 / Pub. L. 97-307 To amend the Act of March 16, 1934, as amended, to credit entrance fees for the migratory-bird hunting and conservation stamp contest to the account which pays for the administration of the contest. (Oct. 14, 1982; 96 Stat. 1450) Price: $1.75.

H.R. 4468 / Pub. L. 97-308 To amend chapter 84, section 1752 of title 18, United States Code, to authorize the Secretary of the Treasury to establish zones of protection for certain persons protected by the United States Secret Service. (Oct. 14, 1982; 96 Stat. 1451) Price: $1.75.

H.R. 5930 / Pub. L. 97-309 To extend aviation insurance program for five years. (Oct. 14, 1982; 96 Stat. 1453) Price: $1.75.

H.R. 7293 / Pub. L. 97-310 Wolf Trap Farm Park Act. (Oct. 14, 1982; 96 Stat. 1455) Price: $1.75.

H.R. 6422 / Pub. L. 97-311 To direct the Secretary of Agriculture to release on behalf of the United States a reversionary interest in certain land previously conveyed to the State of Connecticut (Oct. 14, 1982; 96 Stat. 1459) Price: $1.75.

H.R. 2035 / Pub. L. 97-312 To authorize certain employees of the United States Department of Agriculture charged with the enforcement of animal quarantine laws to carry firearms for self-protection and to improve the quality of table grapes for marketing in the United States. (Oct. 14, 1982; 96 Stat. 1461) Price: $1.75.

H.R. 5658 / Pub. L. 97-313 To authorize the use of education block grant funds to teach the principles of citizenship. (Oct. 14, 1982; 96 Stat. 1462) Price: $1.75.

H.R. 5941 / Pub. L. 97-314 To designate the building known as the Federal Building and United States Courthouse in Greenville, South Carolina, as the "Clement F. Haynsworth, Jr., Federal Building", the building known as the Quincy Post Office in Quincy, Massachusetts, as the "James A. Burke Post Office", and the United States Post Office Building in Portsmouth, Ohio, as the "William H. Harsha United States Post Office Building". (Oct. 14, 1982; 96 Stat. 1463) Price: $1.75.

H.J. Res. 588 / Pub. L. 97-315 To provide for the designation of the month of October, 1982, as "Head Start Awareness Month". (Oct. 14, 1982; 96 Stat. 1464) Price: $1.75.

S.J. Res. 113 / Pub. L. 97-316 To designate the week beginning November 28 through December 4, 1982, as "National Home Health Care Week". (Oct. 14, 1982; 96 Stat. 1465) Price: $1.75.

S.J. Res. 197 / Pub. L. 97-317 To provide for the designation of the week of October 17 through October 23, 1982, as "Myasthenia Gravis Awareness Week". (Oct. 14, 1982; 96 Stat. 1466) Price: $1.75.

S.J. Res. 235 / Pub. L. 97-318 To proclaim March 21, 1983, as "National Agriculture Day". (Oct. 14, 1982; 96 Stat. 1467) Price: $1.75.

S. J. Res. 249 / Pub. L. 97-319 To provide for the designation of the month of October 1982, as "National Spinal Cord Injury Month". (Oct. 14, 1982; 96 Stat. 1468) Price: $1.75.